

Helena Laboratories
Working for you

AggRAM™

Remote Analyzer Module System



Operator's Manual

Catalog Number 1484, 110/220 VAC, 50/60 Hz

Catalog Number 1487, 110/220 VAC, 50/60 Hz

AggRAMTM
System

Operator's Manual

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DO NOT ATTEMPT TO MOVE, INSTALL, OR
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PARTICULARLY THE PRECAUTIONS, LIMITATIONS AND
HAZARDS IN SECTIONS THREE AND FOUR.

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List of Sections

Section 1 - Instrument Use and Function	1-1
Section 2 - Principles of Operation	2-1
2.1. Measurement Theory.....	2-1
2.1.1. Platelet Aggregation.....	2-1
2.1.2. Ristocetin Cofactor.....	2-1
2.2. AggRAM Operation.....	2-2
Section 3 - Precautions and Limitations	3-1
Section 4 - Hazards	4-1
Section 5 - Installation Instructions	5-1
5.1. Unpacking and Inspection	5-1
5.2. Installation	5-2
5.2.1. Select Instrument Location.....	5-2
5.2.2. Component Interface and Power Connections.....	5-2
5.2.2.1. Computer.....	5-2
5.2.2.2. AggRAM Module	5-2
5.2.2.3. Printer	5-2
5.2.2.4. Monitor.....	5-3
5.2.2.5. Keyboard and Mouse.....	5-3
5.2.2.6. Power Connections.....	5-3
5.3. Powering Up	5-3
5.3.1. Components.....	5-3
5.3.2. Computer	5-3
5.4. Software Installation and Module Letter Designation.....	5-3
5.4.1. HemoRAM Software Installation	5-3
5.4.2. Printer Driver Installation	5-3
5.4.3. Module Letter Designation	5-4
5.5. Verification of Functionality	5-4
5.6. Helpful Hints	5-4
5.6.1. Mouse	5-4
5.6.2. Keyboard.....	5-4
5.6.3. HemoRAM/AggRAM Displays and Manual	5-4
5.7. Setup Programming.....	5-5
Section 6 - Setup	6-1
6.1. Patient Demographics	6-1
6.2. Test Parameters	6-1
6.2.1. Platelet Aggregation Tests	6-1
6.2.2. Ristocetin Cofactor Tests	6-3
6.2.3. Test Sequence	6-4
6.2.4. Display Parameters	6-4
6.3. QC Parameters.....	6-5
6.4. Import/Export Parameters.....	6-6
6.5. User ID and Passwords	6-6
6.6. Report Parameters	6-7
6.7. Auto-Output Devices.....	6-7

Section 7 - Operating Instructions	7-1
7.1. Preparing the Instrument for Use.....	7-1
7.2. Performing Tests Summary.....	7-1
7.2.1. Platelet Aggregation.....	7-1
7.2.2. Ristocetin Cofactor.....	7-2
7.2.2.1. Ristocetin - Standard Curves.....	7-2
7.2.2.2. Ristocetin - Patient Tests.....	7-4
7.3. Enter/Edit Patient Identification.....	7-5
7.4. Importing Patient Information and Worklists.....	7-6
7.5. Creating Worklists.....	7-6
7.5.1. Platelet Aggregation Worklist.....	7-6
7.5.2. Ristocetin Cofactor Patient Worklist.....	7-7
7.5.3. Ristocetin Cofactor Standard Worklist.....	7-8
7.6. Run and Steps Windows.....	7-9
7.6.1. Run Window Prior to Beginning a Test.....	7-9
7.6.2. Run Window During a Test.....	7-9
7.6.2.1. Abort Run.....	7-9
7.6.2.2. Show Parameters / Show Graph.....	7-9
7.6.2.3. Results Chart.....	7-9
7.6.2.3.1. Smooth.....	7-10
7.6.2.3.2. View.....	7-10
7.6.2.3.3. Abort.....	7-10
7.6.2.3.4. Print.....	7-10
7.6.2.3.5. Stop.....	7-10
7.6.3. Steps Window.....	7-10
7.7. View/Edit Results.....	7-11
7.7.1. File.....	7-11
7.7.2. Edit.....	7-12
7.7.2.1. Slope.....	7-12
7.7.2.1.1. Show/Hide Slope Lines.....	7-12
7.7.2.1.2. Automatic Slope.....	7-12
7.7.2.1.3. Manual Slope.....	7-12
7.7.2.1.4. Alter Slope Window.....	7-13
7.7.2.1.5. Adjust Slope Search Start Point.....	7-13
7.7.2.2. Apply/Remove Smoothing.....	7-13
7.7.2.3. Add Comments.....	7-13
7.7.3. Search.....	7-14
7.7.4. View.....	7-15
7.7.4.1. View Style.....	7-15
7.7.4.2. Channels Displayed.....	7-15
7.7.4.3. Display Chart.....	7-15
7.7.4.4. Display Demographics.....	7-15
7.7.4.5. Display Parameters.....	7-15
7.7.5. Print Report.....	7-16
7.7.6. Delete.....	7-16
7.7.7. TestType and RunType.....	7-16
7.7.8. Limit Days.....	7-17
7.7.9. Overlay Reference.....	7-17
7.7.10. Slope vs. Standard Show Standard Curve.....	7-17

7.7.10.1. Print	7-17
7.7.10.2. Delete	7-17
7.7.10.3. Plot Type	7-18
7.7.10.4. Parameters	7-18
7.7.11. Levey-Jennings Chart	7-18
7.7.11.1. Print Ristocetin Report.....	7-18
7.7.11.2. Print QC Summary Report.....	7-18
7.7.11.3. Delete	7-18
7.7.11.4. Manual Entry	7-18
7.7.11.5. Level Group	7-19
7.7.11.6. Change Over	7-19
7.7.11.7. End-of-Month.....	7-19
7.7.11.8. Westgard Resolutions.....	7-19
7.7.12. Zooming and Panning	7-19
7.8. File Utilities	7-20
7.8.1. Backup/Restore/Delete	7-20
7.8.2. Rebuild Indexes	7-20
7.9. Change Operator	7-20
7.10. Print Setup.....	7-20
7.11. Show Error Messages	7-21
7.12. Exit.....	7-21
7.13. Help	7-21
7.13.1. Operator's Manual.....	7-21
7.13.2. Update Manual from CD.....	7-21
7.13.3. About - Software Version Information	7-21
7.14. Results.....	7-21
Section 8 - Quality Control	8-1
8.1. Daily Optical Calibration Check	8-1
8.2. Ristocetin Cofactor QC	8-1
8.2.1. Setup QC	8-1
8.2.2. Run QC	8-1
8.2.3. View QC and QC Lot Change Over	8-1
8.2.4. Westgard Rules.....	8-1
Section 9 - Instrument Specifications	9-1
Section 10 - Maintenance, Troubleshooting, Warranty.....	10-1
10.1. Maintenance	10-1
10.1.1. Optical Calibration Check.....	10-1
10.1.2. Cleaning Instrument	10-2
10.1.3. Cleaning Accessories.....	10-2
10.1.4. Cleaning Optical Wells	10-2
10.1.5. Scale Set.....	10-2
10.1.6. Adjust Temperature / Enter Module Parameters	10-3
10.1.7. Cleaning Filter	10-3
10.2. Troubleshooting.....	10-7
10.3. Warranty	10-9

Section 11 - Symbology	11-1
Section 12 - Communication Specifications	12-1
Section 13 - Reports	13-1
Section 14 - Index	14-1

List of Figures

Figure 1-1. AggRAM Remote Analyzer Module System.....	1-2
Figure 2-1. Block Diagram.....	2-3
Figure 5-1. AggRAM System.....	5-6
Figure 5-2. AggRAM Module.....	5-6
Figure 6-1. Main Menu	6-8
Figure 6-2. Test Parameters - Platelet Aggregation	6-8
Figure 6-3. Test Parameters - Ristocetin Cofactor	6-9
Figure 6-4. Test Sequence.....	6-9
Figure 6-5. Display Parameters.....	6-10
Figure 6-6. QC Parameters	6-10
Figure 6-7. Import/Export Parameters.....	6-11
Figure 6-8. User ID and Passwords	6-11
Figure 6-9. Report Editor.....	6-12
Figure 6-10. Auto-Output Devices.....	6-12
Figure 7-1. Main Menu	7-22
Figure 7-2. Run	7-23
Figure 7-3. Patient Demographics Entry	7-24
Figure 7-4. Worklist Preparation.....	7-24
Figure 7-5. Steps.....	7-24
Figure 7-6. View/Edit.....	7-25
Figure 7-7. Demographics.....	7-25
Figure 7-8. Parameters	7-25
Figure 7-9. Standard Curve (Ristocetin).....	7-26
Figure 7-10. Levey-Jennings Chart.....	7-26
Figure 7-11. Failure Resolutions	7-27
Figure 7-12. Archive.....	7-27
Figure 10-1. Preventive Maintenance Checklist.....	10-4
Figure 10-2. Optical Calibration Check.....	10-5
Figure 10-3. Scale Set.....	10-5
Figure 10-4. Module Parameter Entry	10-6
Figure 13-1. QC Summary - Assigned	13-1
Figure 13-2. QC Summary - Lot-to-Date	13-2
Figure 13-3. QC Report - Assigned.....	13-3
Figure 13-4. Platelet Aggregation (PIAgg Long Report)	13-4
Figure 13-5. Ristocetin Cofactor Patient (Ris CoF Long Report).....	13-5
Figure 13-6. Ristocetin Cofactor QC (Ris CoF Long Report)	13-6
Figure 13-7. Ristocetin Cofactor Standard (Ris CoF Long Report)	13-7
Figure 13-8. Ristocetin Cofactor QC (Ris CoF for STD-QC Report).....	13-8
Figure 13-9. Ristocetin Cofactor (Standard-Patients-QC Report)	13-9
Figure 13-10. Ristocetin Cofactor (Standard-QC Report).....	13-10

List of Tables

Table 5-1. Inventory5-1
Table 5-2. Additional Materials5-1
Table 5-3. System Requirements5-1
Table 10-1. Preventative Maintenance10-1
Table 10-2. Troubleshooting10-7

Section 1 - Instrument Use and Function

The AggRAM (Figure 1-1) is a platelet aggregation recorder. It measures human platelet aggregation by the absorbance method using up to four channels per module simultaneously.

The absorbance curve for each channel is displayed during data acquisition. The absorbance data is displayed and stored at the conclusion of the measurements, and can be printed for permanent records. The AggRAM requires no additional recording device. It is intended for in-vitro diagnostic use only and is for use in a laboratory or similar environment.

Refer to the procedures supplied with the reagents for information on the following areas:

- Summary
- Principle
- Reagents
- Specimen Collection and Handling
- Reagent Preparation
- Results
- Interpretation of Results
- Bibliography



Figure 1-1. AggRAM Remote Analyzer Module System

Section 2 - Principles of Operation

A block diagram of the AggRAM system is shown in Figure 2-1. All these components are controlled and monitored by a computer. Software and memory are provided via a hard disk and one CD drive.

All user input is through the keyboard and mouse. The entries are used to select the type of test, start or stop the automatic sequence of operations, enter patient data, select instrument parameters, and to change displays. The printer is used to print test results. An RS232 output is provided for data transfer to an external computer.

The computer runs a self-test at power on to detect error conditions or potential problems. If an error is detected, the computer responds by displaying an error message (section 10.2).

2.1. Measurement Theory

2.1.1. Platelet Aggregation

The blood platelet plays a major role in thrombus formation. Blood coagulation also depends on the presence of several other substances, such as thrombin, prothrombin, thromboplastin, ionic calcium, and fibrinogen. Platelet function can be measured optically since the optical density of plasma decreases with platelet aggregation. Changes in blood chemistry or blood abnormalities can alter platelet function, and aggregation measurements are of diagnostic value.

A number of substances (aggregation reagents) will induce platelet aggregation. These reagents include adenosine diphosphate (ADP), collagen, epinephrine, serotonin, arachidonic acid* and ristocetin. The clinician selects the aggregation reagent(s), which will generate the most significant clinical information.

Platelet rich plasma (PRP) is prepared according to the procedure supplied with the reagents, and optically measured. The initial

absorbance is caused by light scattered by the floating platelets in the solution. This absorbance is nearly proportional to the number of platelets. Platelet poor plasma (PPP) made from the same sample simulates 100% aggregation. Absorbance caused by factors other than platelets is determined by measuring the absorbance of the PPP.

The aggregation capacity of the platelets is determined by the amount of aggregation induced when a known amount of reagent is added to the PRP. The absorbance of the un-reacted PRP mixed with the aggregation reagent represents 0% aggregation, and the absorbance of the PPP control represents 100% aggregation (no floating platelets). As platelets aggregate, the number of floating platelets decreases, reducing the light absorbed by the PRP. Various parameters related to the aggregation curve, or the maximum aggregation rate, are used as data.

2.1.2. Ristocetin Cofactor

The von Willebrand factor protein is the protein that corrects the bleeding time abnormality in von Willebrand's disease. Several variant forms have been identified. The Ristocetin cofactor activity is a property of von Willebrand factor, which promotes agglutination of platelets in the presence of Ristocetin. The estimation of ristocetin cofactor activity allows the quantitation of an activity considered to reflect the level of von Willebrand factor activity.**

A diluted suspension of lyophilized platelets is prepared and used to set 100% activity. Ristocetin is added to undiluted platelet suspensions and allowed to incubate at 37°C. Upon addition of a diluted plasma specimen, the AggRAM makes an immediate absorbance measurement of the mixture (platelets, ristocetin and plasma). This reading establishes the 0% agglutination baseline. A standard curve is run by adding 3 concentrations of a plasma standard to the

*It has been suggested that arachidonic acid be run before other tests to screen for drug effects that might affect platelet responsiveness. Refer to Sirridge, M.S. and Shannon, R., Laboratory Evaluation of Hemostasis and Thrombosis, Lea and Febiger, Phil., p. 95, 1983.

**Zimmerman, T.S., Ruggeri, Z.M., "Von Willebrand's Disease", Spaett (ed.), Progress in Thrombosis and Hemostasis, 6:203-236, 1982.

platelet/ristocetin mixture and measuring activity. The curve is stored. Finally, patient sample or calibrator dilutions are added to the platelet/ristocetin mixtures and the reaction measured. The slope of the reaction (agglutination vs. time) is compared to the standard curve to determine % activity.

2.2. AggRAM Operation

The functional units of AggRAM are shown in Figure 2-1. The CPU (central processing unit) of the computer accesses test information, patient data and other user-entered information stored in the CPU's memory to control instrument operation. Test information is retained in memory on the hard disk. If loss of power (to the computer) occurs before completion of a test, the test data will be lost and the test must be repeated.

The CPU receives user input from the keyboard, mouse, and controls. This allows the operator to calibrate, enter identification, and enter test parameter information for each channel. As directed by the CPU, the display shows instrument status and user input.

At power on, the system performs a self-test to verify proper operation. If problems are detected, the display shows an appropriate error code or message. If operation is normal, the CPU begins instrument warm up. An incubator block surrounds the incubation wells and the optical chambers, pre-warming samples and reagents, and maintaining the aggregation/agglutination reaction at 37°C. The samples and reagents in each optical chamber are mixed at a constant speed with a magnetic stirrer. The CPU is used to define stirring speed through keyboard and mouse entry. Each channel button is used to initiate calibration, for PPP "blinking", to time incubation, and to start the measurements.

The optical section of each of the four channels consists of a photo detector and a laser diode. The sample inside the cuvette is flooded with laser light (at 650 nm) emitted by the laser. Platelets suspended in the mixture

cause reduced transmission, so that the amount of light reaching the photo detector is proportional to the number of platelets in the solution. The photo detector converts the light intensity into an analog signal, which is digitized and sent to the CPU for processing.

For agglutination tests, the channel button is pressed to start a 1-minute incubation of platelet/ristocetin mixture before plasma sample is added. To begin measurements, simultaneously press the channel button while the sample plasma dilution is added to the cuvette in the optical chamber. To begin measurements for aggregation tests, simultaneously press the channel button while the reagent is added to the cuvette in the optical chamber. Optical measurements are made continuously until the test ends.

The digital signals are produced by converting the optics' analog signals to digital signals. These are used to calibrate optical reference levels, establish optical scale before data acquisition, and establish optical curves during data acquisition. The channels are calibrated, setting 0% and 100% activity levels for each sample.

Continuous optical measurements are made after reagent is added to patient or control samples. The raw analog signal is digitized and converted into % activity for each sample, and the results are displayed. Another output port is provided for sending information to an external computer (LIS). Measurement data can be printed out for a permanent record at the end of the measurement period. Up to two modules, with four optical chambers each can be used for simultaneous measurements. Since the AggRAM is microcomputer controlled, no manual adjustments are required after measurements are started.

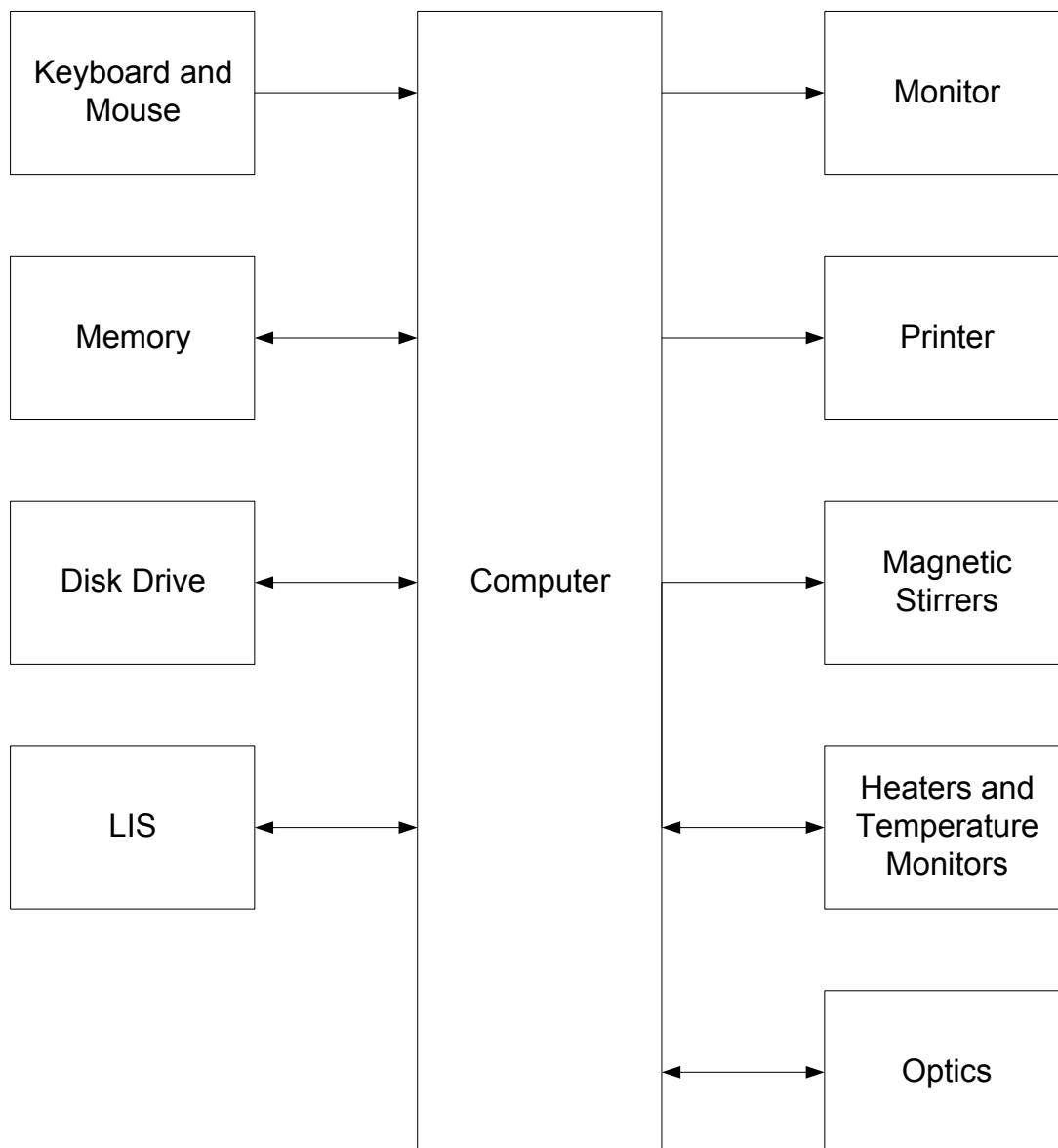


Figure 2-1. Block Diagram

Section 3 - Precautions and Limitations

3.1. The entire operator's manual should be read and understood before attempting instrument operation.

3.2. Refer to the procedure supplied with the reagents for reagent preparation and handling and other information. Use only reagents made specifically for use with the AggRAM. All reagents should be used in accordance with the manufacturer's instructions.

3.3. The AggRAM should be used only as a measuring device for Platelet Aggregation and Ristocetin-Cofactor assays.

3.4. Use only cuvettes and stir bars designed especially for the AggRAM.

3.5. Cuvettes must be kept clean. Always handle open end only to avoid contaminating optical path.

3.6. All measurements should be made within the time guidelines given in the procedures supplied with the reagents.

3.7. Aggregation studies are generally performed on platelet rich plasma (PRP) having a platelet count of 300,000 - 400,000/mm³. While the AggRAM estimates and indicates suitable platelet numbers*, platelet counts should be performed on equipment designed for this purpose or counted by accepted phase microscopy techniques.

PRP values exceeding 500,000/mm³ should be diluted with the patient's own platelet poor plasma (PPP). Patient samples with a platelet count of less than 100,000/mm³ may be increased by preparing multiple samples and then concentrating the platelets by re-centrifugation at 2000G and pooling the platelet pellets. This however is not generally recommended. Patients with platelet counts of less than 100,000/mm³ have a quantitative platelet problem irrespective of any qualitative or functional defect.

3.8. The minimum volume required to cover the light path is 250 µL for Platelet Aggregation and Ristocetin Cofactor (with a stir bar).

3.9. Provide adequate room at the sides and back of the instrument for good air circulation.

3.10. Should instruments be contaminated by blood or blood derivatives, spray commercial virucidal and germicidal agent onto the area contaminated. Observe where specimens are used inside the instrument, and confine cleaning to that area. Wipe up the agent residue, as these materials may contain alcohol, which is corrosive to metal surfaces.

No harsh cleansers, acids, or bases should be used or spilled on inner or outer surfaces. Do not immerse the unit. **ALWAYS TURN THE POWER SWITCH OFF AND UNPLUG THE MAIN POWER CORD BEFORE CLEANING.**

3.11. Do not expose the instrument to direct sunlight. Do not operate at temperatures above 86°F (30°C) or below 59°F (15°C), or allow prolonged exposure to high humidity.

3.12. Do not place the instrument near a strong source of electromagnetic interference, such as a centrifuge, x-ray machine, etc.

3.13. For emergency shut down, disconnect the power cords and then turn off the power switch on each component.

3.14. The instrument should be kept dust free, if possible.

3.15. Optical chambers must be kept clean in order to obtain the most accurate readings.

3.16. Do not attempt to operate the instrument without plugging the power cord into an easily accessible, grounded wall outlet of the proper voltage and frequency. This information is contained on the serial number plate located on the back of the instrument.

3.17. Installation should not be attempted unless a representative of Helena Laboratories, its subsidiaries, or its distributors is present, or,

*Approximate ranges are indicated based on O.D. of the PRP sample. See Limitations and Precautions sections of the appropriate reagent procedure for additional recommendations.

verbal or written permission to proceed has been given by a representative of Helena Laboratories, its subsidiaries, or its distributors.

3.18. Instructions for the "responsible body*" (*Under IEC 61010-2-101:2002 -- the person(s) responsible for the use and maintenance of equipment and for ensuring that operators are adequately trained for eliminating and reducing hazards involved in removal from use, transportation, or disposal.)

3.19. Action(s) to be taken in case of malfunction: See section 3.13 and 10.2.

3.20. Requirements for handling biohazards: Due to potential biohazard risk from human blood, guidelines pertaining to Universal Precautions shall be adhered to when handling the samples and operating this instrument. This includes the use of protective gloves and any other protective equipment as warranted for safe handling and disposal of test tubes and use, transportation and disposal of this device. For information on minimizing biohazard risk, see section 3.10.

3.21. Storage and transport environmental requirements:

Operating temperature range: 15° – 30° C

Storage and shipping temperatures: -20° – 45° C

3.22. The Helena Agent shall provide a power cord or adapter of the proper configuration for the country in which the instrument is to be installed. The power cord or adapter will comply with IEC 60227, IEC 60245, or be certified as rated for the power specified in section 9 of this manual.

Section 4 - Hazards

4.1. If the instrument is used in a manner not specified by this manual, the protection provided by equipment design may be impaired.

4.2. This device contains very high voltages that can be extremely dangerous. Safeguards are built into the instrument to prevent user contact with high voltage, however, ALWAYS TURN OFF THE POWER, DISCONNECT THE MAIN POWER CORD, AND USE EXTREME CARE when attempting disassembly for cleaning, repair, or adjustments. Do not operate any instrument with the cover removed unless instructed to do so by a qualified service technician directly representing Helena Laboratories, its subsidiaries, or its distributors.

4.3. Do not attempt to operate the instrument without plugging the power cord into an easily accessible, grounded wall outlet of the proper voltage and frequency. This information is contained on the serial number plate located on the back of the instrument.

4.4. Do not place the instrument near a strong source of electromagnetic interference, such as a centrifuge, X-Ray machine, etc. or damage to the program may result and/or erroneous results may be produced.

4.5. Do not introduce any liquids into the instrument except those contained in an appropriate cuvette. Liquids inside the instrument will cause damage.

4.6. Do not lubricate the instrument.

4.7. For emergency shut down, disconnect the power cords and then turn off the power switch on each component.

4.8. WARNING: External equipment (barcode reader, keyboard, computer, etc.) that is connected to the instrument must have no live parts that are accessible.

Section 5 - Installation Instructions

WARNING: Read Section Three (Precautions and Limitations) and Section Four (Hazards) before attempting installation or operation.

5.1. Unpacking and Inspection

1. Check all shipping containers for signs of damage. If damage is found, immediately notify the shipping carrier.

2. Carefully unpack the instrument and accessories and remove them from the shipping cartons. The packing material should be removed undamaged, if possible, should repacking be necessary.

CAUTION: The instrument and its components are heavy. Lift only from the bottom surface on the instrument. Use approved lifting techniques when moving the instrument.

3. Remove plastic wrappings from the instrument and accessories. If scissors or a knife are used to cut the plastic or binding tape, take care not to scratch the instrument.

4. Inspect the instrument for any obvious signs of damage. If damage is found, notify the shipping carrier and Helena Laboratories.

5. Inventory all items: If any parts are missing, recheck the packing materials before notifying Helena Laboratories.

Table 5-1. Inventory.

1484 - AggRAM Analyzer

- AggRAM module
- Computer (Keyboard and Mouse)
- Monitor
- Printer
- Customer ID Label
- Module Identificaiton Labels
- Cuvette Rack
- Magnet Retriever
- Printer Interface Cable
- Module Interface Cable
- Module Power Cord
- Cuvettes, Cat. No. 1473
- AggRAM Stir Bars, Cat. No. 1489
- HemoRAM Program Disk
- Installation Verification Report
- Operator's Manual
- Operator's Manual on CD

1487/1488 - AggRAM Module for Export

- AggRAM module
- Customer ID Label
- Module Identificaiton Labels
- Cuvette Rack
- Magnet Retriever
- Module Interface Cable
- Cuvettes, Cat. No. 1473
- AggRAM Stir Bars, Cat. No. 1489
- HemoRAM Program Disk
- Installation Verification Report
- Operator's Manual
- Operator's Manual on CD

Table 5-2. Additional Materials

Required Materials

- 1473 Siliconized Cuvettes, 200/pkg
- 1479 Scale Set Solutions (650nm) for Platelet Assays, 1 each Low and High Calibrator
- 1489 AggRAM Stir Bars, 30/pkg

Available Materials

- 1346 Barcode Reader and Cabling
- 1486 AggRAM module
- 5185 S.A.R.P.
- 5199 Ristocetin
- 5301 S.A.C.-1
- 5356 Lyophilized Platelets
- 5364 Arachidonic Acid
- 5365 Tris-Buffered Saline
- 5366 ADP
- 5367 Epinephrine
- 5368 Collagen
- 5369 Platelet aggregation Kit
- 5370 Ristocetin Cofactor Assay Kit
- 5371 Lyophilized Platelets
- 5372 Ristocetin for Cofactor Assays
- 5373 Ristocetin Cofactor Abnormal Control Plasma

Table 5-3. System Requirements

- PC with:
- 800 MHz or higher processor (Intel Pentium/ Celeron family processor recommended)
 - 64 MB or higher recommended of RAM
 - 1.5 GB of available hard disk space
 - RS-232 Serial Ports (1 per Module and LIS Connection)
 - Microsoft® Windows® 2000 Operating System
 - CD-RW drive
 - Super VGA (800 x 600) or higher resolution video adapter monitor.

Keyboard and Microsoft Mouse or compatible pointing device.
Hp DeskJet 6122 Printer.
Optional, Handheld Wedge Type Bar Code Scanner (Unitech or compatible) Capable of reading: Code 39, Codabar, EAN 128, Interleaved 2 of 5, Code 128.

5.2. Installation

The AggRAM is for in-vitro diagnostic use only and is for use in a laboratory or similar environment.

5.2.1. Select Instrument Location

1. Select an environment free of direct sunlight, excessive humidity and dust, corrosive vapors, large temperature fluctuations, or excessive vibration. Ambient temperature should not be above 86°F (30°C) or below 59°F (15°C).
2. Do not place the instrument near a strong source of electromagnetic interference, such as a centrifuge, X-Ray machine, etc.
3. Select an area with enough space to place the instrument's components as shown in Figure 5-1.
4. Select a location close to the needed wall outlets. Grounded wall outlets must be of the proper voltage and frequency as described on the serial plates located on the back of the instrument's components and be easily accessible. The wall outlets should not be on the same circuit as any large load device such as a refrigerator, compressor, centrifuge, etc. The instrument's circuitry contains filters to reduce the effect of line voltage fluctuations. However, if the operator experiences difficulty in operation, it may be necessary to install an isolation transformer. Transformer specifications are available from Helena Laboratories.

5.2.2. Component Interface and Power Connections

1. Check each component to make sure that each has the same power rating (110 to 120 VAC or 220 to 240 VAC). This information is located on the back of each component.

2. Check each component to ensure that each power switch is off.
3. When inserting interface cables into connectors, make sure that they are firmly seated.

5.2.2.1. Computer

1. Place the computer in the center of the area designated for the instrument (Figure 5-1). Keep in mind that the back of the computer will need to be accessible to interface it with the other components.
2. Plug the female end of the power cord into the back of the computer.

5.2.2.2. AggRAM Module

1. Place the module(s) relative to the computer, as shown in Figure 5-1.
2. Plug the female end of the module interface cable in the back of the AggRAM module labeled Host Computer.
3. Plug the other end of the module interface cable into the back of the computer.
4. Plug the female end of the power cord in the back of the AggRAM module.

5.2.2.3. Printer

1. Place the printer relative to the computer, as shown in Figure 5-1.
2. Plug the USB printer interface cable into the back of the printer.
3. Plug the other end of the printer interface cable into the USB port on the back of the computer.
4. Plug the female end of the power cord into the back of the printer.
5. For information on installing and removing toner or ink cartridges and on loading printer paper, see the printer owner's guide.

5.2.2.4. Monitor

1. Place the monitor relative to the computer, as shown in Figure 5-1
2. Plug the female end of the power cord into the back of the monitor.
3. Plug the monitor interface cable into the matching receptacle on the back of the computer. Hand tighten the thumbscrews.

5.2.2.5. Keyboard and Mouse

1. Place each device relative to the computer, as shown in Figure 5-1.
2. Plug each device cable into the appropriate receptacle on the back of the computer.

5.2.2.6. Power Connections

Once each component is interfaced and has its power cord, plug each power cord into a grounded wall outlet of the proper voltage and frequency. This information can be found on the serial number plates located on the back of the instrument's components. Do not turn the power on at this time.

5.3. Powering Up**5.3.1. Components**

With the components interfaced with the computer, turn each of the power switches on for the module(s), printer, and monitor. The HemoRAM software will automatically setup all of the components for operation once the software is started.

5.3.2. Computer

Once the module(s), printer, and monitor are powered on, then turn on the computer's power switch. The Windows program opens and displays the HemoRAM software icon (once the software is installed, section 5.4.1). Select the icon; if the main menu (Figure 6-1) appears on the monitor, the system is operating correctly. If an error message appears instead, refer to section 10.2.

5.4. Software Installation and Module Letter Designation**5.4.1. HemoRAM Software Installation**

The HemoRAM software auto-installs:

1. Place the CD in the CD drive of the computer running Microsoft® Windows® 2000.
2. Close the CD drive and the software installation automatically begins.
3. If installation does not automatically begin,
 - a. double left-click on the *My Computer* folder on the computer desktop,
 - b. then double left-click on the CD drive,
 - c. and lastly, double left-click on the file *SETUP.EXE* which has an icon of a computer.
 - d. Once the *Welcome* window displays, follow the displayed prompts, available in English only, to complete installation.
4. Once installation is complete, the *Setup* window closes and the HemoRAM icon is available on the computer desktop.
5. Place the HemoRAM software disk in the sleeve located at the end of this manual.

5.4.2. Printer Driver Installation

1. With the printer connected to the computer, insert the printer driver CD in the CD drive.
2. Close the CD drive and the printer driver installation automatically begins.
3. To complete the installation, select the applicable responses to the prompts, referring to the owner's guide provided with the printer as needed.
4. Place the printer driver disk in the sleeve located at the end of this manual.

5.4.3. Module Identification

If multiple modules are in use, once installation of the entire system is complete, determine the letter designation of each module. Access the Enter Module Parameters window (section 10.1.6), and from the information displayed, match each module's serial number with its assigned letter designation. Then apply the applicable module identification label to that module. Note that this letter designation could change if modules are removed, added, and/or moved at which time the modules designation will need to be re-confirmed and/or re-labeled as appropriate.

5.5. Verification of Functionality

After reading and understanding the Operator's Manual, complete the applicable section of the Installation Verification Report as the following steps are performed:

Instrument Data

1. Record the serial numbers of the computer, monitor, and printer.
2. Record the serial number of the module(s). Refer to section 10.1.6.
3. Record the software version. Refer to section 7.13.3.

Functionality

4. The instrument is calibrated by Helena Laboratories during the manufacturing process. At installation, the instrument should be calibrated using Helena Scale Set Solution, Catalog Number 1479. If during this calibration the instrument cannot be returned to acceptable ranges, any additional calibration must be performed by Helena Laboratories or their representatives. Once calibration is complete, printout the scale set results and attach to the verification form. Refer to section 10.1.5 for instructions on performing a scale set calibration.

5. Return the report and calibration printout to Helena Laboratories per the instructions on the report.

5.6. Helpful Hints

5.6.1. Mouse

The mouse may be used to make selections and indicate where information is to be entered. Move the white arrow, or a symbol resembling a black Roman numeral one, 1, around the screen to the desired selection or location by moving the mouse. With the white arrow over the desired area, click the button located on the left of the mouse. Clicking this button twice is required to select some options. In this manual, any statement to "click" or "double click" an area refers to these instructions. Any instruction to "select" something can be completed using the mouse.

5.6.2. Keyboard

The keyboard is used to enter information and in some areas to make selections. On most screens, you can also access an area by pressing the Tab key until the desired area is indicated. The up, down, left, and right arrow keys can be used in areas where information is entered either to scroll through the available selections or to position your cursor within an indicated area.

5.6.3. HemoRAM/AggRAM Displays and Manual

In understanding this manual, keep the following things in mind:

"click" or "double click" - refers to the instructions given in section 5.6.1.

"field" - is the area into which information is entered.

"cursor" - refers to the location entered information will be placed and is most often indicated by a white arrow or a symbol resembling a black Roman numeral one, 1.

"drop down menu" or "drop down list" - refers to a list of options available for your selection. A field has a drop down menu or list when the right side of the field has a square containing

an arrow. Access the drop down menu/list by clicking on the arrow or the field.

“highlight” or “highlighted” - refers to the information currently selected and is displayed as white text with a blue background.

“slide bar” - refers to the display allowing use of either the mouse or arrow keys to move an indicator bar in order to define the desired setting or access additional fields.

5.7. Setup Programming

For information on setup, see Section 6 - Setup.



Figure 5-1. AggRAM System

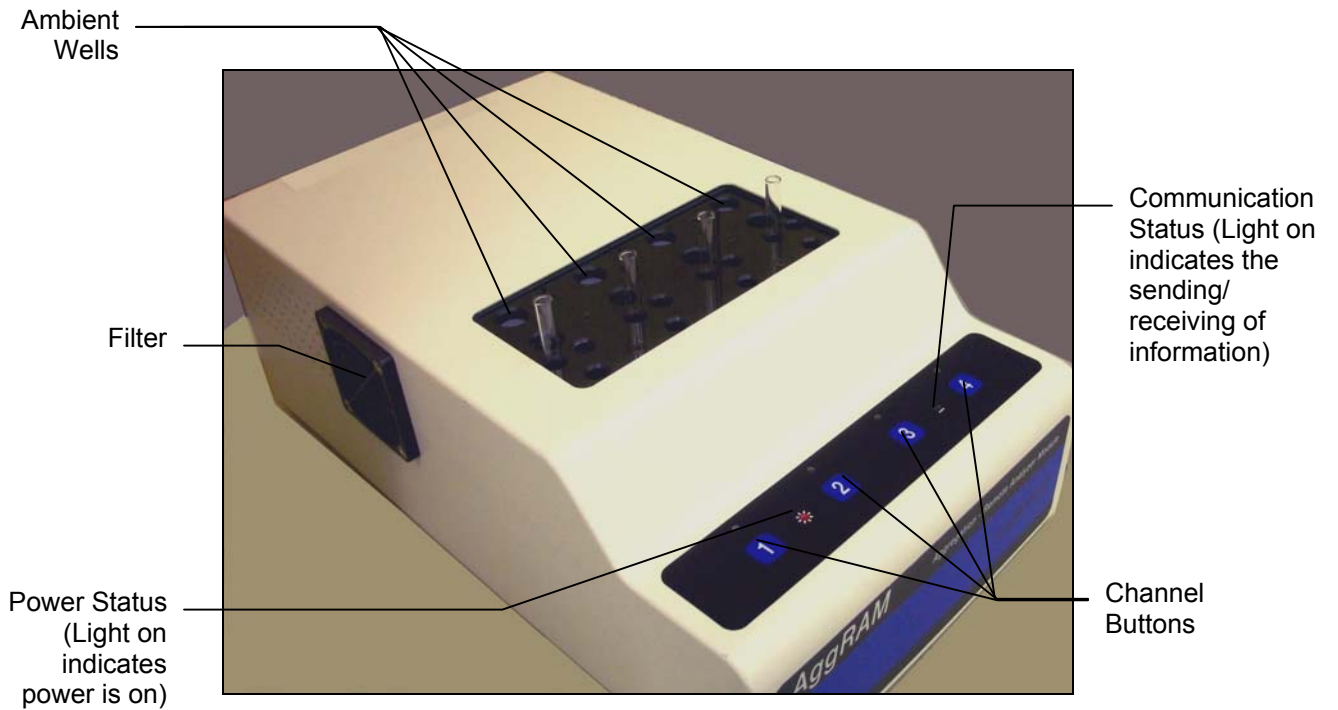


Figure 5-2. AggRAM Module

Section 6 - Setup

1. Turn power on for the module, printer, and monitor, and then for the computer.

2. The Microsoft® Windows® program opens and displays the HemoRAM software icon. Select the icon; if the main menu (Figure 6-1) appears on the monitor, the system is operating correctly. If an error message appears, refer to section 10.2.

3. When the *Login* window displays, enter the applicable *User ID*, press **Tab**, and enter the *Password*. If user IDs have been setup, the access level of the ID entered determines the functions accessible. The assigned access level of the ID entered is displayed on the top right of the main menu. See section 6.5 for additional information on access levels. If no user ID/passwords are setup for use, press **Enter** to proceed.

4. *Setup* is accessed by selecting *File* on the main menu, and, from the drop down menu, selecting *Setup*. Note that if a user ID with Run Only access is in use, *Setup* is not accessible.

a. A second drop down menu displays and contains *Patient Demographics* (not accessible on this version of software), *Test Parameters*, *QC Parameters*, *Import/Export Parameters*, *User ID and Passwords*, *Report Parameters*, and *Auto-Output Devices*. Note that if a user ID with Setup access is in use, *User ID and Passwords* is not accessible.

6.1. Patient Demographics

This feature is not available on this version of software.

6.2. Test Parameters

6.2.1. Platelet Aggregation Tests

The AggRAM can run both micro and standard volumes. It is recommended that the laboratory establish their normal ranges with the same volume that will be utilized in their laboratory. All default settings for the AggRAM are for Micro volumes; however, the settings can be altered if using Standard volumes.

Volumes

	Micro	Standard
PPP	225µL	450µL
PRP	225µL	450µL
Aggregating Reagent	25µL	50µL
Stir Speed	600 rpm	1000 rpm

Factory Programmed Platelet Aggregation Tests

Single Reagent Tests - the following applies to all channels in use:

Reagent	Unit of Measure	Concentration
Adenosine Diphosphate	µM	20
Arachidonic Acid	µg/ml	500
Collagen	µg/ml	10
Epinephrine	µM	300
Ristocetin	µg/ml	1500

Multi-Reagent/Concentration Tests - the following applies to each set of four channels in use:

Screen 1*			
Channel	Reagent	Unit of Measure	Concentration
1	Adenosine Diphosphate	µM	20
2	Collagen	µg/ml	10
3	Epinephrine	µM	300
4	Ristocetin	µg/ml	1500
Screen 2*			
Channel	Reagent	Unit of Measure	Concentration
1	Adenosine Diphosphate	µM	20
2	Collagen	µg/ml	10
3	Epinephrine	µM	300
4	Arachidonic Acid	µg/ml	500
Screen 3*			
Channel	Reagent	Unit of Measure	Concentration
1	Adenosine Diphosphate	µM	20
2	Adenosine Diphosphate	µM	5
3	Adenosine Diphosphate	µM	2.5
4	Adenosine Diphosphate	µM	1

To setup or alter test parameters, beginning from the main menu, select *File, Setup*, and then *Test Parameters*. The *Test Parameters* screen (Figure 6-2) displays:

1. *Test Type* - select Platelet Aggregation.
2. *Test* - select from the drop down list or use the keyboard to enter/alter.

a. If the channels need to have different parameters, an asterisk must be the first character of the *Test* name. Do not place an asterisk within the name other than as the first character.

3. *Test/Reag. Abbrev.* - Enter/alter, using the keyboard, an abbreviation for the test/reagent name.

4. *No. of Modules to use for test* - if more than one module is in use, use the drop down list to select the applicable number.

5. *Block Temperature (°C)* - select from the drop down list or use the keyboard to enter/alter the block temperature for all Platelet Aggregation tests.

6. *Stir Speed (RPM)* - use the drop down list to select from 500 through 1500 in increments of 100.

7. *Patient demographic name & date entry syntax checking* - once set, this feature applies to the instrument as a whole and is not a per test setting. Select this feature, if it is preferred that certain patient demographic information is entered in a standardized way. Otherwise, inactivate this feature. With this feature in use, the Patient Name must be entered last name-comma-first name and the Birthdate must be entered using the applicable country date code.

8. *Channels* - For tests with names containing no asterisk, the parameters for each channel are the same, except for *Concentration*. For test names containing an asterisk, each channel can contain different parameters, unless the same *Reagent* is selected, in which case, all the parameters for the channels with the same *Reagent* are the same, except for *Concentration*.

- a. *Reagent* - select from the drop down list.

- b. *Unit of Measure* - select from the drop down list or use the keyboard to enter/alter.

- c. *Concentration* - select from the drop down list or use the keyboard to enter/alter.

- d. *Window seconds (points not available on this version of software)* - select from the drop down list or use the keyboard to enter/alter.

- e. *Slope II* - If the reaction is a biphasic reaction, select Slope II, and if the reaction is single phase, do not. Once all the channels needed have Slope II selected and/or deselected, confirm that within the Select Display Parameters function (section 6.2.4) Slope 2 is set correctly. Set to display if at least one channel is to include Slope II or set not to display if none of the channels will use Slope II.

- f. *Test Sequence* - For information on this feature, see section 6.2.3.

- g. *Area Under Curve (Research Use Only)* - select to calculate the area under the curve for research use only.

9. *Save Test Parameters* - select to save the parameters for the displayed test without exiting the *Test Parameters* window. To setup/alter additional tests, see step 1.

10. *Delete Test* - select to delete the currently displayed test. Once selected, a *Confirm* message displays. To delete the displayed test, select *Yes*. To retain the displayed test, select *No*. To setup/alter additional tests, see step 1.

11. *Select Display Parameters* - For information on this feature, see section 6.2.4.

12. To exit, select the **X** located on the top right of the window.

13. If a *Confirm* prompt displays, changes were made and not saved. Note that these changes may be within the Test Sequence parameters. If this is the case, the changes must be saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*.

6.2.2. Ristocetin Cofactor Tests

The AggRAM can run both micro and standard volumes. It is recommended that the laboratory run standard curves, controls, and patient samples using the same volume conditions. All default settings for the AggRAM are for Micro volumes; however, the settings can be altered if using Standard volumes.

Volumes

		Micro	Standard
Aggregation blank	Platelet suspension	125µL	250µL
	Tris-buffered Saline	125µL	250µL
Platelet suspension		200µL	400µL
Ristocetin		25µL	50µL
Plasma dilution		25µL	50µL
Stir Speed		600 rpm	1000 rpm

Factory Programmed Ristocetin Cofactor Test

Channel	Unit of Measure	Concentration
1	%	50
2	%	25
3	%	12.5
4	%	100

To setup or alter test parameters, beginning from the main menu, select *File*, *Setup*, and *Test Parameters*. The *Test Parameters* screen (Figure 6-3) displays:

1. *Test Type* - select *Ristocetin*.
2. *Test* - select *Ristocetin*.
3. *Test/Reag. Abbrev.* - Enter/alter, using the keyboard, an abbreviation for the test/reagent name.
4. *No. of Modules to use for test* - if more than one module is in use, use the drop down list to select the applicable number.
5. *Block Temperature (°C)* - select from the drop down list or use the keyboard to enter/alter the block temperature for all Ristocetin Cofactor tests.
6. *Stir Speed (RPM)* - use the drop down list to select from 500 through 1500 in increments of 100.

7. *Patient demographic name & date entry syntax checking* - once set, this feature applies to the instrument as a whole and is not a per test setting. Select this feature, if it is preferred that certain patient demographic information is entered in a standardized way. Otherwise, inactivate this feature. With this feature in use, the Patient Name must be entered last name-comma-first name and the Birthdate must be entered using the applicable country date code.

8. *Channels* - The parameters for each channel are the same, except for *Concentration*.

- a. *Reagent* - select from the drop down list.
- b. *Unit of Measure* - select from the drop down list or use the keyboard to enter/alter.
- c. *Concentration* - select from the drop down list or use the keyboard to enter/alter.
- d. *Window seconds (points not available on this version of software)* - select from the drop down list or use the keyboard to enter/alter.
- e. *Slope II* - is not recommended for use with *Ristocetin* tests.

f. *Test Sequence* - For information on this feature, see section 6.2.3.

g. *Standard Curve Scale* - select from *Log-Log* and *Semi-Log*. The setting can be altered from the View/Edit window, if needed.

h. *Area Under Curve (Research Use Only)* - is not recommended for use with *Ristocetin* tests.

9. *Save Test Parameters* - select to save the parameters for the displayed test without exiting the *Test Parameters* window. To setup/alter additional tests, see step 1.

10. *Delete Test* - select to delete the currently displayed test. Once selected, a *Confirm* message displays. To delete the displayed test, select *Yes*. To retain the displayed test, select *No*. To setup/alter additional tests, see step 1.

11. *Select Display Parameters* - For information on this feature, see section 6.2.4.

12. To exit, select the **X** located on the top right of the window.

13. If a *Confirm* window displays, changes were made and not saved. Note that these changes may be within the Test Sequence parameters. If this is the case, the changes must be saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*.

6.2.3. Test Sequence

1. From the *Test Parameters* window, select *Test Sequence* for the desired channel.

2. The *Test Sequence* window (Figure 6-4) displays the applicable channel number and reagent, and the parameters for the first step.

3. For each *Step Number* needed, setup the following:

a. *Step Identification* - use the keyboard to enter/alter the name used to identify the step.

b. *Volume (uL)* - use the keyboard to enter/alter the volume of the material that is to be inserted into the cuvette during the step.

c. *Step Time (min:sec)* - use the keyboard to enter/alter the time duration of the step.

d. *100%* - select to designate the chart point of the step as the maximum point determination. It is required that one step be designated as *100%*.

e. *zero* - select to designate the chart point of the step as the zero point determination. It is required that one step be designated as *zero*.

f. *Determination Time (sec)* - is only available with *100%* or *zero* selected. The *Determination Time* cannot exceed the *Step Time*.

4. *Save Step* - select to save the currently displayed step. Note that if a step is added, the entire Test Parameters must also be saved, see step 9 for section 6.2.1 or 6.2.2.

5. *Delete Step* - select to delete the currently displayed step. Note that once this feature is used, the entire Test Parameters must also be saved, see step 9 for section 6.2.1 or 6.2.2.

6. *Previous* and *Next* - use these buttons to access each step within the sequence. If changes were made and not saved, a *Confirm* message displays. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

7. To exit, select the **X** located on the top right of the window.

8. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

6.2.4. Display Parameters

1. From the *Test Parameters* window, select *Select Display Parameters*.

2. The *Select Display Parameters* window (Figure 6-5) displays. Use this window to select/alter the parameters displayed when viewing and editing. Note that altering the parameters affects how both previous and future data will be displayed.

3. *Select RunType* - is only available for *Ristocetin TestType*. Select *Patient*, *Standard*, or *QC*.

4. *Available* - from this list of available parameters, click on the parameter desired displayed during viewing and editing. The selected parameter is added to the *Shown* list.

5. *Shown* - this list contains all the parameters currently selected to display during viewing and editing.

a. To remove a parameter from this list, double click on the parameter and a *Confirm* message displays. To remove the parameter, select *Yes*. To retain the parameter, select *No*.

b. To rearrange the order of the parameters,

i. First, click and hold down the left button on the mouse on the parameter to be moved.

ii. Then, move the mouse over the parameter that the selected parameter needs to precede.

iii. Lastly, release the button on the mouse and the selected parameter is repositioned.

6. *Save* - select to save the currently displayed *Shown* list.

7. To exit, select the **X** located on the top right of the window.

8. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*.

9. Note that if Slope 2 was removed from the *Shown* list then it will not display, even if the Test Parameters have a channel set to include Slope II. To confirm the settings are as needed, follow the instructions for Slope II in section 6.2.1, step 8.e.

6.3. QC Parameters

QC Parameters must be setup for Ristocetin Cofactor QC. The control information for each lot number must be entered prior to running assays. To enter control information, beginning from the main menu, select *File*, *Setup*, and *QC Parameters*. The *QC Parameters* screen (Figure 6-6) displays.

1. *Test Type* - select *Ristocetin*.

2. *Reagent* - select *Ristocetin*.

3. *Mean Calculation Method* - use the drop down list to select one of the following:

a. *Assigned* - if selected, the *Assigned Mean* and *Assigned SD* (step 8) must be entered.

b. *Lot-to-Date* - select for the mean to be automatically figured based on all the QC results per lot. A lot number for each of the 6

levels should be entered (step 8). Initially, when using *Lot-to-Date*, levels 1, 2, and 3 will be used for all of the QC testing. When the material for a lot gets low, begin to run new lots of QC, attributed to levels 4, 5, and 6. Continue to use up the remainder of the material attributed to lots 1, 2, and 3. After at least 6 runs of levels 4, 5, and 6, perform a change over. This removes the current levels 1, 2, and 3 from being used in future QC calculations and transfers levels 4, 5, and 6 into 1, 2, and 3 respectively (section 7.7.11).

c. *Month-to-Date* - select for the mean to be automatically figured based on all the QC per lot for a user specified period (section 7.7.11). A lot number for levels 1 through 3 should be entered (step 8).

4. *Method* - no entry is required. This field is for future use with Helena's QAR program.

5. *Entry Codes* - no entry is required. This field is for future use with Helena's QAR program.

6. *Account Number* - no entry is required. This field is for future use with Helena's QAR program.

7. *Westgard Rules Applied* - use this feature to monitor trends in QC data; select either *No* or *Yes*. If *Yes* is selected, select the desired rule(s) - *1-3s*, *2-2s*, *4-1s*, *r4s*, and/or *10x*. For additional information on these rules, see section 8.2.4. If Westgard Rules are in use, a QC fails, and the failure is not resolved (section 7.7.11), then any additional patient data is flagged to indicate a failure exists. Also, any additional QC data generated is not included in the Levey-Jennings chart results until the failure is resolved.

8. *Level 1* through *Level 6* - *Level 1* is usually a normal control and *level 3* an abnormal control.

a. *Lot Number* - use the keyboard to enter/alter. Note that if a Lot Number is altered/corrected for which QC has already been run, then when *Save* is selected, a prompt displays listing all the Curve Sequence Numbers, which have the original

lot number. To use the new lot number, record these sequence numbers, select *OK*, and then *Yes*. The lot number can then be corrected for the previously run QC (section 7.7.4.5).

b. *Assigned Mean* - use the keyboard to enter/alter. This information must be entered if the *Mean Calculation Method* in use is *Assigned*.

c. *Assigned SD* - use the keyboard to enter/alter. This information must be entered if the *Mean Calculation Method* in use is *Assigned*.

9. *Save* - select to save the currently displayed QC parameters.

10. To exit, select the **X** located on the top right of the window.

11. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

6.4. Import/Export Parameters

Refer to the external computer Operator's Manual for information on the computer's requirements and to Section 12 - Communication Specifications. To setup for importing and exporting data, beginning from the main menu, select *File*, *Setup*, and *Import/Export Parameters*. The *Import/Export* screen (Figure 6-7) displays:

1. *External Computer Port* - select from the drop down list.

2. *Baud Rate* - select from the drop down list.

3. *Data Bits* - select from the drop down list.

4. *Stop Bits* - select from the drop down list.

5. *Parity* - select from the drop down list.

6. *Protocol* - select from the drop down list. If data is to be imported and exported, use *ASTM*. If data is only to be exported, *X-on*/*X-off* or *None* can be used.

7. *Bypass LIS Locator on power up* - select to require that the parameters displayed be

used even if the software detects a possible additional LIS connection. This would also be used for those cases where the LIS may be temporarily off (and therefore undetectable) when the program is starting up.

8. *Auto Import* - select and the instrument continuously monitors for data coming from an LIS.

9. *Save* - select to save the selections.

10. To exit, select the **X** located on the top right of the window.

11. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

6.5. User ID and Passwords

Only operators with Supervisor access can enter/alter user IDs and passwords. To enter/alter user IDs and passwords, beginning from the main menu, select *File*, *Setup*, and *User ID and Passwords*. The *User ID and Passwords* window (Figure 6-8) displays. Note that IDs and passwords are case sensitive and neither should exceed 32 characters.

1. *User ID* - enter/alter using the keyboard and/or the drop down list to select a previously entered ID.

2. *Password* - use the keyboard to enter/alter.

3. *Access Level* - use the drop down list to select one of the following. (Note that if no user is given a Supervisor access level, then users with the next highest level have Supervisor access to the software.)

a. *Run Only* - access may perform runs and view, print, and export data; however, is restricted from all editing, *Setup*, and *Maintenance* activities.

b. *Setup* - access level may perform all run and data handling functions, all setup functions, except *User ID and Password Setup*, and, all user maintenance activities except, *Enter Module Parameters*.

c. *Supervisor* - access level may perform all of the same functions as Setup access level with the addition of *User ID and Password Setup* and *Enter Module Parameters*.

4. *Delete* - select to delete the displayed user.

5. *Save* - select to save the displayed user.

6. To exit, select the **X** located on the top right of the window.

7. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

6.6. Report Parameters

To enter/alter report header information, beginning from the main menu, select *File, Setup, and Report Parameters*. The *Report Editor* window (Figure 6-9) displays. For examples of some of the different report styles, see Section 13 - Reports.

1. *Printer Type* - select *Monochrome, Color, or Fancy* for use with all reports.

2. *Print Resolution* - use the drop down list to select the resolution used with all reports.

3. *Report Name* - select the desired report from the drop down list.

4. *Font* button - with the cursor placed on the report where text needs to be entered or with the text needing alteration highlighted, select to display the *Font* window:

a. *Font* - select the desired font type.

b. *Font Style* - select the desired font style.

c. *Size* - select the desired font size.

d. *Effects* - select *Strikeout, Underline* and/or select a *Color*.

e. To exit the window and use the selections, select *Apply* and *OK*. To exit without applying the selections, select *Cancel*.

5. *Font* - indicates the currently set font type.

6. *Font Size* - indicates the currently set font size and can be used to alter the font size.

7. *Color* - indicates the currently set color and can be used to alter the font color.

8. *Test Print* - select to printout an example of the currently displayed report.

9. *Save* - select to save the currently displayed report.

10. To exit, select the **X** located on the top right of the window.

6.7. Auto-Output Devices

To specify automatic data handling per run type, beginning from the main menu, select *File, Setup, and Auto-Output Devices*. The *Auto-Output Parameters* window (Figure 6-10) displays:

1. For each of the *Run Types* needed, select *Display* and/or *LIS* from the *Devices* columns to have the test data automatically displayed/sent once a run is complete. Regardless of the selections made on this window, test data can be transmitted and/or displayed at user request (section 7.7).

2. *Printer, Floppy, Email, and Include View-and-Accept Checkbox* are not available for use with this version of software.

3. To exit, select the **X** located on the top right of the window.

4. If a *Confirm* window displays, changes were made. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

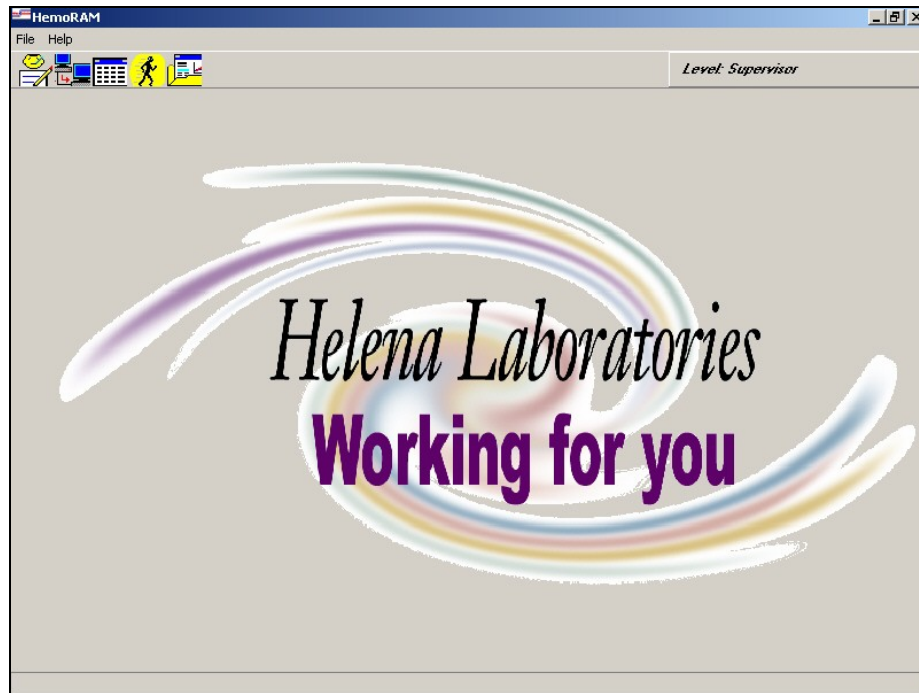


Figure 6-1. Main Menu

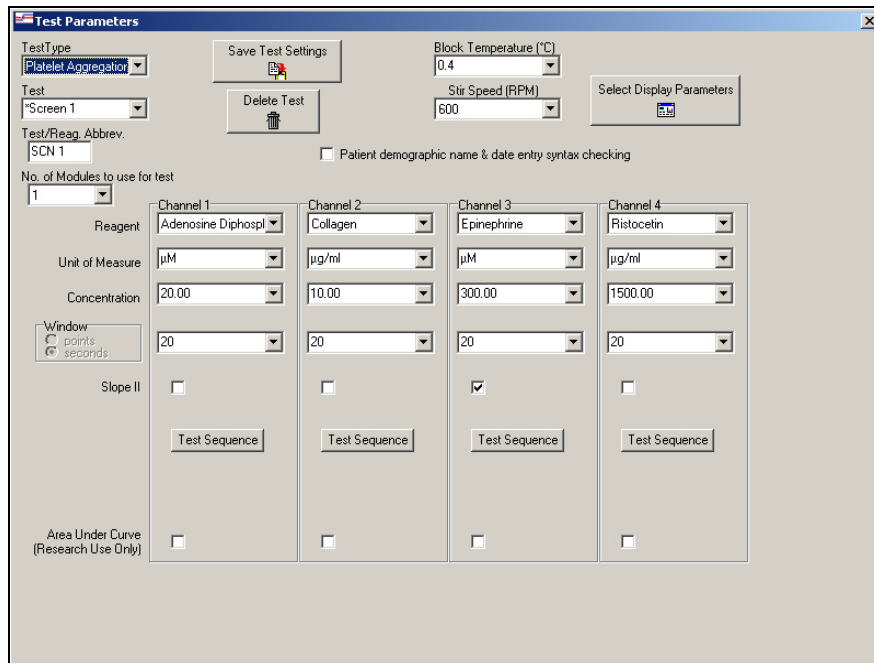


Figure 6-2. Test Parameters - Platelet Aggregation

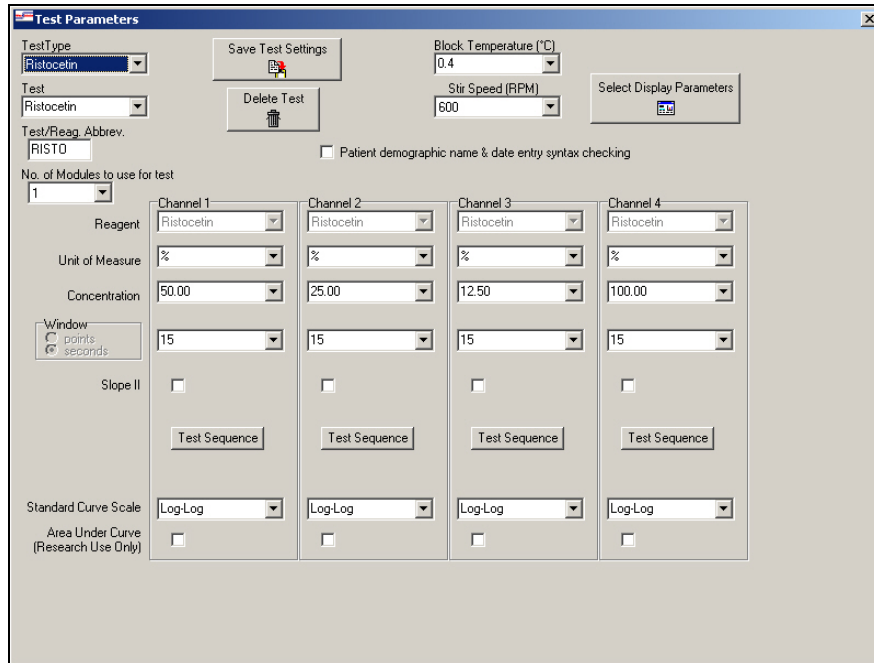


Figure 6-3. Test Parameters - Ristocetin Cofactor

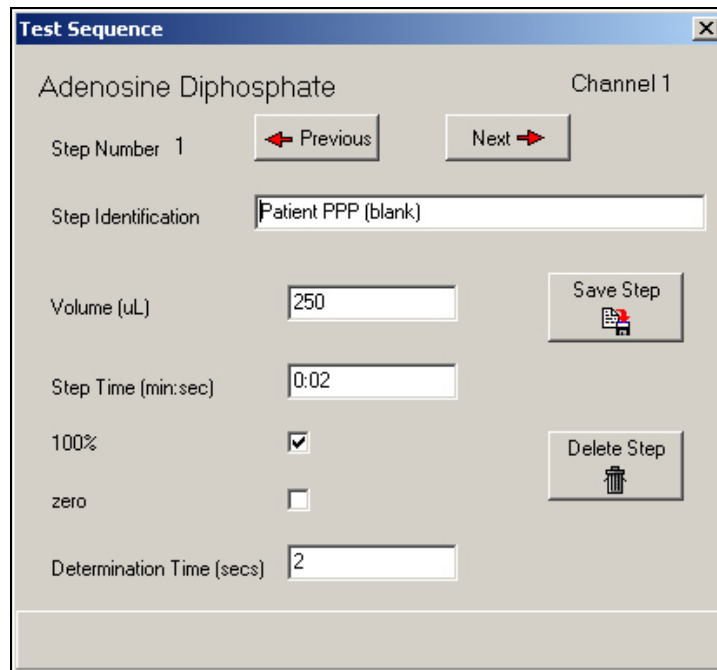


Figure 6-4. Test Sequence

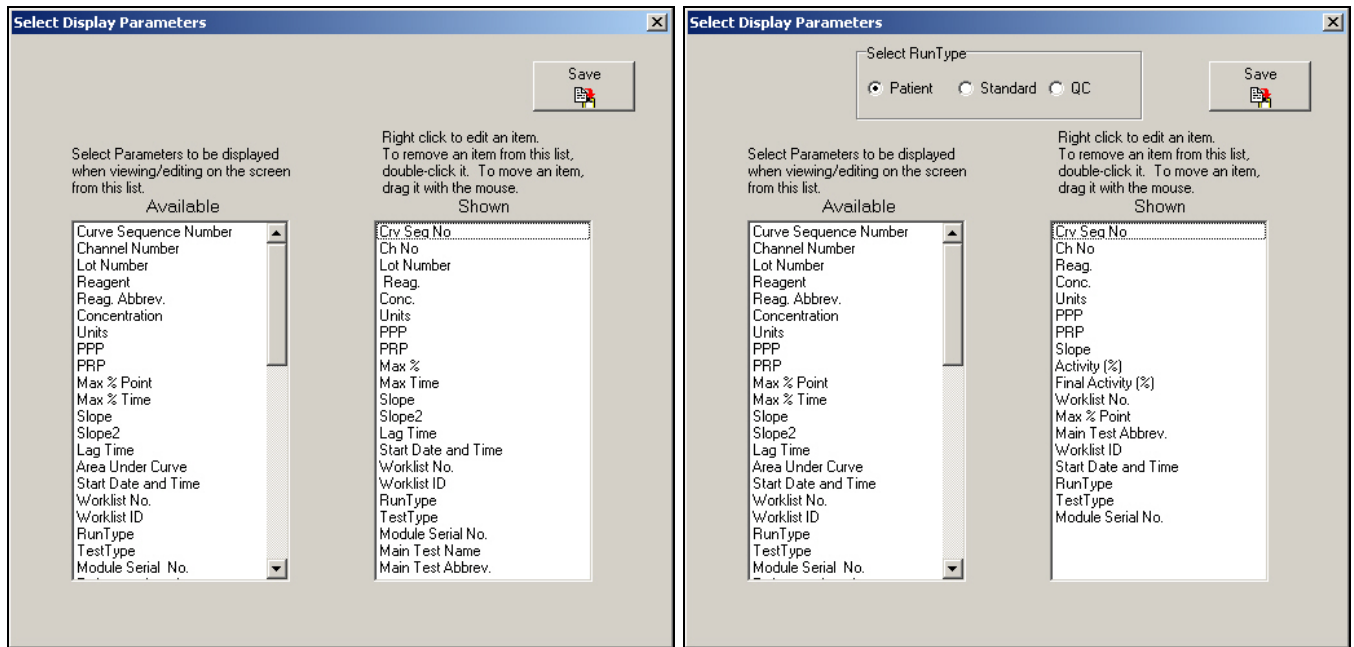


Figure 6-5. Display Parameters

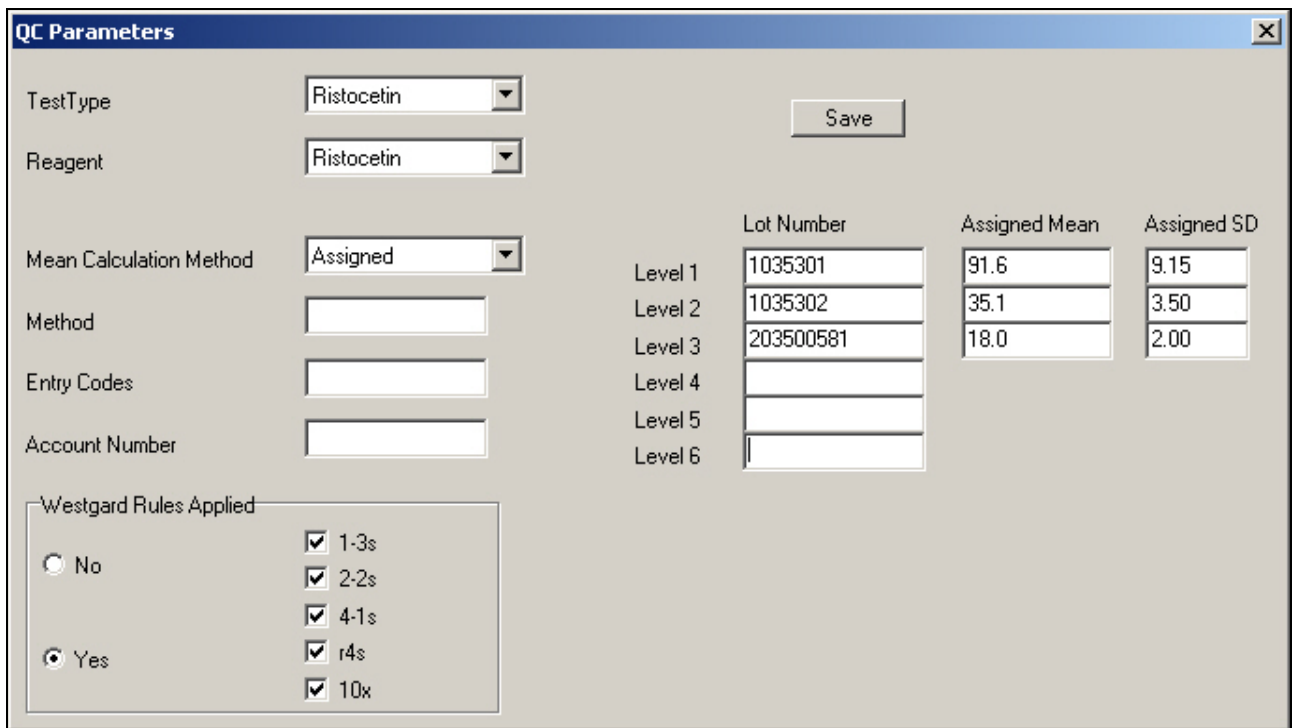


Figure 6-6. QC Parameters

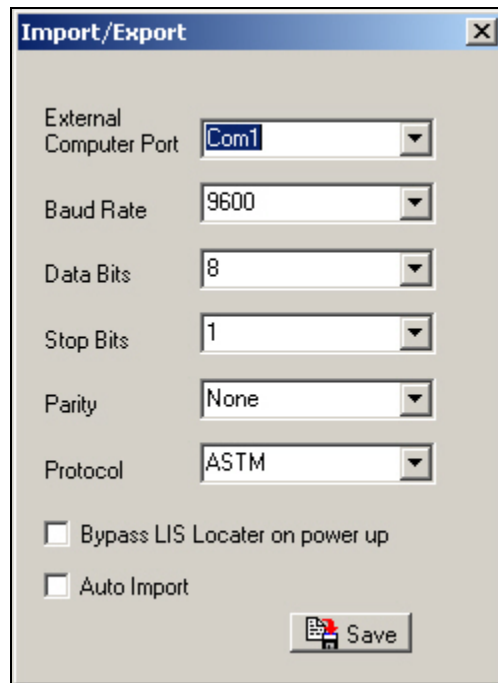


Figure 6-7. Import/Export Parameters



Figure 6-8. User ID and Passwords

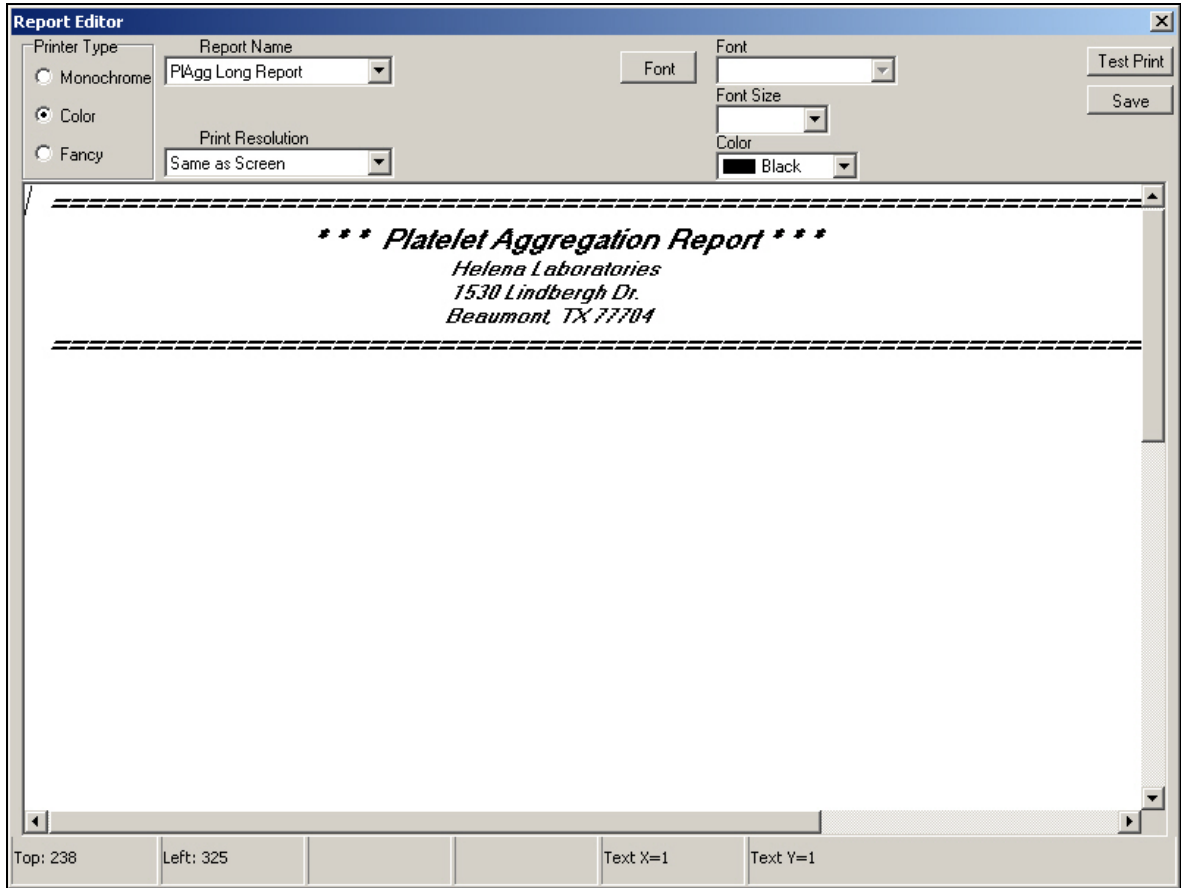


Figure 6-9. Report Editor

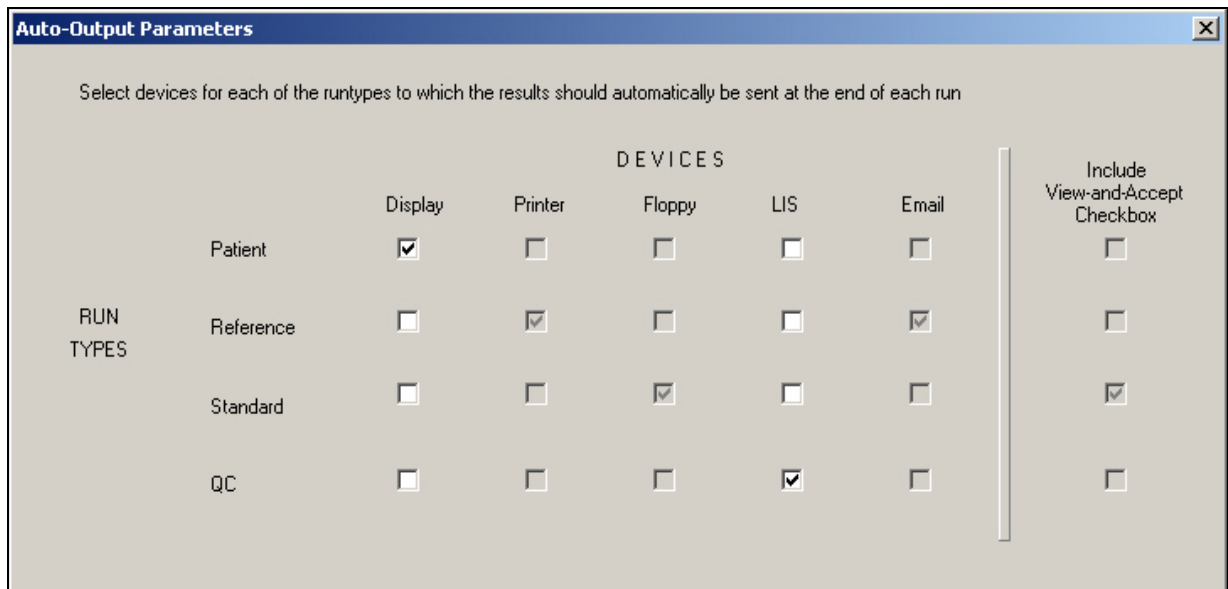


Figure 6-10. Auto-Output Parameters

Section 7 - Operating Instructions

7.1. Preparing the Instrument for Use

1. Turn power on for the module, printer, and monitor, and then for the computer.
2. The Microsoft® Windows® program opens and displays the HemoRAM software icon. Select the icon; if the main menu (Figure 7-1) appears on the monitor, the system is operating correctly. If an error message appears, refer to section 10.2.
3. When the *Login* window displays, enter the applicable *User ID*, press **Tab**, and enter the *Password*. If user IDs have been setup, the access level of the ID entered determines the functions accessible. The assigned access level of the ID entered is displayed on the top right of the main menu. See section 6.5 for additional information on access levels. If no user ID/passwords are setup for use, press **Enter** to proceed.
4. Allow the instrument to warm up for 20 minutes.
5. Prior to the instrument's first daily use, perform the Optical Calibration Check (section 10.1.1).

7.2. Performing Tests Summary

7.2.1. Platelet Aggregation

The AggRAM can run both micro and standard volumes. It is recommended that the laboratory establish their normal ranges with the same volume that will be utilized in their laboratory. All default settings for the AggRAM are for Micro volumes; however, the settings can be altered if using Standard volumes (section 6.2.1).

Volumes

	Micro	Standard
PPP	225µL	450µL
PRP	225µL	450µL
Aggregating Reagent	25µL	50µL
Stir Speed	600 rpm	1000 rpm

1. Prepare the specimens (PPP and PRP) and reagents per the procedures provided with the reagents.

2. Put the cuvettes in the ambient section of the module (Figure 5-2).

3. If needed, enter the patient information (section 7.3), import the patient information/worklist from the LIS (section 7.4), and/or setup the worklist (section 7.5.1).

4. Access the *Run* window (Figure 7-2) by selecting either *File* and then *Run* or by selecting the Run icon.

- a. Select the appropriate *Worklist* from the drop down list.

- b. The worklist's current parameters display. Confirm that all the parameters are as desired and that the correct demographic parameters are entered for all, and only, the channels to be used. The parameters are entered/alterd as on the *Worklist Preparation* window. If additional instructions are needed, see section 7.5.1.

- c. If multiple modules are in use, using the *Base Module* option, select the letter of the first module to be used for the run.

- d. Select *Begin Run*. The *Run* window (Figure 7-2) now displays an area for the chart, an *Abort Run* button, a *Show Parameters* button, and, if set to automatically display, the *Steps* window. For additional information on the *Run* and *Steps* windows, see section 7.6.

5. Prepare the needed blanks: Pipette the needed volume (micro or standard) of PPP into a cuvette. If the channels will be used for different patients and/or controls, prepare each of the needed PPPs. Set the PPP blank(s) aside.

6. Pipette, into a cuvette with a stir bar, the needed volume (micro or standard) of each sample of PRP. Incubate the PRP cuvettes at 37°C for 1 to 3 minutes.

7. Use the PPP cuvette blank(s) to set the 100% aggregation:

- a. Into the first channel, insert the correct PPP cuvette and press the corresponding channel button (Figure 5-2). The channel indicator light flickers red-green and the

Percent aggregation versus Time (seconds) chart displays.

b. Two seconds after the channel button is released, the channel indicator light turns green and, if displayed, the *Steps* window includes the PPP O.D. value. The channel is now calibrated for 100% aggregation (no platelets).

c. Remove the cuvette from the channel.

d. Repeat for each additional channel needed using the correct PPP cuvette blank.

e. Remove the PPP cuvette blank(s) from the channel(s).

8. Insert the warmed PRP cuvette(s) into the appropriate channel(s).

9. Load the pipette with the needed volume (micro or standard) of reagent.

10. Simultaneously, pipette the reagent into the cuvette and press the channel button to begin the timing of the final reaction.

11. The channel indicator light turns red and, if displayed, the *Steps* window includes the PRP O.D. value.

12. Withdraw the pipette tip from the cuvette taking care not to pull the cuvette up.

13. Repeat steps 8 through 12 for the remaining channels.

14. The instrument automatically monitors the aggregation response using the initial value of each PRP sample, which set the 0% aggregation level, and the PPP value, which set the 100% level. Each sample is continuously measured and plotted on the chart, displaying each channel in a different color.

15. For instructions on aborting or stopping, either the entire test or specific channels, and on using the window(s) displayed during the running of the test, see section 7.6.2.

16. Once the test is complete, a *Confirm* prompt displays. If the worklist that was used needs to be retained for future use, select *Yes*; otherwise, select *No*.

17. The *Run* (and *Steps*) window(s) closes, and, if set to automatically occur (section 6.7), the data is exported and/or the *View/Edit* window displays the results, see section 7.7.

18. If a baseline aggregation or a check for spontaneous aggregation needs to be performed, replace the aggregation reagent with 0.9% saline during the platelet aggregation study. For the worklist in use, change the Concentration to zero for the channel on which the baseline/check will be performed.

7.2.2. Ristocetin Cofactor

7.2.2.1. Ristocetin - Standard Curves

The AggRAM can run both micro and standard volumes. It is recommended that the laboratory run standard curves, controls, and patient samples using the same volume conditions. All default settings for the AggRAM are for Micro volumes; however, the settings can be altered if using Standard volumes (section 6.2.2).

Volumes

		Micro	Standard
Aggregation blank	Platelet suspension	125µL	250µL
	Tris-buffered Saline	125µL	250µL
Platelet suspension		200µL	400µL
Ristocetin		25µL	50µL
Plasma dilution		25µL	50µL
Stir Speed		600 rpm	1000 rpm

1. Prepare the needed reagents per the procedures provided with the reagents.

2. Put the cuvettes in the ambient section of the module (Figure 5-2).

3. If needed, import the worklist from the LIS (section 7.4) and/or setup the worklist (section 7.5.3).

4. Access the *Run* window (Figure 7-2) by selecting either *File* and then *Run* or by selecting the Run icon.

- a. Select the appropriate *Worklist* from the drop down list.
 - b. The worklist's current parameters display. Confirm that 1) *RunType Standard* is selected, 2) all the parameters are as desired, and 3) the correct *Concentration* is entered for all the channels to be used. The parameters are entered/alterd as on the *Worklist Preparation* window. If additional instructions are needed, see section 7.5.3.
 - c. If multiple modules are in use, using the *Base Module* option, select the letter of the first module to be used for the run.
 - d. Select *Begin Run*. The *Run* window (Figure 7-2) now displays an area for the chart, an *Abort Run* button, a *Show Parameters* button, and, if set to automatically display, the *Steps* window. For additional information on the *Run* and *Steps* windows, see section 7.6.
5. Prepare the lyophilized platelet suspension and test samples per the procedures provided with the reagents.
 6. Prepare the needed aggregation blank: Pipette, into a cuvette with a stir bar, the needed volumes (micro or standard) of platelet suspension and Tris-buffered saline.
 7. Use the aggregation blank to set 100% aggregation:
 - a. Into the first channel, insert the blank and press the corresponding channel button (Figure 5-2). The channel indicator light flickers red-green and the *Percent* aggregation versus *Time (seconds)* chart displays.
 - b. Five seconds after the channel button is released, the channel indicator light turns green and, if displayed, the *Steps* window includes the 100% activity value (shown as PPP O.D.). The channel is now calibrated to zero.
 - c. Remove the cuvette from the channel.
 - d. Repeat for each additional channel needed.
 8. Incubate the platelet suspension and ristocetin:
 - a. In each channel in use, place a cuvette with a stir bar.
 - b. Pipette the needed volume (micro or standard) of platelet suspension into the cuvette(s).
 - c. Simultaneously, pipette the needed volume (micro or standard) of ristocetin into the cuvette(s) and press the channel button.
 - d. Withdraw the pipette tip from the cuvette taking care not to pull the cuvette up.
 - e. Incubate for 1 minute.
 9. During incubation, prepare to pipette the needed volume (micro or standard) of plasma dilution.
 10. Once incubation is complete, simultaneously, pipette the plasma dilution into the cuvette in the first channel and press the channel button to begin timing of the final reaction.
 11. The channel indicator light turns red.
 12. Withdraw the pipette tip from the cuvette taking care not to pull the cuvette up.
 13. If the *Steps* window is displayed, the 0% activity value is shown as PRP O.D. once the value is determined.
 14. Repeat steps 9 through 13 for the remaining channels.
 15. The instrument automatically monitors the activity using the initial value of the final reaction, represented as PRP O.D., which set the 0% aggregation level, and the blank value, represented as PPP O.D., which set the 100% level. Each sample is continuously measured and plotted on the chart, displaying each channel in a different color.
 16. For instructions on aborting or stopping, either the entire test or specific channels, and on using the window(s) displayed during the running of the test, see section 7.6.2.
 17. Once the test is complete, a *Confirm* prompt displays. If the worklist used needs to

be retained for future use, select *Yes*; otherwise, select *No*.

18. The *Run* (and *Steps*) window(s) closes, and, if set to automatically occur (section 6.7), the data is exported and/or the *View/Edit* window displays the results, see section 7.7.

19. If the Standard needs editing (section 7.7.2), this should be done prior to running any Patients or QCs for which the Standard will be used. Once Patient/QC runs are completed, a copy of the applicable Standard is stored with that run. As a result, any editing performed on the Standard after that is not applied to the Standard saved with the Patient/QC results. The edited Standard can be used with the Patient/QC run by editing the applicable Patient/QC run after editing the Standard. At that time, a copy of the edited Standard is stored with the run, replacing the previously stored Standard.

20. With Westgard rules in use, if a QC was included in the run and failed, an error message displays. For information on Westgard Failure Resolution, see section 7.7.11.

7.2.2.2. Ristocetin - Patient Tests

The AggRAM can run both micro and standard volumes. It is recommended that the laboratory run standard curves, controls, and patient samples using the same volume conditions. All default settings for the AggRAM are for Micro volumes; however, the settings can be altered if using Standard volumes (section 6.2.2).

Volumes

		Micro	Standard
Aggregation blank	Platelet suspension	125µL	250µL
	Tris-buffered Saline	125µL	250µL
Platelet suspension		200µL	400µL
Ristocetin		25µL	50µL
Plasma dilution		25µL	50µL
Stir Speed		600 rpm	1000 rpm

1. Prepare the needed reagents per the procedures provided with the reagents.

2. Put the cuvettes in the ambient section of the module (Figure 5-2).

3. If a new reagent lot is in use, see section 7.2.2.1 for instructions on running a new standard curve.

4. If needed, enter the patient information (section 7.3), import the patient information/worklist from the LIS (section 7.4), and/or setup the worklist (section 7.5.2).

5. Access the *Run* window (Figure 7-2) by selecting either *File* and then *Run* or by selecting the Run icon.

a. Select the appropriate *Worklist* from the drop down list.

b. The worklist's current parameters display. Confirm that 1) *RunType Patient* is selected, 2) all the parameters are as desired, and 3) the correct demographic and standard parameters are entered for all, and only, the channels to be used. The parameters are entered/altered as on the *Worklist Preparation* window. If additional instructions are needed, see section 7.5.2.

c. If multiple modules are in use, using the *Base Module* option, select the letter of the first module to be used for the run.

d. Select *Begin Run*. The *Run* window (Figure 7-2) now displays an area for the chart, an *Abort Run* button, a *Show Parameters* button, and, if set to automatically display, the *Steps* window. For additional information on the *Run* and *Steps* windows, see section 7.6.

6. Prepare the lyophilized platelet suspension and test samples per the procedures provided with the reagents.

7. Prepare the needed aggregation blank: Pipette, into a cuvette with a stir bar, the needed volumes (micro or standard) of platelet suspension and Tris-buffered saline.

8. Use the aggregation blank to set 100% aggregation:

a. Into the first channel, insert the blank and press the corresponding channel button (Figure 5-2). The channel indicator light flickers red-green and the *Percent aggregation versus Time (seconds)* chart displays.

b. Five seconds after the channel button is released, the channel indicator light turns green and, if displayed, the *Steps* window includes the 100% activity value (shown as PPP O.D.). The channel is now calibrated to zero.

c. Remove the cuvette from the channel.

d. Repeat for each additional channel needed.

9. Incubate the platelet suspension and ristocetin:

a. In each channel in use, place a cuvette with a stir bar.

b. Pipette the needed volume (micro or standard) of platelet suspension into the cuvette(s).

c. Simultaneously, pipette the needed volume (micro or standard) of ristocetin into the cuvette(s) and press the channel button.

d. Withdraw the pipette tip from the cuvette taking care not to pull the cuvette up.

e. Incubate for 1 minute.

10. During incubation, prepare to pipette the needed volume (micro or standard) of plasma dilution.

11. Once incubation is complete, simultaneously, pipette the plasma dilution into the cuvette in the first channel and press the channel button to begin timing of the final reaction.

12. The channel indicator light turns red.

13. Withdraw the pipette tip from the cuvette taking care not to pull the cuvette up.

14. If the *Steps* window is displayed, the 0% activity value is shown as PRP O.D. once the value is determined.

15. Repeat steps 10 through 14 for the remaining channels.

16. The instrument automatically monitors the activity using the initial value of the final reaction, represented as PRP O.D., which set the 0% aggregation level, and the blank value, represented as PPP O.D., which set the 100% level. Each sample is continuously measured and plotted on the chart, displaying each channel in a different color.

17. For instructions on aborting or stopping, either the entire test or specific channels, and on using the window(s) displayed during the running of the test, see section 7.6.2.

18. Once the test is complete, a *Confirm* prompt displays. If the worklist used needs to be retained for future use, select *Yes*; otherwise, select *No*.

19. The *Run* (and *Steps*) window(s) closes, and, if set to automatically occur (section 6.7), the data is exported and/or the *View/Edit* window displays the results, see section 7.7.

20. With Westgard rules in use, if a QC was included in the run and failed, an error message displays. For information on Westgard Failure Resolution, see section 7.7.11).

7.3. Enter/Edit Patient Identification

The Patient information can either be imported via the LIS (section 7.4) or entered through the *Patient Demographics Entry* window.

1. To access the *Patient Demographics Entry* window (Figure 7-3), from the main menu either select *File* and then *Patient Identification* or select the New Patient icon.

2. The six available patient demographic labels display:

a. *Patient ID* - this demographic is the primary index demographic used for data retrieval. At minimum, information for this demographic must be entered. This demographic field also contains a drop down list that can be used to select a previously entered patient.

b. *Patient Name* - enter/edit as needed. Note that if *Patient demographic name and date entry syntax checking* is in use, this information must be entered per those requirements (section 6.2.1 or 6.2.2).

c. *Birthdate* - enter/edit as needed. Note that if *Patient demographic name and date entry syntax checking* is in use, this information must be entered per those requirements (section 6.2.1 or 6.2.2).

d. *Patient Sex* - enter/edit as needed.

e. *Attending Physician ID* - enter/edit as needed.

f. *Diagnosis* - enter/edit as needed. Note that this data will display and export; however, will not print.

3. *Save* - select once all the demographics for the patient are entered.

4. *Delete* - select to delete the demographics for the currently displayed patient.

5. Repeat as needed to enter/edit all the patient information.

6. To exit, select the **X** located on the top right of the window.

7. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

7.4. Importing Patient Information and Worklists

To download patient information and/or worklists from the LIS, either select *File* and *LIS* or select the LIS icon. The information is downloaded and accessible, as applicable, in the *Patient Demographic Entry* window (section 7.3) and/or the *Worklist Preparation* and *Run* windows (sections 7.5 and 7.6).

7.5. Creating Worklists

7.5.1. Platelet Aggregation Worklist

Access the *Worklist Preparation* window (Figure 7-4) by either selecting *File* and *Worklist* or selecting the Worklist icon. Note that once some of the following selections are made, the window expands to allow channel specific information to be entered. Use the following to setup/alter the worklist information:

1. *Clear for New* - with a worklist displayed, select to clear all the displayed information in order to create a new worklist.

2. *Save* - once a worklist is setup, select to save the worklist.

3. *Delete* - with a worklist displayed, select to remove the worklist. A *Confirm* message displays. To permanently remove the worklist, select *Yes*. To retain the worklist, select *No*.

4. *Worklist* -

a. For new worklists, use the keyboard to enter the label.

b. For a previously setup worklist, select a Platelet Aggregation worklist from the contents of the drop down list. Note that if a worklist is currently being run, it is not available for selection.

5. *TestType* - confirm as selected or use the drop down list to select *Platelet Aggregation*.

6. *Test* - select from the contents of the drop down list. The contents are determined by the tests previously setup (section 6.2). Note a *Test* name which begins with an asterisk, *, indicates a profile allowing each channel to have a different reagent.

7. *Stir Speed* - if needed, use the drop down list to select a stir speed of from 500 through 1500 in increments of 100. Note that users with Run Only access cannot alter the setting.

8. *Reference* - select to designate as a reference. If selected, the demographic field (step 9.b) is automatically shown as *REFERENCE*. To better define the reference

for later selection as an overlay, the ID can be replaced/alterd (for example, ADP ref). Note that if multiple references are run with patients, the last channel used must be a patient; however, if only one reference is run, it can be in any of the channels used.

9. For each channel needed, setup/alter the following:

a. *Reagent* - is automatically entered as the selected *Test*, unless the selected *Test* contains an asterisk. In which case, select the reagent for each channel from the drop down list.

b. *Patient ID* - is the primary index demographic and is used for data retrieval. Enter using the keyboard or the drop down list. With a selection made for channel 1, to copy that same selection to the other channels, select *Copy Ch1 PatID*. If the channel is being used for a Reference (step 8), enter/alter using the keyboard. Neither the drop down list nor the copy feature is available for references. All the channels, and only those channels, to be used must have a selection.

c. *Unit of Measure* - select from the drop down list or use the keyboard to enter/alter.

d. *Concentration* - select from the drop down list or use the keyboard to enter/alter.

e. *Lot Number* - Use the keyboard to enter. With an entry made for channel 1, to copy that same lot number to the other channels, select *Copy Ch1 Lot #*.

10. To save the currently displayed worklist, select *Save*. To setup another worklist, select *Clear for New* and see step 4.

11. To exit, select the **X** located on the top right of the window.

12. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

7.5.2. Ristocetin Cofactor Patient Worklist

Access the *Worklist Preparation* window (Figure 7-4) by either selecting *File* and *Worklist* or selecting the Worklist icon. Note that once some of the following selections are made, the window expands to allow channel specific information to be entered. Use the following to setup/alter the worklist information:

1. *Clear for New* - with a worklist displayed, select to clear all the displayed information in order to create a new worklist.

2. *Save* - once a worklist is setup, select to save the worklist.

3. *Delete* - with a worklist displayed, select to remove the worklist. A *Confirm* message displays. To permanently remove the worklist, select *Yes*. To retain the worklist, select *No*.

4. *Worklist* -

a. For new worklists, use the keyboard to enter the label.

b. For a previously setup worklist, select a Ristocetin worklist from the contents of the drop down list. Note that if a worklist is currently being run, it is not available for selection.

5. *TestType* - confirm as selected or use the drop down list to select *Ristocetin*.

6. *RunType* - confirm as selected or select *Patient*.

7. *Test* - select from the contents of the drop down list. The contents are determined by the tests previously setup (section 6.2).

8. *Stir Speed* - if needed, use the drop down list to select a stir speed of from 500 through 1500 in increments of 100. Note that users with Run Only access cannot alter the setting.

9. For each channel needed, setup/alter the following:

a. *QC* - select to designate as *QC*. If *QC* is selected, then the *Patient/QC ID* field (see next step) automatically contains *Quality Control* and cannot be altered.

b. *Patient/QC ID* - enter using the keyboard or select from the drop down list. With a selection made for channel 1, to copy that same selection to the other channels, select *Copy Ch1 PatID*. All the channels to be used must have a selection.

c. *QC Level* - if *QC* is selected, then *QC Level* is available for use. Make a selection from the contents of the drop down list.

d. *Standard* - make a selection from the contents of the drop down list. With a selection made for channel 1, to copy that same selection to the other channels, select *Copy Ch1 Std*. All the channels to be used must have a selection.

e. *Concentration* - select from the drop down list or use the keyboard to enter/alter.

10. To save the currently displayed worklist, select *Save*. To setup another worklist, select *Clear for New* and see step 4.

11. To exit, select the **X** located on the top right of the window.

12. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

7.5.3. Ristocetin Cofactor Standard Worklist

Access the *Worklist Preparation* window (Figure 7-4) by either selecting *File* and *Worklist* or selecting the *Worklist* icon. Note that once some of the following selections are made, the window expands to allow channel specific information to be entered. Use the following to setup/alter the worklist information:

1. *Clear for New* - with a worklist displayed, select to clear all the displayed information in order to create a new worklist.

2. *Save* - once a worklist is setup, select to save the worklist.

3. *Delete* - with a worklist displayed, select to remove the worklist. A *Confirm* message displays. To permanently remove the worklist, select *Yes*. To retain the worklist, select *No*.

4. *Worklist* -

a. For new worklists, use the keyboard to enter the label.

b. For a previously setup worklist, select a *Ristocetin* worklist from the contents of the drop down list. Note that if a worklist is currently being run, it is not available for selection.

5. *TestType* - confirm as selected or use the drop down list to select *Ristocetin*.

6. *RunType* - confirm as selected or select *Standard*.

7. *Test* - select from the contents of the drop down list. The contents are determined by the tests previously setup (section 6.2).

8. *Stir Speed* - if needed, use the drop down list to select a stir speed of from 500 through 1500 in increments of 100. Note that users with *Run Only* access cannot alter the setting.

9. *ID of Standard* - should automatically include the *Worklist* name entered, unless that name has already been used for another standard; use the keyboard to enter/alter as needed.

10. *Lot Number* - use the keyboard to enter.

11. *Reference Level %* - use the keyboard to enter.

12. *Expiration Date* - use the keyboard to enter.

13. *Concentration* - for each channel needed:

a. *Channel* - use the drop down list or keyboard to enter/alter the concentration amount. All the channels to be used must have a selection.

b. QC - for each channel as needed, select QC to designate as such. Once selected the following is accessible:

i. *Level* - select from the contents of the drop down list.

14. To save the currently displayed worklist, select *Save*. To setup another worklist, select *Clear for New* and see step 4.

15. To exit, select the **X** located on the top right of the window.

16. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*. To return to the window, select *Cancel*.

7.6. Run and Steps Windows

7.6.1. Run Window Prior to Beginning a Test

1. Access the *Run* window (Figure 7-2) by selecting either *File* and then *Run* or by selecting the Run icon.

2. Select the needed *Worklist* from the drop down list.

3. The worklist's current parameters display. Confirm that all the parameters are correct. The parameters are entered/alterd as on the *Worklist Preparation* window. If additional instructions are needed, see section 7.5.

4. The current temperature of the module(s) displays on the top right corner. If the temperature is out of range, it will appear with a blue background if too low and a red background if too high.

5. If multiple modules are in use, using the *Base Module* option, select the letter of the first module to be used for the run.

6. Once the displayed information is as needed, select *Begin Run*.

7.6.2. Run Window During a Test

1. Once *Begin Run* is selected, the *Run* window (Figure 7-2) displays the following:

a. the selections made for *Worklist*, *TestType*, *Test*, *Stir Speed*, and, as applicable, for *Base Module* and *RunType*,

b. an *Abort Run* button (section 7.6.2.1),

c. a *Show Parameters* button (section 7.6.2.2),

d. an area for the results chart (section 7.6.2.3),

e. and, if so set, the *Steps* window (section 7.6.3).

2. To exit, select the **X** on the top right of the window. The *Run* window can be closed during the running of tests.

3. To reopen the *Run* window, select either *File* and *Run* or the *Run* icon.

7.6.2.1. Abort Run

If the entire test needs to be aborted, from the *Run* window, select *Abort Run*. If needed, individual channels can be aborted, see section 7.6.2.3.3. Once aborted, test results are deleted.

7.6.2.2. Show Parameters / Show Graph

To view the test parameters, from the *Run* window, select the *Show Parameters* button, which then becomes the *Show Graph* button. Note that this window cannot be scrolled to view any information not currently displayed. As needed use the *Show Parameters/Show Graph* button to toggle between the two screens.

7.6.2.3. Results Chart

Once a test is in process, and with the chart displayed (section 7.6.2.2), use the following options as needed:

7.6.2.3.1. Smooth

1. From the *Run* window, select *Edit* and then *Custom Smooth* to access the *Filter selection* window. Enter the desired smoothing, 0 through 30. Select *OK* to exit the window and use the selection. Select *Cancel* to exit the window without smoothing. Note that any smoothing applied on this window is automatically removed on the *View/Edit* window.

2. From the *Run* window, select *No Smoothing* to remove any smoothing performed.

3. From the *Run* window, select *Smooth* to smooth the chart. To specify the amount of smoothing, see step 1. Note that any smoothing applied on this window is automatically removed on the *View/Edit* window.

7.6.2.3.2. View

From the *Run* window, select *View* and then one of the following:

1. *Show Steps* - if not currently displayed, select to display the *Steps* window (Figure 7-5). For more information on the *Steps* window, see section 7.6.3.

2. *Turn ON Auto-Show Steps* or *Turn OFF Auto-Show Steps* - use the option displayed to automatically display (ON) or not display (OFF) the *Steps* window. The setting chosen will not be used until the next test is run. For more information on the *Steps* window, see section 7.6.3.

3. *Channels* - select to access the *Channel Selector* window. The channels indicated with a check mark will display. Click on the appropriate box to add or remove the check mark. To control the display of all the channels at once, use the *All Channels* box.

4. *Full/Partial Screen* - select to increase or decrease the display size of the chart. With the chart at full screen, the *Run* portion of the screen is removed and the chart area is enlarged. Select *Full/Partial Screen* as needed to toggle between the two display

options. The graph can also be enlarged and then maneuvered to aid in viewing, for additional information, see section 7.7.12.

7.6.2.3.3. Abort

From the *Run* window, select *Abort* to access the buttons used to *Abort All Channels* or to individually abort the channels in use. Once aborted, test results are deleted.

7.6.2.3.4. Print

From the *Run* window, select *Print* and then *Print Graph* to access the *Print* window. Use this window to select the appropriate *Printer Name* and *Number of copies*. To exit the window and print the chart, select *OK*. To exit the window without printing, select *Cancel*.

7.6.2.3.5. Stop

From the *Run* window, select *Stop* to access the buttons used to *Stop All Channels* or to individually stop the channels in use. Once all or the last channel running is stopped, if set to automatically display (section 6.7), the *View/Edit* window displays the results (section 7.7).

7.6.3. Steps Window

For information on displaying the *Steps* window, see section 7.6.2.3.2.

The *Steps* window (Figure 7-5) displays the following information during a test for each channel in use:

1. *Channel* - lists the channel numbers in use.
2. *Reag* - lists the reagent setup for use.
3. *Conc* - lists the concentration setup for use.
4. *Units* - lists the unit of measure setup for use.
5. *Step No* - indicates the sequence number of the step that either is to be performed or is currently being performed.
6. *Step ID* - displays the step name for the step that either is about to be performed or is currently being performed.

7. *Volume(uL)* - indicates the volume setup for the step that either is to be performed or is currently being performed.

8. *Step Time (min:sec)* - indicates the time duration setup for the step that either is to be performed or is currently being performed.

9. *Time Left (sec)* - indicates the remaining time duration of the step the test is currently performing.

10. *PPP O.D.*

a. For Platelet Aggregation tests, *PPP O.D.* indicates the 100% aggregation value of the platelet poor plasma blank.

b. For Ristocetin Cofactor tests, *PPP O.D.* indicates the 100% activity value of the platelet solution blank.

11. *PRP O.D.*

a. For Platelet Aggregation tests, *PRP O.D.* indicates the 0% aggregation value of the platelet rich plasma and reagent.

b. For Ristocetin Cofactor tests, *PRP O.D.* indicates the 0% activity value of the platelet solution, ristocetin, and sample/control solution.

12. To exit, select the **X** on the top right of the window. The *Steps* window can be closed during the running of tests.

13. To reopen the *Steps* window, see section 7.6.2.3.2.

14. The *Steps* window can be set to either automatically display or not display, see section 7.6.2.3.2.

7.7. View/Edit Results

The *View/Edit* window is accessed either automatically, once a test is completed, or manually from the main menu by selecting either *File* and *View/Edit File* or the *View/Edit* icon.

With the *View/Edit* window (Figure 7-6) displayed:

1. To transmit the displayed worklist, see section 7.7.1.

2. To edit the displayed worklist, see section 7.7.2.

3. To select a different worklist to view, see section 7.7.7, and then section 7.7.3.

4. To alter what information is displayed and how it is displayed, see section 7.7.4, 7.7.8, and/or 7.7.12.

5. To print the displayed worklist, see section 7.7.1 or 7.7.5.

6. To delete the curves within a worklist or an entire worklist, see section 7.7.6.

7. With a Platelet Aggregation curve displayed, to overlay a reference curve, see section 7.7.9.

8. With a Ristocetin Cofactor curve displayed, to view the Standard Curve, see section 7.7.10.

9. With a Ristocetin Cofactor QC curve displayed, to view the Levey-Jennings Chart, see section 7.7.11.

7.7.1. File

To export or print the displayed data, from the *View/Edit* window, select *File* and use following options:

1. *Send To* -

a. *Email* - this feature is not available on this version of software.

b. *LIS* - select and the displayed data is exported to the LIS.

c. *Spreadsheet file* - this feature is not available on this version of software.

2. *Print* - select and the *Report Selection* window displays. For examples of some of the different report styles, see Section 13 - Reports.

a. *Select Report* - use the drop down list to select the needed report style. The report styles available vary based on the currently displayed information.

b. *Print Resolution* - use the drop down list to select the appropriate resolution quality.

c. *Setup* - For additional information, see section 7.10.

d. *Print* - select to print the report style and resolution indicated.

7.7.2. Edit

Note that users with Run Only access cannot access *Edit*.

Occasionally, a pattern may need to be edited due to an "impulse" in the raw data that deflects the slope. The available editing functions allow for smoothing of the chart line created by the raw data for easier viewing, data averaging, altering the slope, changing the slope window, and relocating the slope. As a curve(s) is edited, it is automatically resaved.

If Ristocetin Cofactor Standards need editing, this should be done prior to running any Patients or QCs for which the Standard will be used. Once Patient/QC runs are completed, a copy of the applicable Standard is stored with that run. As a result, any editing performed on the Standard after that is not applied to the Standard saved with the Patient/QC results. The edited Standard can be used with the Patient/QC run by editing the applicable Patient/QC run after editing the Standard. At that time, a copy of the edited Standard is stored with the run, replacing the previously stored Standard.

7.7.2.1. Slope

7.7.2.1.1. Show/Hide Slope Lines

To toggle between the lines marking the slope and the slope point being displayed and not displayed, from the *View/Edit* window, select *Edit*, *Slope*, and *Show/Hide*. Note that if the dotted line marking the slope point displays without the corresponding solid lines marking the slope, the slope is either a negative or zero. The slope must be corrected, either re-edited or returned to the automatic slope selection, to correct the problem and display all the lines.

7.7.2.1.2. Automatic Slope

To return the slope(s) to those automatically determined by the software, from the *View/Edit* window, select *Edit*, *Slope*, and *Automatic*. All manual changes to the slope(s) are deleted.

7.7.2.1.3. Manual Slope

In addition to the instructions that follow, for Slope 1 only, the slope can be altered either by changing the appropriate numeric value displayed in the parameters or can be altered directly on the chart by clicking on the curve at the desired location. When the chart is used to alter, the slope is relocated with its center at the location indicated.

Once a slope has been manually edited, regardless of the method used, an (M) is placed next to the slope value parameter.

To manually edit the slope(s), from the *View/Edit* window, select *Edit*, *Slope*, and *Manual*. The *Manual Slope Change* window displays.

1. *Select Channel* - select the number of the channel to be altered.

2. *Slope Window* - initially, the slope window for Platelet Aggregation is 20 seconds and for Ristocetin Cofactor is 15 seconds. As the window size changes, so will the slope value. Use the ◀ left and ▶ right arrow buttons to change the slope window. For Ristocetin Cofactor, note that the slope window for the standard curve and patients must be consistent.

3. *Slope Location* - is automatically selected by the software from the fastest rate change of % aggregation (or activity) versus time. To alter the location, first click on either the ◀ left or ▶ right arrow button for the desired slope, *Slope1* or *Slope2*. Then use either the square that is now blinking or the slope's arrow buttons to change the slope location.

4. *Slope* - the angle of the slope is automatically selected by the software. To alter the angle, first click on either the ▲ up or ▼ down arrow button for the desired slope,

Slope1 or *Slope2*. Then use either the square that is now blinking or the slope's arrow buttons to change the slope.

5. Once a slope has been manually edited, an (M) is placed next to the slope value parameter.

6. If manual editing results in a N/A slope, the editing done should be removed either using the editing feature (Slope Window, Slope, etc.) that resulted in the N/A or by returning to the software-selected slope.

7. If needed, see section 7.7.4 to display the parameters, or to return the slopes to their pre-edited state, see section 7.7.2.1.2.

7.7.2.1.4. Alter Slope Window

To alter the slope windows of all the curves displayed, from the *View/Edit* window, select *Edit*, *Slope*, and *Slope Window*. The *Slope Window Width* window displays. Initially, the slope window for Platelet Aggregation is 20 seconds and for Ristocetin Cofactor is 15 seconds. As the window size changes, so will the slope value. Use the keyboard to enter/alter the number of seconds to include in slope calculation. To exit the window and apply the selections made, select *OK*. To exit the window without applying the selections, select *Cancel*. For Ristocetin Cofactor, note that the slope window for the standard curve and patients must be consistent.

7.7.2.1.5. Adjust Slope Search Start Point

To alter the time duration set to elapse before the software searches for the slope, from the *View/Edit* window, select *Edit*, *Slope*, and *Slope Search Start*. The *Slope Search Start* window displays. Use the keyboard to enter/alter the number of seconds to delay from the beginning of the run. To exit the window and apply the selections made, select *OK*. To exit the window without applying the selections, select *Cancel*.

7.7.2.2. Apply/Remove Smoothing

Note that smoothing used in Ristocetin Cofactor determinations, should be used consistently for the standard curve, QC, and patient, as the slope will change with smoothing.

1. To remove any smoothing previously applied, from the *View/Edit* window, select *Edit*, *Smoothing Filter*, and *None*. The curve(s) return to their pre-smoothed appearance.

2. To smooth the displayed curve(s), from the *View/Edit* window, select *Edit*, *Smoothing Filter* and one of the following:

a. 5 - smoothes by 5

b. 20 -smoothes by 20.

c. *Custom* - select and the *Filter Selection* window displays allowing the smoothing to be specified. Use the keyboard to enter/alter the amount of smoothing needed, from 0-30. To exit the window and apply the selections made, select *OK*. To exit the window without applying the selections, select *Cancel*.

7.7.2.3. Add Comments

1. Comments can be entered for the displayed data that will be included only when the data is exported. To add comments, from the *View/Edit* window, select *Edit*, *Slope* and *Comment*. The *Comment* window displays.

2. If multiple channels are displayed, then *Select Channel* is available. Select the number of the appropriate channel.

3. In the space provided, use the keyboard to enter the desired comment.

a. *Font* - select to access the *Font* window. Select the desired *Font*, *Font Style*, *Size*, *Effects*, and *Script*. To exit the window and apply the selections made, select *Apply* and *OK*. To exit the window without applying the selections, select *Cancel*.

4. If comments need to be entered for other channels, see step 2.

5. Once the comment(s) is as needed, select *Save*.
6. To exit, select the **X** located on the top right of the window.
7. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*.

7.7.3. Search

Use *Search*, in conjunction with *TestType*, *RunType*, *View*, and/or *Limit Days* to narrow or broaden the list of worklists accessible in the drop down menu(s) titled according to the search criteria in use.

1. From the *View/Edit* window, select *Search*.
2. From the displayed drop down list select one of the following search criteria options: *Worklist ID*, *Worklist Number*, *Curve Sequence Number*, *Date Range*, *Date and Time*, and *Primary Patient ID*.
3. The *View/Edit* window displays showing the criteria title(s) selected. The contents of the first (or only) drop down list are the selected search criteria that match the current selections for *TestType* and *RunType*.
4. If needed, the *TestType* and/or *RunType* selection can be altered to narrow or broaden the search criteria (section 7.7.7).
5. If the *View Style Single Channel Curve Only* feature (section 7.7.4.1) is in use, and the indicated worklist contains multiple channel curves, the search criteria *Select Curve Sequence Number* is available.
6. If needed, the *Limit Days* feature can be used/altered to narrow or broaden the search criteria (section 7.7.8).
7. With the search criteria selections made, use the first (or only) drop down list to select the desired worklist. The following describes the drop down lists based on the selected search criteria:
 - a. *Worklist ID* - Use the drop down list to select the applicable worklist/curve. If the

Worklist ID selected contains multiple worklists, or as applicable multiple curves, additional search criteria display. The *Worklist ID* is the label designated by the user when the worklist is created.

b. *Worklist Number* - Use the drop down list to select the applicable worklist/curve. If the worklist contains multiple curves, additional search criteria display. The *Worklist Number* is a unique number automatically assigned by the software for each worklist run.

c. *Curve Sequence Number* - Use the drop down list to select the applicable worklist/curve. The *Curve Sequence Number* is a unique number automatically assigned by the software for each curve run.

d. *Date Range* - Use the drop down lists to select the needed *Start* and *End* date. If the range contains multiple worklists, or as applicable multiple curves, additional search criteria display. Use the drop down list(s) to select the applicable worklist/curve.

e. *Date and Time* - Use the drop down lists to select the needed *Date of Run* and then the needed *Time of Run*. If the date and time selected contain multiple worklists, or as applicable multiple curves, additional search criteria display. Use the drop down list(s) to select the applicable worklist/curve.

f. *Primary Patient ID* - is the *Patient ID* demographic. Use the drop down list to select the desired ID. If the ID selected contains multiple worklists, or as applicable multiple curves, additional search criteria display. Use the drop down list(s) to select the applicable worklist/curve.

8. Once all the needed selections are made, the desired worklist/curve chart, demographic information, and/or result parameters are displayed according to the current *View* selections (section 7.7.4).

7.7.4. View

Use the features available through the *View* drop down list to control what information is displayed on the *View/Edit* window.

7.7.4.1. View Style

To display either the entire worklist contents or one curve at a time, from the *View/Edit* window, select *View*, *View Style*, and one of the following:

1. *Complete Worklist* - select to view all the channels within a worklist.
2. *Single Channel Curve Only* - select to view each channel within a worklist individually. Once selected, the *View/Edit* window provides the additional search criteria *Select Curve Sequence Number*. If the worklist contains multiple channels matching the search criteria (section 7.7.3), use these criteria to indicate which channel, within the indicated worklist, to display.

7.7.4.2. Channels Displayed

With a worklist containing multiple channels displayed, to specify which channels to display, from the *View/Edit* window, select *View* and *Channels*. The *Channel Selector* window displays. The channels indicated with a check mark will display. Click on the appropriate box to add or remove the check mark. To control the display of all the channels at once, use the *All Channels* box. To exit, select the **X** on the top right of the window.

7.7.4.3. Display Chart

To toggle between the chart being displayed and not displayed, from the *View/Edit* window, select *View* and *Chart (Show/Hide)*.

The size of the chart displayed increases/decreases depending on whether or not the *Demographics* (section 7.7.4.4) and/or *Parameters* (section 7.7.4.5) are displayed.

The chart can be zoomed in and out and, when zoomed in, different areas viewed. For additional information, see section 7.7.12.

7.7.4.4. Display Demographics

To toggle between the demographics (Figure 7-7) being displayed and not displayed, with at least one patient curve displayed, from the *View/Edit* window, select *View* and *Demographics (Show/Hide)*.

Some of the information can be altered/edited. With the arrow over the Demographic area, a message displays at the bottom of the screen reporting which of the information is editable. If needed, to edit data, highlight the data, use the keyboard to alter, and select **Enter** or **Tab**. Note that users with Run Only access cannot alter the settings.

7.7.4.5. Display Parameters

To toggle between the parameters (Figure 7-8) being displayed and not displayed, from the *View/Edit* window, select *View* and *Parameters (Show/Hide)*. The selections made in test setup, within the Select Display Parameters (section 6.2.4), determine which parameters display. Note that for Ristocetin Cofactor tests, the parameters displayed depend on the type of curve (Patient, QC, or Standard) currently displayed as the first or only curve.

Some of the information can be altered/edited. With the arrow over the Parameter area, a message displays at the bottom of the screen reporting which of the information is editable. If needed, to edit data, highlight the data, use the keyboard to alter, and select **Enter** or **Tab**. Note that users with Run Only access cannot alter the settings.

It is not recommended that this method of editing be performed on the Slope parameter with a single curve displayed. If it is used, after the single curve was printed, then in order for the Slope editing to be used, a different curve must be displayed and printed, and then the original curve displayed and printed.

The following is a list of possible symbols included with the parameter data and their meanings:

1. *M* - indicates the slope has been manually edited.
2. *N/A* - indicates the slope is less than or equal to zero.
3. *W* - indicates an unresolved Westgard failure occurred during or prior to the run.
4. *#* - indicates the slope is out of range. The patient or QC slope is either lower than the lowest or higher than the highest slope measured for the standard.
5. *L* - indicates the PRP O.D. is out of range, less than .2, implying low platelet count or that calibration may be off.
6. *H* - indicates the PRP O.D. is out of range, greater than 1.2, implying high platelet count or that calibration may be off.

7.7.5. Print Report

For examples of some of the different report styles, see Section 13 - Reports.

The chart, with all the curves to be printed, must be displayed when print is selected to be included on the printout (section 7.7.4.2 and 7.7.4.3).

1. To print the report, select the first of the two buttons that makeup the icon, *Print Report*.
2. To specify the report type to print, select the second of the two buttons, ..., and the *Report Selection* window displays.
 - a. *Select Report* - use the drop down list to select the needed report style. The report styles available vary based on the currently displayed information.
 - b. *Print Resolution* - use the drop down list to select the appropriate resolution quality.
 - c. *Setup* - For additional information, see section 7.10.
 - d. *Print* - select to print the report style and resolution indicated.
 - e. To exit without printing, select the **X** at the top right of the window.

7.7.6. Delete

Note that users with Run Only access cannot access this feature.

1. With the worklist or curve needing deletion displayed, select *Delete*.
2. If a multi-curve worklist is displayed, the first *Confirm* prompt displayed allows for all the curves in the worklist to be deleted.

a. Select *Cancel* and exit the window without deleting. Select *Yes* and all the curves are deleted. Select *No* and another *Confirm* prompt displays.

b. This prompt allows for the first curve in the worklist to be deleted. Select *Cancel* and exit the window without deleting. Select *Yes* or *No* as needed and the *Confirm* prompt again displays.

c. This prompt allows for the next curve in the worklist to be deleted. Continue as needed to delete the appropriate curves.

3. If only one curve is displayed, when the *Confirm* prompt displays, select *Yes* to delete or select *No* or *Cancel* to exit the window without deleting.

7.7.7. TestType and RunType

Use *TestType* and/or *RunType*, in conjunction with *Search*, to narrow or broaden the worklists accessible in the drop down list(s) titled according to the search criteria in use.

1. Confirm the desired search criteria are in use or select the desired criteria (section 7.7.3).
2. For *TestType*, select from *All TestTypes*, *Platelet Aggregation*, or *Ristocetin*.
3. For *RunType*, select from *All Types*, *Patients*, *References*, *Standards*, or *QC*. Note that the selections available for *RunType* depend on the selection made for *TestType*.

7.7.8. Limit Days

Limit to Days is available for use with all *Search* criteria except *Date Range* and *Date and Time*. Using the keyboard, enter the number of days worth of results desired accessible from the search drop down list(s) displayed. For example, if set to *Limit to 10 Days*, then the curves that match the *Search*, *TestType*, *RunType*, and/or *View* settings for the last 10 days are accessible in the drop down list(s) displayed.

7.7.9. Overlay Reference

Overlay Reference is only available with a Platelet Aggregation curve displayed.

1. Select the *Overlay Reference* icon and the *Reference Selector* window displays.
2. *Select Reference* - use the drop down list to select the appropriate reference.
3. *Select curve sequence number* - use the drop down list to select the appropriate reference.
4. *OK* - select to apply the indicated reference.
5. *Cancel* - select to exit without selecting/ changing the reference.

7.7.10. Slope vs. Standard Show Standard Curve

1. *Slope vs Standard* icon is only available with a Ristocetin Cofactor Patient or QC curve displayed.
2. *Show Standard Curve* icon is only available with a Ristocetin Cofactor Standard curve displayed.
3. If needed, the curve can be edited from the *View/Edit* window (section 7.7.2).
4. Select either icon. The *Standard Curve* window (Figure 7-9) displays a chart of *Slope* versus *Activity %* and the applicable result parameters. The test results show percent activity based on the slope of their reactions.

5. See section 7.7.10.1 through 7.7.10.4 for information on the features available on this window.

6. To exit, select the **X** on the top right of the window.

7.7.10.1. Print

1. To print the report, select the first of the two buttons that makeup the icon, *Print Report*.
2. To specify the report type to print, select the second of the two buttons, ..., and the *Report Selection* window displays.
 - a. *Select Report* - use the drop down list to select the needed report style.
 - b. *Print Resolution* - use the drop down list to select the appropriate resolution quality.
 - c. *Setup* - For additional information, see section 7.10.
 - d. *Print* - select to print the report style and resolution indicated.
 - e. To exit without printing, select the **X** at the top right of the window.

7.7.10.2. Delete

Note that users with Run Only access cannot access *Delete*.

1. Select *Delete*.
2. If a multi-curve worklist is displayed, the first *Confirm* prompt displayed allows for all the curves in the worklist to be deleted.
 - a. Select *Cancel* and exit the window without deleting. Select *Yes* and all the curves are deleted. Select *No* and another *Confirm* prompt displays.
 - b. This prompt allows for the first curve in the worklist to be deleted. Select *Cancel* and exit the window without deleting. Select *Yes* or *No* as needed and the *Confirm* prompt again displays.
 - c. This prompt allows for the next curve in the worklist to be deleted. Continue as needed to delete the appropriate curves.

3. If only one curve is displayed, when the *Confirm* prompt displays, select *Yes* to delete or select *No* or *Cancel* to exit the window without deleting.

7.7.10.3. Plot Type

Plot Type is selected in test setup; however, can be altered by selecting either *Semi-Log* or *Log-Log*.

7.7.10.4. Parameters

Of the parameters displayed, the *Name* of the standard can be altered on this screen by double clicking on the current name and altering with the keyboard.

7.7.11. Levey-Jennings Chart

1. *Levey-Jennings Chart* is only available with a Ristocetin Cofactor QC curve displayed.

2. A minimum of 6 points is required to make a clinically significant calculation of the mean and SD. However, the software will calculate with as few as 2 points.

3. Select the *Levey-Jennings Chart* icon and the *Levey-Jennings Chart* window (Figure 7-10) displays. The window contains a chart of *Standard Deviation* versus *QC Point Count* and the parameters for the QC tests run. The information contained in the parameters depends on selections made in test setup (section 6.2) and the QC method in use (section 6.3).

7.7.11.1. Print Ristocetin Report

1. To print the report (Figure 13-3), select the first of the two buttons that makeup the icon, *Print Report*.

2. If needed, to specify *Print Resolution* and/or the *Printer*, select the second of the two buttons, ..., and the *Report Selection* window displays.

a. *Print Resolution* - use the drop down list to select the appropriate resolution quality.

b. *Setup* - For additional information, see section 7.10.

c. *Print* - select to print the report style and resolution indicated.

d. To exit without printing, select the **X** at the top right of the window.

3. If this report is printed prior to generating the required number of data points for printing (6 for lot-to-date, and 3 for month-to-date and assigned), then the summary information printed at the top of the report may be incomplete. If this occurs, to obtain a printout of this section in its entirety, print the QC summary report (section 7.7.11.2).

7.7.11.2. Print QC Summary Report

To print the summary report (Figure 13-1 and Figure 13-2), select *Print Summary*.

7.7.11.3. Delete

Note that users with Run Only access cannot access this feature. Additionally, note that a QC point that failed a Westgard rule should not be manually deleted. See section 7.7.11.8 for handling Westgard failures.

1. To delete a QC point, first left click on the point to be deleted.

2. When the *Confirm* prompt displays, verify the level, date, and time of the indicated point is the desired QC point.

a. To delete the point, select *Yes*.

b. To exit the window without deleting, select *No* or *Cancel*.

7.7.11.4. Manual Entry

Note that users with Run Only access cannot access this feature. Additionally, note that if the QC curve contains only manually entered data, no printout can be generated.

1. *Level* - select the level of the point to be entered using the drop down.

2. *Manual Entry* - select and the *QC Manual Point Entry* window displays.

3. *Enter Final Activity* - enter/alter using the keyboard.

4. *Cancel* - select to exit the window without entering a point.

5. *OK* - select to apply the entered information and exit the window. The point is plotted and the information is calculated and displayed.

7.7.11.5. Level Group

With Lot-to-Date the QC mean calculation method in use (section 6.3), *Level Group 123/456* is available.

Select *123/456* to alternate between viewing the QC for levels 1, 2, and 3 and levels 4, 5, and 6.

7.7.11.6. Change Over

Note that users with Run Only access cannot access this feature.

1. With Lot-to-Date the QC mean calculation method in use (section 6.3), *Change Over* is available.

2. When QC levels 4, 5 and 6 are ready to be used as levels 1, 2 and 3 (a minimum of 6 runs of lots 4, 5, and 6 must be completed), select *Change Over*.

3. A *Confirm* prompt displays. To remove the current levels 1, 2, 3, and switch 4, 5, and 6 to their position, select *Yes*. To exit without altering the QC levels, select *No*.

7.7.11.7. End-of-Month

1. With Month-to-Date the QC mean calculation method in use (section 6.3), the QC data used is determined by a user-selected begin date and the current date.

2. With Month-to-Date in use, *End-of-Month* is available for use to specify the begin date.

3. *End-of-Month* - select and the *EOM Change-Over* window displays.

4. *Year*, *Month*, and *Day* - use each of the drop down lists to specify the begin date.

5. *OK* - select to use the date specified.

6. *Cancel* - select to exit without altering the begin date.

7.7.11.8. Westgard Resolutions

1. *Westgard Resolutions* - select to review or enter a QC failure resolution. The *Westgard Failure Resolutions* window (Figure 7-11) displays.

2. *TestType* - select *Ristocetin*.

3. *Test* - select *Ristocetin*.

4. *Date/Time of Failure* - select the QC to display by the date and time of the run.

5. *Failure* - view the Westgard rule the QC failed.

6. *Resolution* - view or enter the resolution of or reason for the failure.

7. *Font* - select to access the *Font* window. Select the desired *Font*, *Font Style*, *Size*, *Effects*, and *Script*. To exit the window and apply the selections made, select *Apply* and *OK*. To exit the window without applying the selections, select *Cancel*.

8. *Save* - if a resolution is entered, select to save the entered information.

9. To exit, select the **X** on the top right of the window.

10. If a *Confirm* window displays, changes were made and not saved. To save the changes and proceed, select *Yes*. To proceed without saving, select *No*.

7.7.12. Zooming and Panning

A chart can be enlarged, maneuvered, and reduced as needed to aid in viewing.

1. With a chart displayed, to zoom in on the chart, press and hold the left mouse button while moving the mouse to the right and down marking the area of the chart to enlarge. Once the area is indicated with the gray box, release the mouse button and the selected area is enlarged.

2. Once an area has been enlarged, to pan around the chart to view different areas, press and hold the right mouse button while moving the mouse up, down, left, and/or right as needed to cause the desired area to display.

3. Zoom in and pan as needed to aid in viewing the chart.

4. To return the chart to its original appearance, press and hold the left mouse button while moving the mouse to the left and up. Once the gray box appears, release the mouse and the entire chart is again displayed.

7.8. File Utilities

7.8.1. Backup/Restore/Delete

Note that users with Run Only access cannot access this feature.

To backup or restore data, beginning from the main menu, select *File*, *File Utilities*, and *Backup/Restore/Delete*. The *Archive* window (Figure 7-12) displays:

1. *Section* - with this version of software, specific files cannot be indicated for handling, this software version handles the *Entire Database* per the selection made in *Select Function*.

2. *Select Function* - select either *Copy to Backup* or *Restore from Backup*. The other options are not available with this version of software.

3. *Backup Path* - use the drop down list or the keyboard to indicate the backup location.

a. The default backup location is C:\HRDBDir\UserBackup. A user specified backup location and/or folder can be used; however, it is recommended that any backup folder used be located within C:\HRDBDir.

i. Two additional initial subfolders are provided under the main HRDBDir folder, which is the location of the main database. The Init subfolder provides a clean, empty database, which can be used to wipe all data from the instrument and restore it to the original Helena Manufactured defaults. In addition, the Demo subfolder provides several scans as examples to be used for demonstration of the instrument.

4. *Start* - with all the selections made, select *Start* to implement. If a *Confirm* message

displays, answer as needed. The data is handled as specified.

5. To exit, select the **X** located on the top left of the window.

7.8.2. Rebuild Indexes

The indexes should rarely need to be rebuilt unless the instrument prompts the user with an error message to do so. To rebuild the indexes, beginning from the main menu, select *File*, *File Utilities*, and *Rebuild Indexes*. A *Confirm* message displays:

1. *Yes* - select to rebuild the indexes.

2. *Cancel* - select to exit without rebuilding.

3. *No* - select to specify the backup location. The *Backup Path Selector* window displays. Use the drop down list or the keyboard to indicate the backup location and select *OK*.

7.9. Change Operator

To change the Operator ID in use, from the main menu, select *File*, and then *Change Operator*. The *Login* window displays:

1. *User ID* - use the keyboard to enter the ID and then use the mouse or press **Tab** to move to the Password field.

2. *Password* - use the keyboard to enter the password that corresponds to the entered User ID.

3. *OK* - select to access the software using the entered user information.

4. The main menu displays with the access level of the ID in use displayed on the top right.

7.10. Print Setup

To select the printer to be used and to setup the printer parameters, from the main menu, select *File*, and then *Print Setup*. The *Print Setup* window displays:

1. *Printer* -

a. *Name* - use the drop down list to select the printer.

b. *Properties* - select if needed. See the owner's guide for the printer selected for additional information.

c. *Status, Type, Where, and Comment* - are automatically entered based on the printer name selected.

2. *Paper* -

a. *Size* - select from the drop down list.

b. *Source* - select from the drop down list.

3. *Orientation* - select either *Portrait* or *Landscape*.

4. To save the selections made and exit the window, select *OK*.

5. To exit without saving, select *Cancel*.

7.11. Show Error Messages

To view recent error messages, from the main menu, select *File*, and then *Show Error Messages*. The *Messages* window displays:

1. Use the scroll bar on the right side to view messages not currently displayed.

2. To exit, select the **X** located on the top right of the window.

7.12. Exit

To close the software, from the main menu, select *File, Exit*, and, when prompted, *Yes*.

7.13. Help

7.13.1. Operator's Manual

If the Operator's Manual has been loaded onto the computer (section 7.13.2), to view the manual, select *Help*, and then *Operator's Manual*. The Operator's Manual opens into Adobe® Reader® software from which it can be viewed and/or printed.

7.13.2. Update Manual from CD

Prior to loading the Operator's Manual, Adobe® Reader® must be installed on the computer, do so by following the instructions on the label of the Helena provided

Operator's Manual CD. To load/update the AggRAM Operator's Manual:

1. From the main menu, select *Help*.

2. From the drop down menu, select *Update Manual from CD*.

3. When prompted, place the Operator's Manual CD into the CD drive and select *OK*.

4. If an error message displays, close the window by selecting the **X**.

5. The *Copy Helena Manual* window displays.

6. If not already indicated, select the CD drive.

7. Open the appropriate language folder, select the file, and select *Open*.

8. The Operator's Manual can now be viewed while running the HemoRAM software (section 7.13.1).

7.13.3. About - Software Version Information

To view the version number of the currently loaded software, from the main menu, select *Help* and *About*. The *About* window displays the software version number and Helena Laboratories contact information.

7.14. Results

The final concentration of the reagent depends on the volume introduced. This should be taken into consideration when evaluating test results.

Refer to the procedure supplied with the reagent for a complete discussion of results and their interpretation.

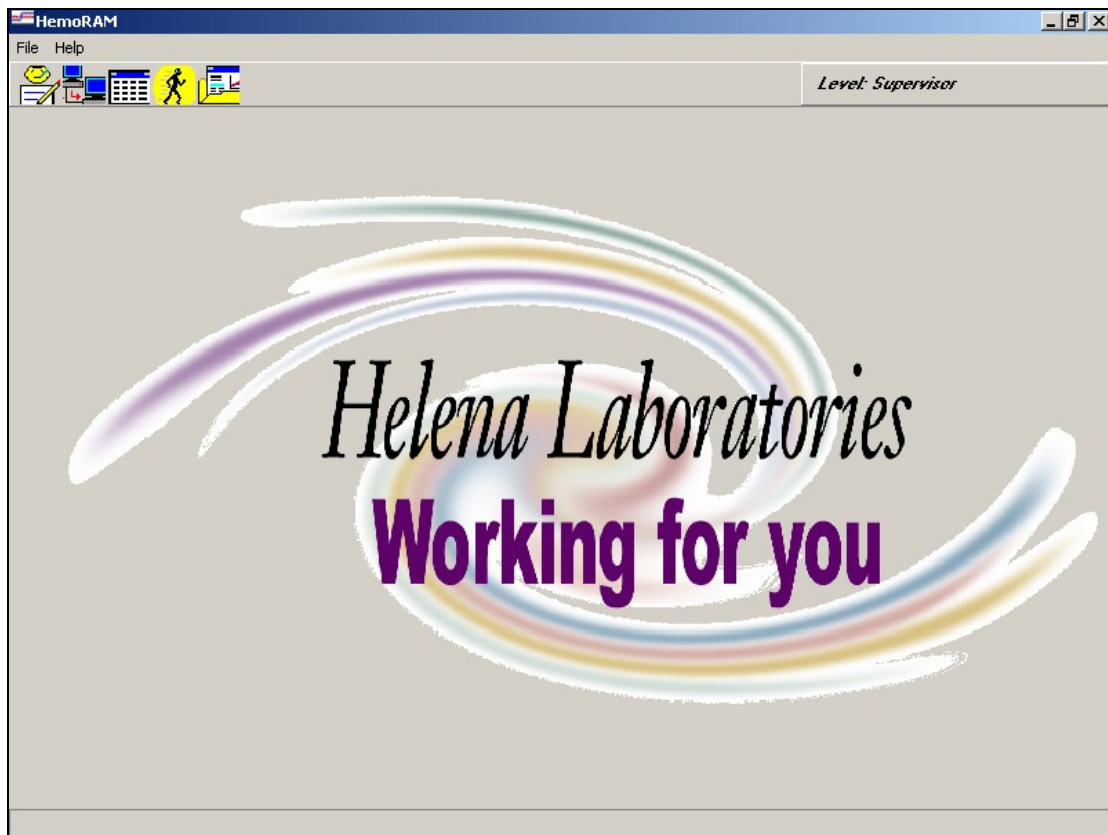
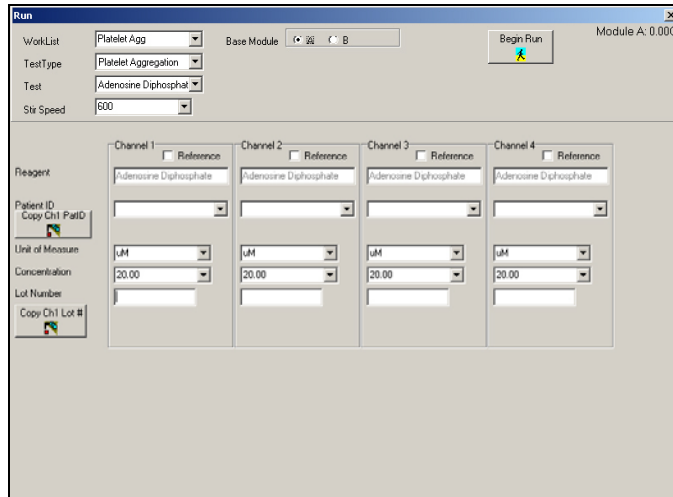
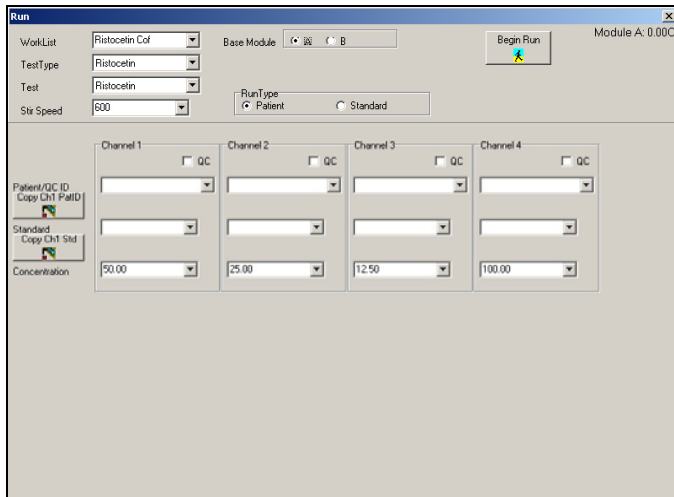


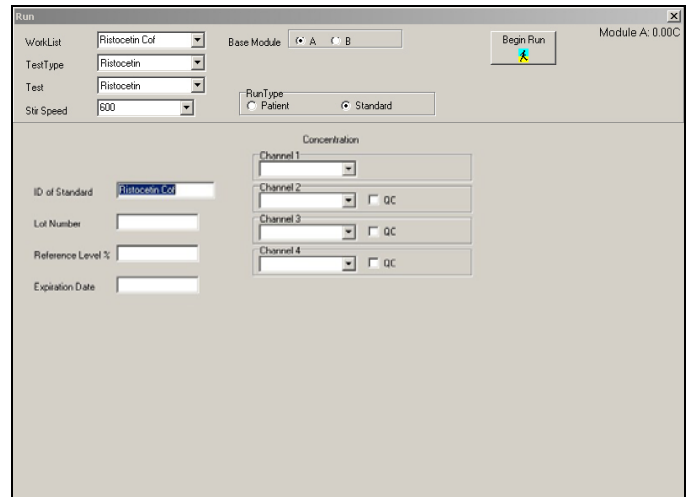
Figure 7-1. Main Menu



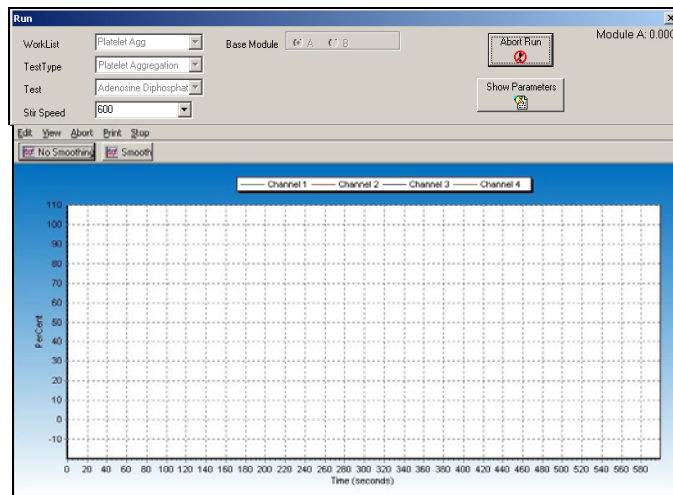
Run Window - Platelet Aggregation



Run Window - Ristocetin Cofactor - Patient



Run Window - Ristocetin Cofactor - Standard



Run Window - During a Test

Figure 7-2. Run

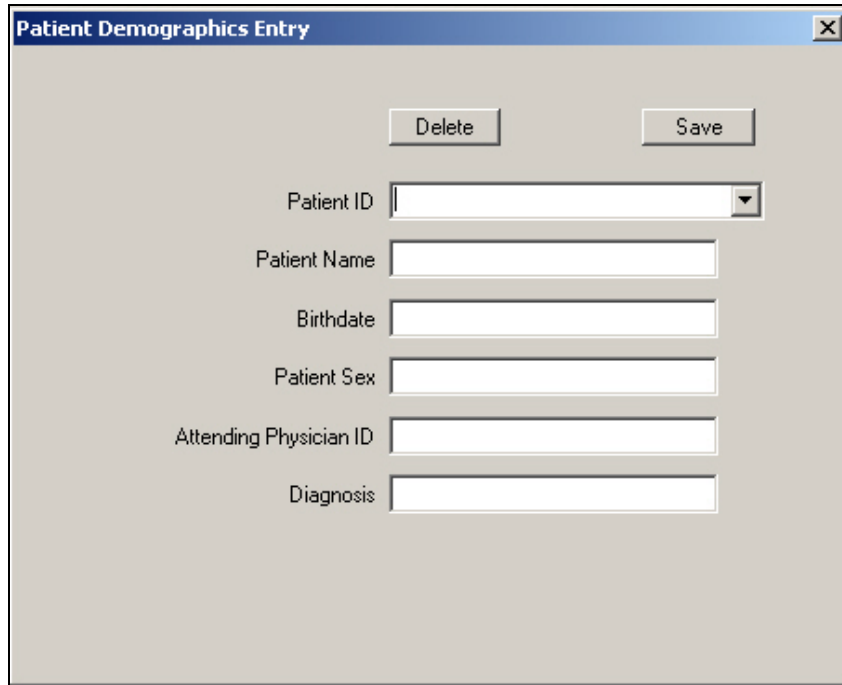


Figure 7-3. Patient Demographics Entry

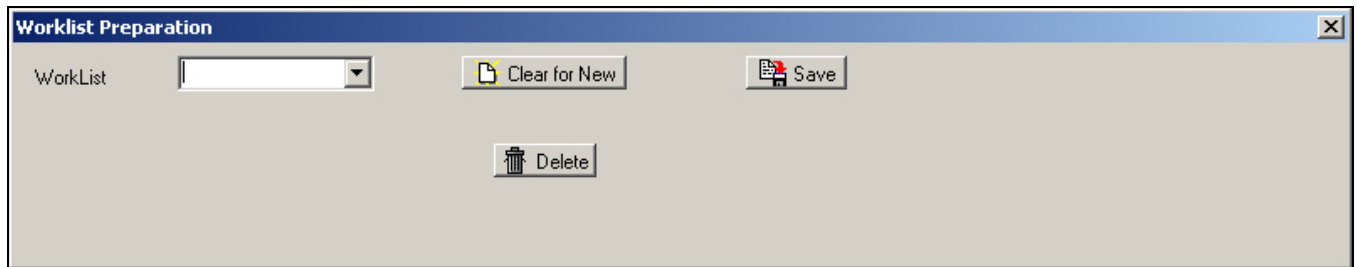
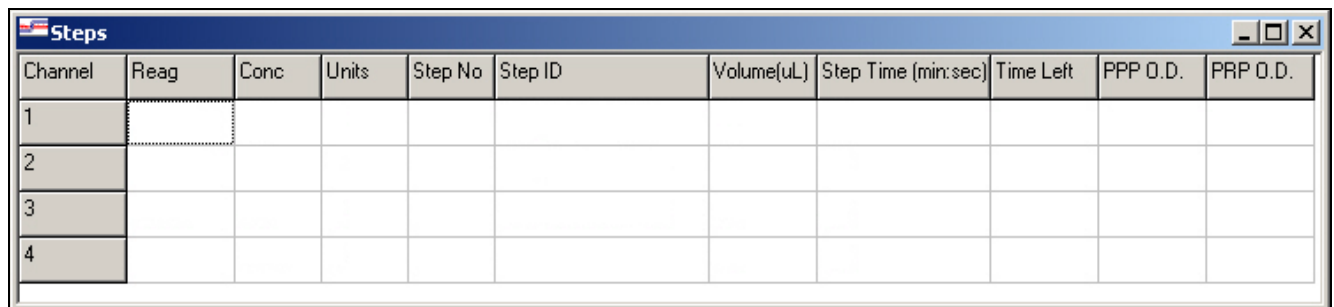


Figure 7-4. Worklist Preparation



Channel	Reag	Conc	Units	Step No	Step ID	Volume(uL)	Step Time (min:sec)	Time Left	PPP O.D.	PRP O.D.
1										
2										
3										
4										

Figure 7-5. Steps

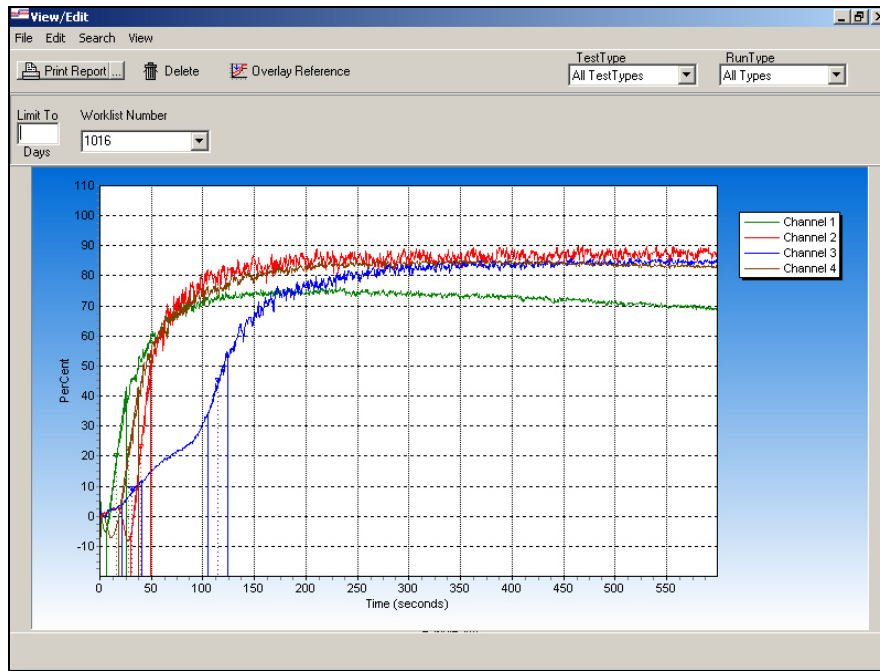


Figure 7-6. View/Edit

Channel	Practice Assigned ID	Patient Name	Birthdate	Patient Sex	Attending Physician ID	Diagnosis
1	1234	Mary Jones	4/9/75	F	Dr. Smith	Easy Bruising
2	1234	Mary Jones	4/9/75	F	Dr. Smith	Easy Bruising
3	1234	Mary Jones	4/9/75	F	Dr. Smith	Easy Bruising
4	1234	Mary Jones	4/9/75	F	Dr. Smith	Easy Bruising

Figure 7-7. Demographics

Channel	Crv Seq No	Ch No	Lot Number	Reag.	Conc.	Units	PPP	PRP	Max %	Max Time	Slope	Slope2	Lag Time
1	3174	1	603	ADP	20.0	µM	0.310	0.970	76.1	228	143.8		5.1
2	3175	2	403	COLL	10.0	µg/ml	0.310	0.860	89.9	530	178.4		27.8
3	3176	3	303	EPI	300.0	µM	0.307	0.892	85.8	456	24.4	61.8	5.6
4	3177	4	104	ACA	500.0	µg	0.308	0.890	85.4	268	130.4		10.6

Figure 7-8. Parameters

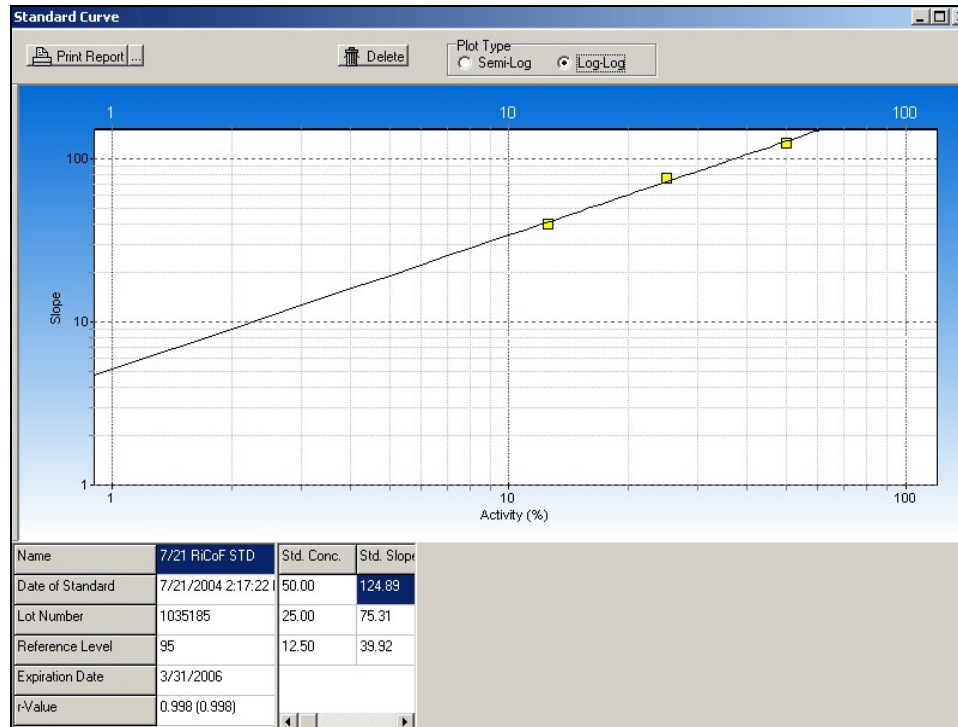


Figure 7-9. Standard Curve (Ristocetin)

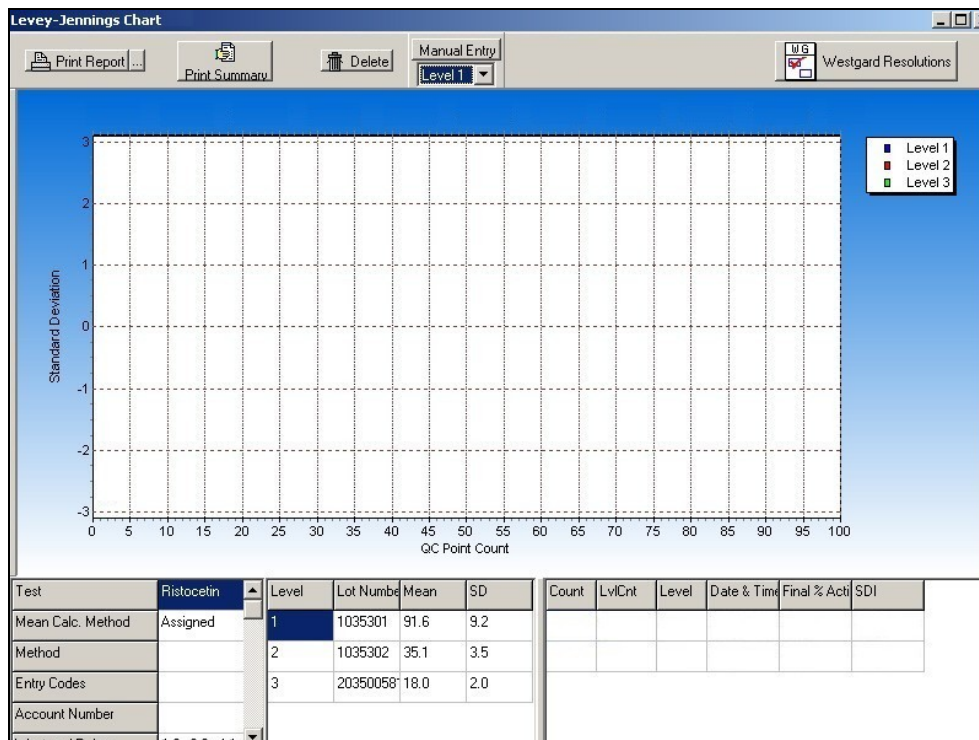


Figure 7-10. Levey-Jennings Chart

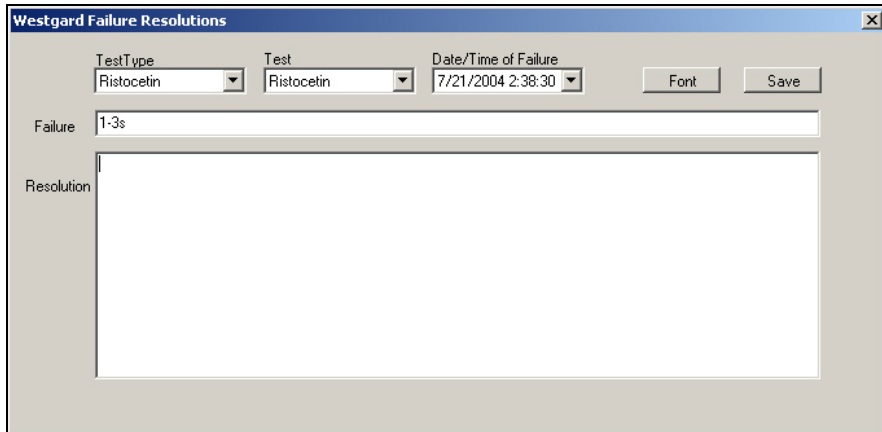


Figure 7-11. Westgard Failure Resolutions

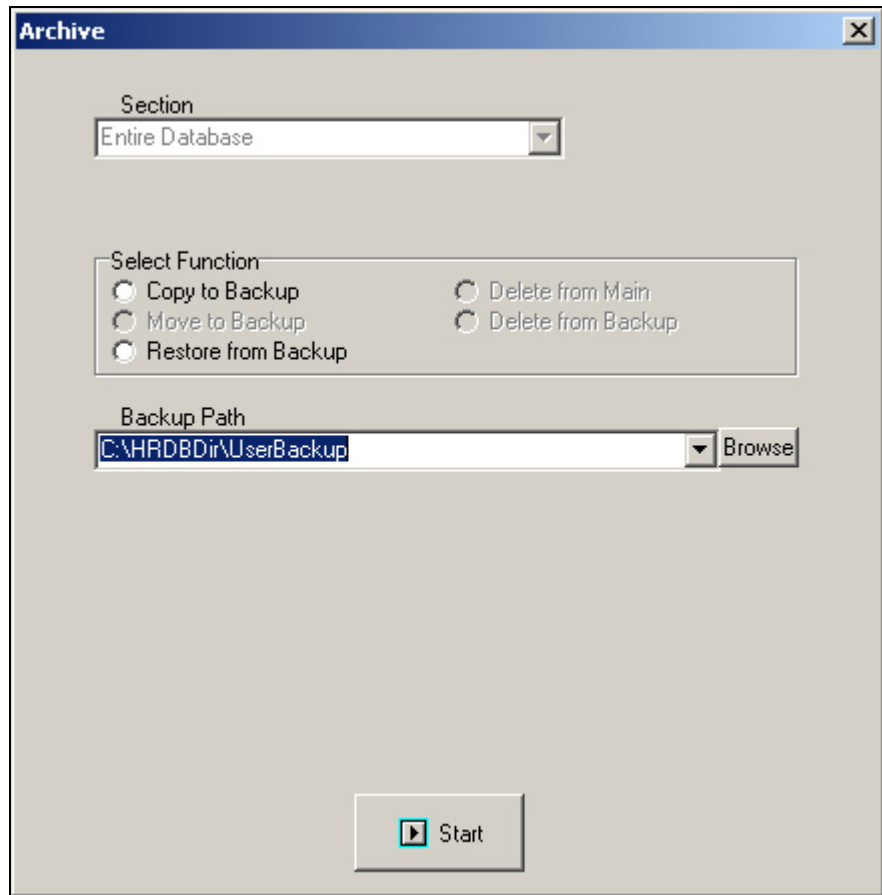


Figure 7-12. Archive

Section 8 - Quality Control

The instrument automatically performs a self-test any time the power is turned on. Should an error message appear on the display, see section 10.2.

Each laboratory should establish its own normal range of expected values for the procedures in use. Refer to the package insert or assay sheet supplied with the reagents for further information. Consistent sample handling and procedural timing are essential for reproducibility and accuracy.

Each laboratory should also establish a quality control program that includes normal and abnormal controls to evaluate the instrument, reagent, and technologist performance. The quality control tests should be performed prior to performing each batch of tests on patient plasmas and with each change of personnel. Control data should be compared to the assay ranges printed on the assay sheet provided with the control. The patient data should be compared to the normal range values for the procedure in use and to the laboratory normal range values. Refer to the procedures supplied with the reagents for further information.

8.1. Daily Optical Calibration Check

Prior to the instrument's first daily use, the Optical Calibration Check must be performed, see section 10.1.1.

8.2. Ristocetin Cofactor QC

8.2.1. Setup QC

For instructions on QC parameter setup, see section 6.3.

8.2.2. Run QC

For instructions on running QC, see section 7.2.2.

8.2.3. View QC and QC Lot Change Over

For instructions on viewing the Levey-Jennings Chart QC and for changing over QC data, see section 7.7.11.

8.2.4. Westgard Rules

The software automatically keeps a record of control values from each run. Five Westgard Rules are included in the software to allow the laboratory to automatically monitor trends in QC data and to determine when QC data will no longer be accepted unless corrective action is taken. If the Westgard rules will not be used, QC data will be stored as usual; Levey-Jennings plots can be printed, but the laboratory must determine if QC data indicates a potential problem.

The Westgard rules used in the software are summarized below:

1-3s: A run will be rejected if one QC data point falls beyond the ± 3 SD range.

2-2s: A run will be rejected if two consecutive control values fall on the same side of the mean (are unipolar) and are greater than ± 2 SD units from the mean.

4-1s: A run will be rejected if four consecutive unipolar control values are greater than ± 1 SD from the mean.

r4s: A run will be rejected if the range between two consecutive bipolar values is greater than or equal to 4 SD units.

10x: A run will be rejected if ten consecutive data points fall on the same side of the mean.

One or more of these rules can be setup for use (section 6.3). If a control data point breaks a selected rule, the run may be accepted or rejected but the QC data is not used in the calculations determining mean and standard deviation. Once a rule has been broken, until an entry is made in the QC Westgard Resolution log (section 7.7.11), no additional QC data will be included in the Levey-Jennings results and any additional patient data will be stored with a W indicating an unresolved Westgard rule failure.

Section 9 - Instrument Specifications

Test Types: Platelet Aggregation and
Ristocetin Cofactor

Charts: -20% to 110% activity ($\pm 0.5\%$)
versus time

Absorbance Range: 0.0 to 2.0 O.D.

Optical Chambers per module: Four
chambers for combined or individual
measurements

Cuvettes: 8 mm x 60 mm (silicone coated
glass)

Stir Bars: 3.5 mm x 4 mm (coated magnet)

Measuring Wavelength: 650 nm

Module Input Power: 110/220 Vac, 50/60 Hz,
1200 Watts Maximum

Incubation and Reaction Temperature:
 $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$

Module Dimensions:

$\leq 6"$ (15.24 cm) Tall

$\leq 10"$ (25.40 cm) Wide

$\leq 17"$ (43.18 cm) Deep

Module Weight: ≤ 15 lbs (6.75 kg)

Module will comply with EN61010-2-101,
EN60601-1-2

Software Operating System: Microsoft[®]
Windows[®] 2000

Instrument Operating Environment:

Ambient Temperature Range $15^{\circ} - 30^{\circ}\text{C}$
($59 - 86^{\circ}\text{F}$)

Humidity 10% – 80% (non-condensing)

Minimum Volume: 250 μL (with a stir bar)

Section 10 - Maintenance, Troubleshooting, Warranty

10.1. Maintenance

Each instrument is calibrated by Helena Laboratories during the manufacturing process. Customer calibration is required as specified in section 10.1.5. If during this calibration the instrument cannot be returned to acceptable ranges, any additional calibration must be performed by Helena Laboratories or their representatives.

This section describes routine operator maintenance procedures. For instrument calibration or for maintenance not described in this manual, call Helena Laboratories for assistance.

Table 10-1. Preventative Maintenance

<u>Daily, If Used, Prior to First Use</u>
Perform Optical Calibration Check
<u>Daily, If Used, End of the Day</u>
Clean Instrument
Clean Accessories
<u>Weekly</u>
Clean Optical Wells
<u>Monthly</u>
Adjust Scale Set
Check/Adjust Temperature
Clean filter

10.1.1. Optical Calibration Check

Daily, or each time turned on, and prior to the first run, perform the Optical Calibration Check. Note that users with Run Only access cannot perform this check.

The intensity values obtained when performing the check should fall within a range of .145 to .217 and there should be less than a 10% difference between each value. Acceptable values are shown with a gray background color. Unacceptable values are shown with different background colors, each representing a type of failure, and a message displays attributing the background color to a specific failure.

To perform the Optical Calibration Check, use the following:

1. Beginning from the main menu, select *File, Maintenance, and Optical Channel Check*.
2. The *Optical Calibration Check* window (Figure 10-2) displays. Note that any previously obtained values have been removed.
3. Add 500 μ L of distilled or deionized water to a clean cuvette. Handle the cuvette by the upper edges only to avoid fingerprints on the lower half of the cuvette where optical readings are taken.
4. Check the cuvette for bubbles and, if present, tap the cuvette to remove them. Insert the cuvette into the first channel and press the channel button.
5. The channel indicator light turns red and green for 5 seconds followed by the intensity value for the *Module* and *Channel* tested displaying.
6. If the value is acceptable (displayed with a gray background), repeat steps 4 and 5 for each remaining channel (for all modules). If the value is not acceptable (displayed with a blue background color if low, pink if high, or yellow if the intra-channel results differ by more than 10%), see step 7.
7. If the values are not acceptable, select *Re-Adjust Beams*. Remove the cuvette(s) from the channel(s) and select *OK* in response to the prompt. Once the instrument finishes *Adjusting beam strengths*, repeat steps 4 and 5 for each channel with an unacceptable value.
8. If any value remains unacceptable, see section 10.2.
9. To obtain a printout of the values, select *Print*.
10. To exit, select the **X** located on the top right of the window.

10.1.2. Cleaning Instrument

After turning off the power and unplugging the power cord(s), clean spills with a cotton swab, soft cloth or sponge. Do not use corrosive or abrasive cleansers. Thoroughly dry before plugging in the power cord(s).

Should an instrument be contaminated by blood or blood derivative, spray any contaminated surface with a commercial virucidal and germicidal agent. Observe where the specimens are used inside the instrument and confine cleaning to that area. Wipe up the residue. These materials contain alcohol and alcohol is corrosive to metal surfaces.

10.1.3. Cleaning Accessories

Clean the stir bars, cuvette rack, and magnet retriever with disinfectant soap, water, and a soft brush (do not submerge the magnet retriever). Rinse thoroughly with deionized water. Dry thoroughly with lint-free tissues.

10.1.4. Cleaning Optical Wells

Optical chamber wells must be kept clean in order to obtain the most accurate absorbance readings. Always turn off the power and unplug the power cord(s) from the wall outlet, prior to performing the following:

1. Remove any cuvettes from the wells.
2. Use a cotton swab, dipped in alcohol, to rub the inside of the optical wells to remove any internal residue.

10.1.5. Scale Set

At initial installation and at least once per month, use Scale Set to calibrate the instrument. This must be done using Helena Scale Set Solution Catalog Number 1479 for Platelet Aggregation and Ristocetin Cofactor assays. If any value remains unacceptable after completing the steps included in section 10.2, Troubleshooting, any additional calibration must be performed by Helena Laboratories or their representatives. User IDs with Run Only access cannot perform this check.

1. The instrument must be allowed to warm up for at least 20 minutes before performing the scale set.
2. Allow the Scale Set Solutions to reach room temperature (15 to 30°C).
3. Beginning from the main menu, select *File*, *Maintenance*, and *Scale Set*.
4. The *Scale Set* window (Figure 10-3) displays.
5. Using the Scale Set #2 Value included on the procedure provided with the Scale Set Solutions, enter/alter the *Scale Set Value* using the keyboard.
6. Clear the currently displayed Scale Set data by selecting *Start*.
7. Prepare cuvettes with Scale Set #1 and #2 per the procedure provided with the Scale Set Solutions.
8. Place the Scale Set #1 cuvette into the first channel and press the channel button. When the indicator light turns green and a value for *Scale Set #1* displays for the *Module* and *Channel* tested, remove the cuvette.
9. Place the Scale Set #2 cuvette into the first channel and press the channel button. When the indicator light turns red and a value for *Scale Set #2* displays for the *Module* and *Channel* tested, remove the cuvette.
10. Repeat steps 8 and 9 for each channel (for all modules).
11. Once both scale sets are run, the *Result (V/O.D.)* for each channel is calculated and displayed. V/O.D. represents the volts change per optical density between the two scale sets and is used to define the upper and lower optical density characteristics.
12. Acceptable V/O.D. values are shown with a gray background color. Any other background color signifies the value is unacceptable. Blue indicates the value is too low, pink that it is too high, yellow that the intra-channel difference is > 10-40%, and orange that the intra-channel difference is > 41%. If the results are acceptable, the instrument is ready for use. If

results are unacceptable, repeat the entire Scale Set procedure.

13. If any value remains unacceptable, see section 10.2.

14. To obtain a printout of the scale set information, select *Print*. A printout of each scale set performed should be retained.

15. To exit, select **X** located on the top right of the window.

10.1.6. Adjust Temperature / Enter Module Parameters

Use the following steps as needed to review module information and/or monthly to check/adjust the module temperatures. Note that only users with Supervisor access can perform these steps.

1. Beginning from the main menu, select *File, Maintenance, and Enter Module Parameters*.

2. The *Module Parameter Entry* window (Figure 10-4) displays.

3. For each module in use, a letter is displayed. Select the letter of the *Module* needed.

a. *Module Serial Number* displays the serial number of the selected module. This is preprogrammed information and cannot be altered.

b. *Module Type* indicates the selected module type as *AggRAM*. This is preprogrammed information and cannot be altered.

4. As needed, the *Temperature Offset* can be used to calibrate the optics/incubation block temperature. Note that during this process the heater status should be alternating between *Heater Regulation, Heater Off, and Heater On*.

a. Place 500 μ L of deionized water in a clean cuvette.

b. Insert the cuvette into one of the channels of the selected module.

c. Allow the cuvette to equilibrate a minimum of 15 minutes.

d. Place a small temperature probe, with an accuracy at 37°C of $\pm 0.2^\circ\text{C}$, into the cuvette so that it contacts the bottom of the cuvette.

e. Allow the temperature probe to stabilize and note the temperature registered. The temperature should be $37^\circ\text{C} \pm 1^\circ\text{C}$.

f. If the temperature is not $37^\circ\text{C} \pm 1^\circ\text{C}$, enter/alter the *Temperature Offset* to adjust the temperature. Adjusting the *Temperature Offset*, either up or down, by 1 should result in a temperature change of 0.1°C and by 10 should result in a temperature change of 1.0°C . For example if the temperature reading is 39° , 2° high, and the current *Temperature Offset* is 10, then change the *Temperature Offset* by 20 to -10. Use either the slide bar or the keyboard to input the *Temperature Offset*. Allow the temperature to stabilize and re-measure the temperature. Repeat until the temperature is correct. Once the *Temperature Offset* is as needed, select *Save* to save the parameters displayed.

5. To obtain a printout of the selected module's parameter information, select *Print*.

6. To exit, select the **X** located on the top right of the window.

7. If the *Temperature Offset* was changed and saved, a prompt displays; select *Yes* to save the new offset number or *No* to exit the window without altering the number.

10.1.7. Cleaning Filter

One filter is located on the left side of each AggRAM module (Figure 5-2) and should be cleaned monthly. Always turn off the power and unplug the power cord(s) from the wall outlet, prior to performing the following:

1. Pull off the snap-on, filter cover and remove the filter.

2. Wash the filter in soap and water.

3. Rinse in water and air-dry the filter.

4. Replace the filter and cover.

Month/Year: _____

Module: _____ Serial Number: _____ Module: _____ Serial Number: _____

AggRAM Preventive Maintenance Schedule																															
Daily Items, If Used	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Optical Calibration Check																															
Clean Instrument																															
Clean Accessories																															
Weekly Items																															
Clean Optical Wells																															
Monthly Items																															
Adjust Scale Set																															
Check/Adjust Temperature																															
Clean Filter																															

Note: Duplicate this page for maintenance copies. Initial each item as required. Refer to section ten, Maintenance, of the Operator's Manual for details. If you are uncertain about how to perform any step, please contact Helena laboratories Electronic Customer Service Dept. (1-800-231-5663) for more information.

Figure 10-1. Preventive Maintenance Checklist

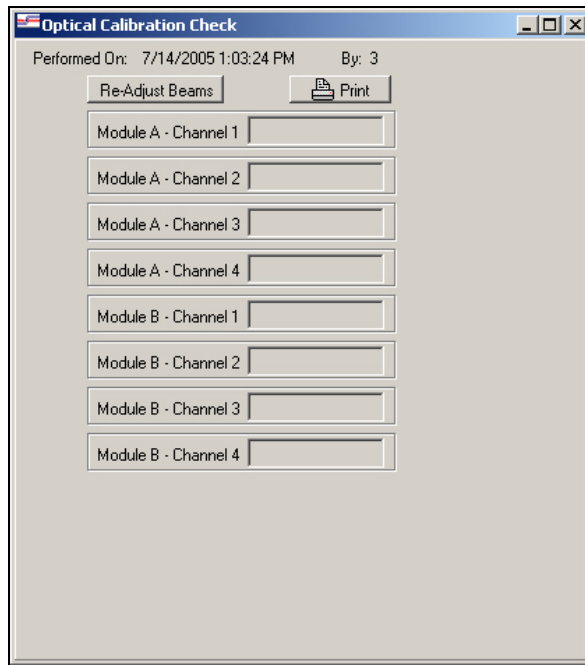


Figure 10-2. Optical Calibration Check

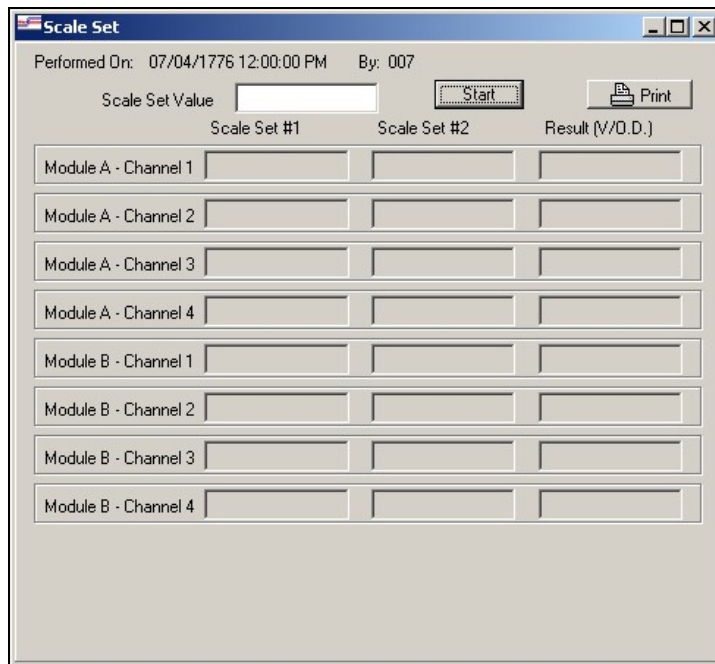


Figure 10-3. Scale Set

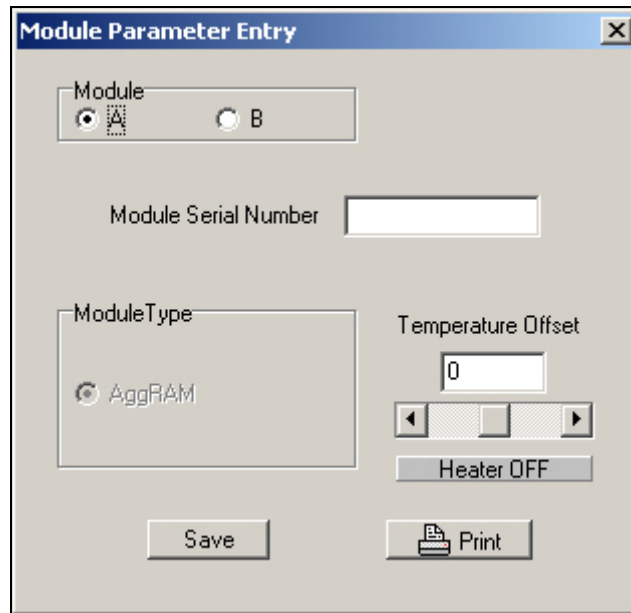


Figure 10-4. Module Parameter Entry

10.2. Troubleshooting

If the recommended solutions should fail to solve a problem, call Helena Laboratories for assistance.

Table 10-2. Troubleshooting

Problem	Possible Cause	Solution
No power to instrument	Power cords unplugged	Plug cords into properly grounded wall outlet
Error message is displayed or error code appears	Error found during self-test or operation	Do as directed by the message. If message returns or an error code appears, call Helena Laboratories for assistance
Error occurs with message: "Index does not exit. Please..."	Database damaged	Rebuild indexes (7.8.2)
Temperature not at 37° C	Temperature needs adjusting	Adjust temperature (10.1.6)
	Electrical problem	Call Helena Laboratories
Will not start run	Power supply problem	Call Helena Laboratories
No power to incubator	Electrical problem	Call Helena Laboratories
Incubator too hot	Temperature needs adjusting	Adjust temperature (10.1.6)
	Electrical problem	Call Helena Laboratories
Fans do not run	Electrical problem	Call Helena Laboratories
PRP too low	PRP platelet level too low	Check PRP specimen
	PPP level misadjusted	Repeat procedure
PRP too high	PRP platelet level too high	Dilute PRP with PPP
	PPP level misadjusted	Repeat calibration (10.1.1) and re-measure
No reaction occurs	No stir bar in cuvette	Repeat with stir bar in cuvette
	Reagent bad or in wrong concentration	Check reagent
	PRP specimen bad	Obtain new specimen
	Stir motor(s) not running	Check for stirring in each chamber. If no stirring, call Helena Laboratories for assistance.
Optical Channel / Calibration Check out of range	Lasers need adjusting	Re-Adjust Beams (10.1.1)
	Dirty optical wells	Clean optical wells (10.1.4)
		Call Helena Laboratories

Problem	Possible Cause	Solution
Bad aggregation / agglutination	No stir bar	Re-measure with stir bar in cuvette
	PPP (100%) level misadjusted	Repeat procedure
	Foreign matter in cuvette	Repeat with clean cuvette
	Reagent or sample on side of cuvette due to pipetting	Repeat procedure
	Incorrect stir rate	Check stirrer rpm, correct if needed
	Stir motor(s) not running	Check for stirring in each chamber. If no stirring, call Helena Laboratories for assistance.
At power on, no response	Not plugged in	Check connections at both ends of power cord
	Electrical problem	Call Helena Laboratories
At power on printer is not ready	Printer power off	Press power button on printer
	Printer off line	Reset printer for use
	Loose interface cable or power cord	Check connections at both ends of cable and power cord
	Other	Call Helena Laboratories
Scale set digital values out of range	Bubbles formed in scale set solution	Remove cuvette and check for bubbles. Tap cuvette if bubbles are present and reread
	Scale set solutions bad	Retry scale set adjustment using new solutions
	Blocked optics reading area	Wipe cuvette clean with lint-free tissue, clean optical wells (10.1.4), and reread
	Lasers need readjusting	Using Optical Calibration Check, readjust beams (10.1.1) Call Helena Laboratories
Setup and Maintenance unavailable for selection	Run Only operator ID in use	Change operators (7.9)
	Tests are in-process	Wait until the run is complete or end the run.
	Tests not aborted correctly	Open the Run window, begin a run, and then select Abort Run
No lines marking the slope	Slope lines set to hide	Show lines (7.7.2.1.1)
	Slope is negative or zero	Slope will display as N/A, edit slope to correct

10.3. Warranty

Helena Laboratories warrants its products to meet Helena's published specifications and to be free from defects in materials and workmanship. Helena's liability under this contract or otherwise shall be limited to replacement or refund of any amount not to exceed the purchase price attributable to the goods as to which such claim is made. These alternatives shall be the buyer's exclusive remedies. In no case will Helena Laboratories be liable for consequential damages even if Helena has been advised as to the possibility of such damages.

The foregoing warranties are in lieu of all warranties expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose. In no event will Helena Laboratories be liable for indirect, incidental or consequential damages; the original user's remedies being limited to repair or replacement at the manufacturer's option.

All software and driver disks provided with this instrument must be retained and be accessible in the sleeves provided at the end of this manual for the warranty to be valid.

Warranty Duration

















This warranty is provided to the original purchaser for **one year from date of sale**.

Particular Exclusions

WARNING! Do not use the AggRAM for any purpose other than that described in this manual. Modification of the software or the use of the computer to run other programs may affect the operation and reliability of the instrument. Helena Laboratories is not liable for any consequential damages should the customer choose to ignore this warning.

Section 11 - Symbology

NOTE: The following symbols may be used in this manual, or on the instrument, to provide information necessary to the user, if applicable.

	Caution, electric shock hazard, high voltages capable of causing personal injury - shut down the instrument and unplug the power cord before touching - do not operate with the cover(s) removed
	Caution, heat hazard - allow heated components to cool before handling
	Caution, general hazard - see Precautions and Hazards (Sections 3 and 4) of Operator's Manual before proceeding
	Direct current
	Alternating current
	Both direct and alternating current
	Ground (earth) terminal
	Protective conductor terminal (grounded conductors)
	Frame or chassis terminal
	Equipotentiality (conductor with all parts at a single potential)
	On (power switch)
	Off (power switch)
	Equipment protected throughout by double insulation or reinforced insulation (equivalent to Class II of IEC 536)
	European authorized representative
	Manufacturer
	Indicates "do not place in trash" in countries or regions requiring recycling and other specific handling, such as in Europe, under the WEEE (Waste Electrical and Electronic Equipment) Directive, 2002/96/EC

Section 12 - Communication Specifications**INTERFACE SPECIFICATIONS:**

The HemoRAM software import/export interface conforms to the EIA standard RS-232C and is configured as a DTE (Data Terminal Equipment). Only receive data, transmit data and signal common lines are used. The baud rate is user selectable at 110, 300, 600, 1200, 2400, 4800, 9600, 14400, 19200, 28800, 38400, and 57600 baud. The number of data bits may be set at 7 or 8 and the number of stop bits may be 1 or 2. Parity may be set to none, even, or odd. Protocol options include no protocol, XON-XOFF flow control, or ASTM protocol.

MECHANICAL SPECIFICATIONS:

9 pin D-shell connector (male):

<u>Pin</u>	<u>Description</u>
1	receive line detect
2	receive data*
3	transmit data*
4	data terminal ready
5	signal common*
6	data set ready
7	request to send
8	clear to send
9	ring indicator

*only these lines are used by the HemoRAM software.

COMMUNICATIONS PROTOCOL:

The protocol used by the HemoRAM software is user selectable. Listed below are the protocol options available.

No Protocol:

Data is transmitted and received as ASCII text with no flow control or error checking/correction. This option is not recommended unless the HemoRAM software is to be connected to a terminal.

XON-XOFF Flow Control:

Data is transmitted and received as ASCII text and XON/XOFF (ASCII codes 17 and 19) handshaking is used to control data flow.

When exporting, the HemoRAM software will recognize an XOFF character and stop transmission until an XON character is received. There is no error checking or correction when using this protocol.

ASTM Protocol (E1381-95 and E1394-97):

This protocol provides procedures for link connection and release, delimiting and synchronism, sequence control, error detection and error correction. Data is transmitted and received as ASCII text and some restrictions are placed on which characters can be used in the data content. The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>, and <DC4>.

There are three distinct phases in transferring information between the HemoRAM software and the computer system. In each phase, one system directs the operation and is responsible for continuity of the communication. The three phases assure the actions of sender and receiver are coordinated. The three phases are Establishment, Transfer, and Terminate.

Establishment Phase

The Establishment phase determines the direction of information flow and prepares the receiver to accept information. The sender notifies the receiver that information is available. The receiver responds that it is prepared to receive before information is transmitted. A system, which does not have information to send normally, monitors the data link to detect the establishment phase. It acts as a receiver, waiting for the other system.

The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the <ENQ> character to the intended receiver. Upon receiving the <ENQ>, the receiver prepares to receive information. All other characters are ignored. It replies with the <ACK> character to signify

AggRAM

it is ready. With this sequence of events, the establishment phase ends and the transfer phase begins.

A receiver that cannot immediately receive information replies with the <NAK> character. Upon receiving the <NAK>, the sender must wait at least 10 seconds before transmitting another <ENQ>.

Should both systems simultaneously transmit an <ENQ>, the data link is in contention. The HemoRAM software has priority to transmit information when contention occurs. Contention is resolved as follows. Upon receiving a reply of <ENQ> to its transmitted <ENQ>, the computer system must stop trying to transmit; it must prepare to receive. When the next <ENQ> is received, it replies with an <ACK> or <NAK> depending on its readiness to receive.

Transfer Phase

During the transfer phase, the sender transmits information to the receiver. The transfer phase continues until all information has been sent.

Information is sent in frames, each frame contains a maximum of 247 characters (including frame overhead). Records or data that are longer than 240 characters are divided between two or more frames. A frame is one of two types, an intermediate frame or an end frame.

Intermediate frames terminate with the characters <ETB>, checksum, <CR> and <LF>. End frames terminate with the characters <ETX>, checksum, <CR> and <LF>. The frame structure is illustrated below:

Intermediate Frame: <STX> FN "data"
<ETB> C1 C2 <CR> <LF>

End Frame: <STX> FN "data" <ETX> C1 C2
<CR> <LF>

Where:

<STX> - Start of text transmission character
FN - single digit frame number "0" to "7"
"data" - data content

TWELVE - Communication Specifications

C1 - first character of checksum

"0" - "9" & "A" - "F"

C2 - second character of checksum

"0" - "9" & "A" - "F"

<ETB> - end of transmission block character

<ETX> - end of text transmission character

<CR> - carriage return character

<LF> - line feed character

The frame number is an ASCII digit ranging from "0" to "7". The frame number begins at "1" with the first frame of the transfer phase. The frame number is incremented by one for each new frame transmitted. After "7", the frame number rolls over to "0".

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters, which are sent after the <ETB>, or <ETX> character. The checksum is computed by adding the binary values of the frame characters, keeping the least significant eight bits of the result. The checksum is transmitted as ASCII hexadecimal.

The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the data is added to the checksum (modulo 256). The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

After the frame is sent, the sender stops transmitting until a reply is received. The receiver replies to each frame. A reply of <ACK> signifies the last frame was received successfully and the receiver is prepared to receive another frame.

A reply of <NAK> signifies the last frame was not received successfully; the receiver is prepared to receive the frame again. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected and automatically corrected. A frame is not successfully received if any of the following occur:

AggRAM

1 - any character errors are detected (parity error, framing error, etc.)

2 - the frame checksum doesn't match the checksum computed on the received frame.

3 - the frame number is not the same as the last accepted frame or one higher (modulo 8).

A frame may be retransmitted up to 6 times. If after 6 tries the frame has still not been successfully transmitted, the sender transmits an <EOT> and regards the data link to be in the neutral state.

A reply of <EOT> signifies the last frame was received successfully, the receiver is ready to receive another frame, but is a request to the sender to stop transmitting. The sender does not have to stop transmitting after receiving the request. If it continues to transmit, there is a possibility of overflowing the receiver's buffers. If the sender chooses to ignore the <EOT>, the receiver must retransmit the request.

Termination Phase

The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all data has been sent.

The sender transmits the <EOT> character and then regards the data link to be in a neutral state. Upon receiving the <EOT>, the receiver also regards the data link to be in the neutral state.

Timeouts

The sender and receiver both use timers to detect loss of coordination between them. The timers provide a method for recovery if the communication line or the other device fails to respond.

During the establishment phase, the sender sets a timer when transmitting the <ENQ>. If a reply of an <ACK>, <NAK> or <ENQ> is not received within 15 seconds, a timeout occurs and the sender regards the link to be in the neutral state.

During the establishment phase, if the computer (as receiver) detects contention, it

TWELVE - Communication Specifications

sets a timer. If an <ENQ> is not received within 20 seconds, a timeout occurs and the receiver regards the link to be in the neutral state.

During the transfer phase, the sender sets a timer when transmitting the last character of a frame. If a reply is not received within 15 seconds, a timeout occurs. After a timeout, the sender aborts transmission by proceeding to the termination phase.

During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete record or set of data and regards the link to be in the neutral state.

DATA TRANSFER FORMAT

The HemoRAM software in general adheres to the ASTM Standard Specification for Transferring Information Between Clinical Instruments and Computer System. The exceptions concern sending a QC record.

General Information

Data is exchanged in records of different types. Each record is introduced by field number 1 identifying the record type, and terminated by a carriage return. There are 5 record types used by the HemoRAM software: Header Record (H), Patient Record (P), Test Order Record (O), Result Record (R), and the Terminator Record (L).

Records are related to each other in a definite hierarchy. At level zero is the Header record and Terminator record. At level one is the Patient record and the Request-Information record. At level two is the Test Order record. At level three is the Result record.

A sequence of patient records, order records, or result records at one level is terminated by the appearance of a record type of the same or higher level. Thus, a sequence of results for one patient is terminated by the next patient record.

Each record is composed of fields, which are position sensitive and variable in length. Each field is separated by a field delimiter (e.g., the vertical bar, "|"). The position sensitivity requires that when the contents of a field are null, its corresponding field delimiter must be included in the record to ensure that the ith field can be found by counting (i-1) delimiters. Delimiters are not included for trailing null fields; that is, if the tenth field was the last containing data, the record could terminate after the tenth field (with a carriage return) and therefore would contain only nine delimiters.

A system may transmit a null value for a field because (1) it does not know the value, (2) it knows the value is irrelevant to the receiving system, or (3) the value has not changed since the last transmission, or any combination thereof. Because the sending system can use null values to indicate no change, a null value does not overwrite existing data in the receiving system. The transmission of a double quote (ASCII 34) in a field tells the receiving system to replace any existing value with a null value.

Each field may be composed of sub-components. These sub-components are separated by a component delimiter (e.g., the caret, "^"). The component delimiter is used to separate data elements of fields of a hierarchical or qualifier nature.

Header Record

The header record must always be the first record in a transmission. When the HemoRAM software transmits a header record, it will have the following format:

```
H|^&|||Helena Laboratories^HemoRAM^n.n.n.n^n^n^Sns|||||P|1394-97|yyyymmddhhmmss
```

If the message is being sent for a QC rather than any other RunType, then the header will be as follows:

```
H|^&|||Helena Laboratories^HemoRAM^n.n.n.n^n^n^Sns|||||Q|1394-97|yyyymmddhhmmss
```

with a Q in the Processing ID field instead of a P.

n.n.n.n - HemoRAM software version number

Sns - Serial numbers of each attached module, starting with Module A, separated by spaces

yyyymmddhhmmss - 4-digit year, 2-digit month, 2-digit day, 2-digit hour, 2-digit min., 2-digit seconds.

Patient Record

A patient record is not included when sending QC data.

EXAMPLE: P|1||12|||||F|||||||0|0|

Order Record

The HemoRAM software will transmit an order record immediately preceding any results records for a patient as required in the ASTM specification. The format will be as follows: O|1||CrvSeqNum|UniversalTestID|||||<CR>

CrvSeqNum – A sequential test number (up to 4 billion) in the fourth field (Instrument specimen ID).

UniversalTestID – (see section below on the Universal Test ID) All components of the Universal Test ID must be sent except the ID of the Result (and since there may be several parameters sent as results, they would be sent in the Result Record instead).

EXAMPLE:

For a patient: O|1||7|^|^Platelet Aggregation
^*Screen1^Collagen^Patient^104551188|||||||
|||||||F

For a QC: O|1||123|^|^Ristocetin ^Ristocetin
^Ristocetin^QC^2035301-2^1^SomeStandard
^99.9

For a standard: O|1||3333|^|^Ristocetin^
Ristocetin^Ristocetin^Standard^1353424-2^^
ThisStd^97.5^25

AggRAM

The HemoRAM software currently does not recognize test order records transmitted by the computer system.

Result Record

Each parameter will be transmitted as a separate result record.

For patient results, if test range limits have been entered (currently not available), they will be included in the sixth (reference ranges) field.

The ninth (result status) field always shows "F" for Final results or is left blank.

A result will be transmitted in the following format:

```
R|n|UniversalTestID|nnnn|unit of measure|
nnnn-nnnn||||F|||date/timestarted|date/time
completed<CR>
```

n - Sequence number.

UniversalTestID – (see section below on the Universal Test ID) Any information sent as part of the Order record may be omitted by using just a series of component delimiters. Since everything but the ID of the result itself is sent during the Order record, only the Result ID is necessary here.

Any components in the UniversalTest ID for the Result Record which are duplicates of the Order record may be omitted.

nnnn - result

nnnn-nnnn - User defined reference range.

date/time started - Date and time the test was started (yyyymmddhhmmss). The date is transmitted with the year first, month second and day last.

date/time completed - Date and time the test finished

EXAMPLE:

```
For patient result record: R|1|^AAAAAAAAAAAAA
PRP|1.39|µg/ml||||F||Eric|20020503143809|20
020503144028|
```

TWELVE - Communication Specifications

```
For QC result record: R|1|^AAAAAAAAAAAA50^
FinalActivity|13.80|%||||F|||20020502094336|2
0020502094546|
```

```
For a standard result record: R|1|^AAAAAAAAAA
^^Activity|66.4|%||||F|||20050502082335|2005
0502094546|
```

Terminator Record

The terminator record must be the last record in a transmission. When the HemoRAM software transmits a terminator record it will have the following format: L|1|N<CR>

Universal Test ID

The UniversalTestID is made up of a series of component fields separated by component delimiters. The UniversalTestID is included in both the Order Record and the Result Record. Several components are only pertinent to the Result Record and would therefore not be included when sending the Order Record. The complete list (including those for both Order and Result Records) follows:

Universal Test ID – Left blank (unused part of ASTM spec)

Universal Test ID Name – Left blank (unused part of ASTM spec)

Universal Test ID Type – Left blank (unused part of ASTM spec)

TestType – The Test Type for the current channel being sent.

MainTest – The test or screen for the module(s) run.

SpecificTest – The test (reagent or assay) for the current channel being sent.

RunType – The Run Type (Patient, Reference, Standard, or QC) for the current channel being sent.

LotNumber – The Lot number of the reagent used during the run.

QCLvl – If for a QC then this is the QC level, otherwise it is left blank or zero.

StdRefID – For a standard or any run referencing a standard, this is the ID of that standard. For a reference, this is the ID of that reference.

RefLvl – If this run references a standard, then this is the Reference level associated with that standard.

Conc – If this is a standard then Conc is the concentration of the dilution for this run.

Units – Units for the Concentrations.

ResultID – The name of the parameter being reported in the current result record. These result parameters are listed below. The first six parameters are sent for all tests and RunTypes:

InitialMax (PPP), InitialMin (PRP), MaxPCPoint (Max % Point), MaxPCTime (Time associated with Max % Point), Slope, and LagTime.

SDI (Standard Deviation Index) is sent if the RunType is a QC.

Activity and FinalActivity are sent if the TestType is Ristocetin.

Slope2 and/or AreaUnderCurve (Area Under the Curve in %) are sent if they are selected on the Test Parameters setup menu.

Section 13 - Reports

The following is a list possible symbols used on reports and their meanings:

1. *L* - indicates the PRP O.D. is out of range, less than .2, implying low platelet count or that calibration may be off.
2. *H* - indicates the PRP O.D. is out of range, greater than 1.2, implying high platelet count or that calibration may be off.
3. *M* - with slope data (Figure 13-3), indicates the slope has been manually edited.
4. *M* - with QC data (Figure 13-4), indicates the QC was manually entered.
5. *r* - correlation coefficient
6. *#* - indicates the slope is out of range, either the patient or QC slope is lower than the lowest or higher than the highest slope measured for the standard.
7. *W* - indicates an unresolved Westgard failure occurred during or prior to the run.
8. *N/A* - indicates the slope is less than or equal to zero.

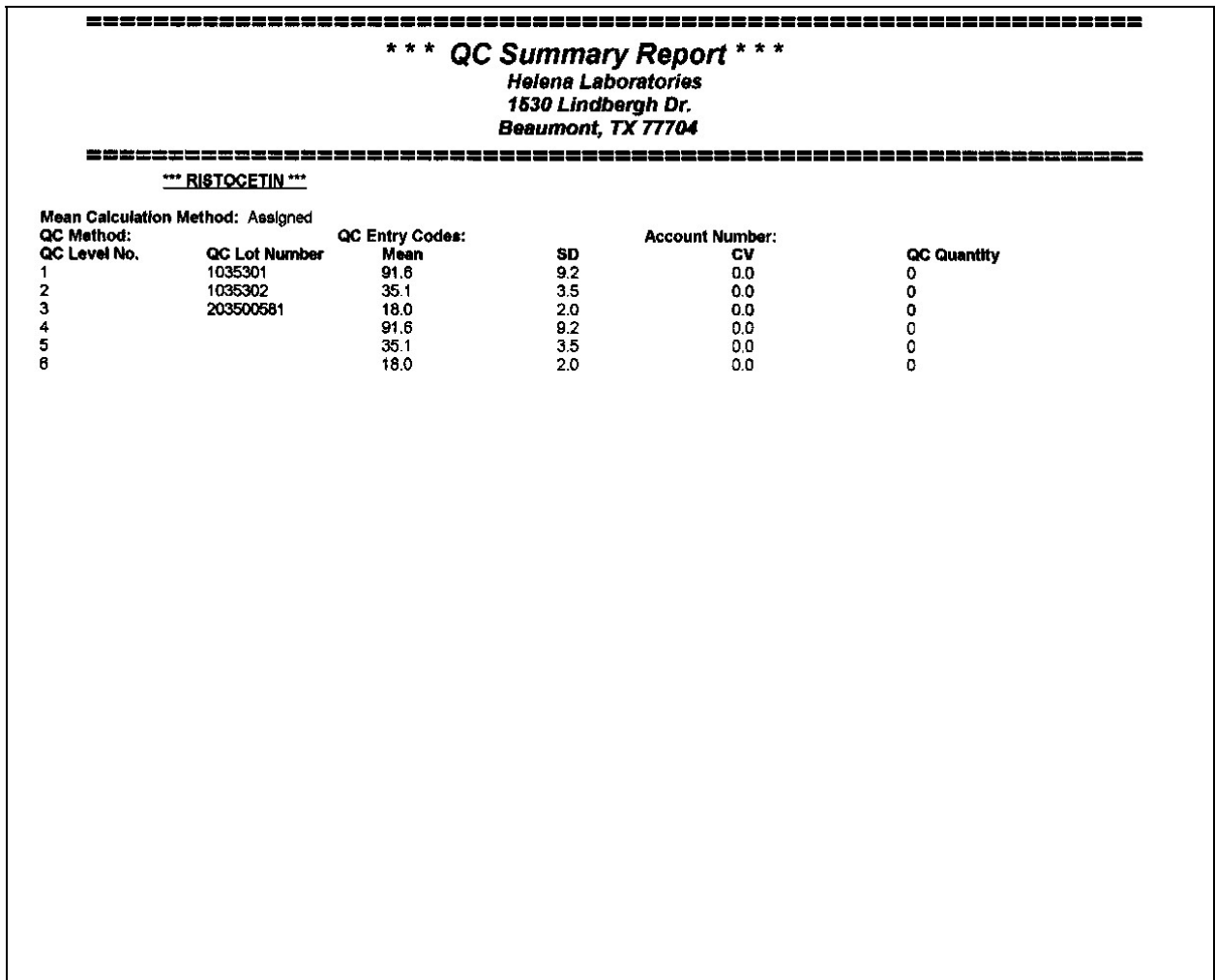


Figure 13-1. QC Summary - Assigned

*** QC Summary Report *** Helena Laboratories 1530 Lindbergh Dr. Beaumont, TX 77704					
*** RISTOCETIN ***					
Mean Calculation Method: Lot-to-Date					
QC Method:	QC Lot Number	QC Entry Codes:	SD	Account Number:	QC Quantity
QC Level No.		Mean		CV	
1	1035301	94.4	7.0	7.4	11
2	1035302	37.2	4.4	11.9	7
3	203500581	19.1	1.2	6.5	6
4		0.0	0.0	0.0	0
5		0.0	0.0	0.0	0
6		0.0	0.0	0.0	0

Figure 13-2. QC Summary - Lot-to-Date

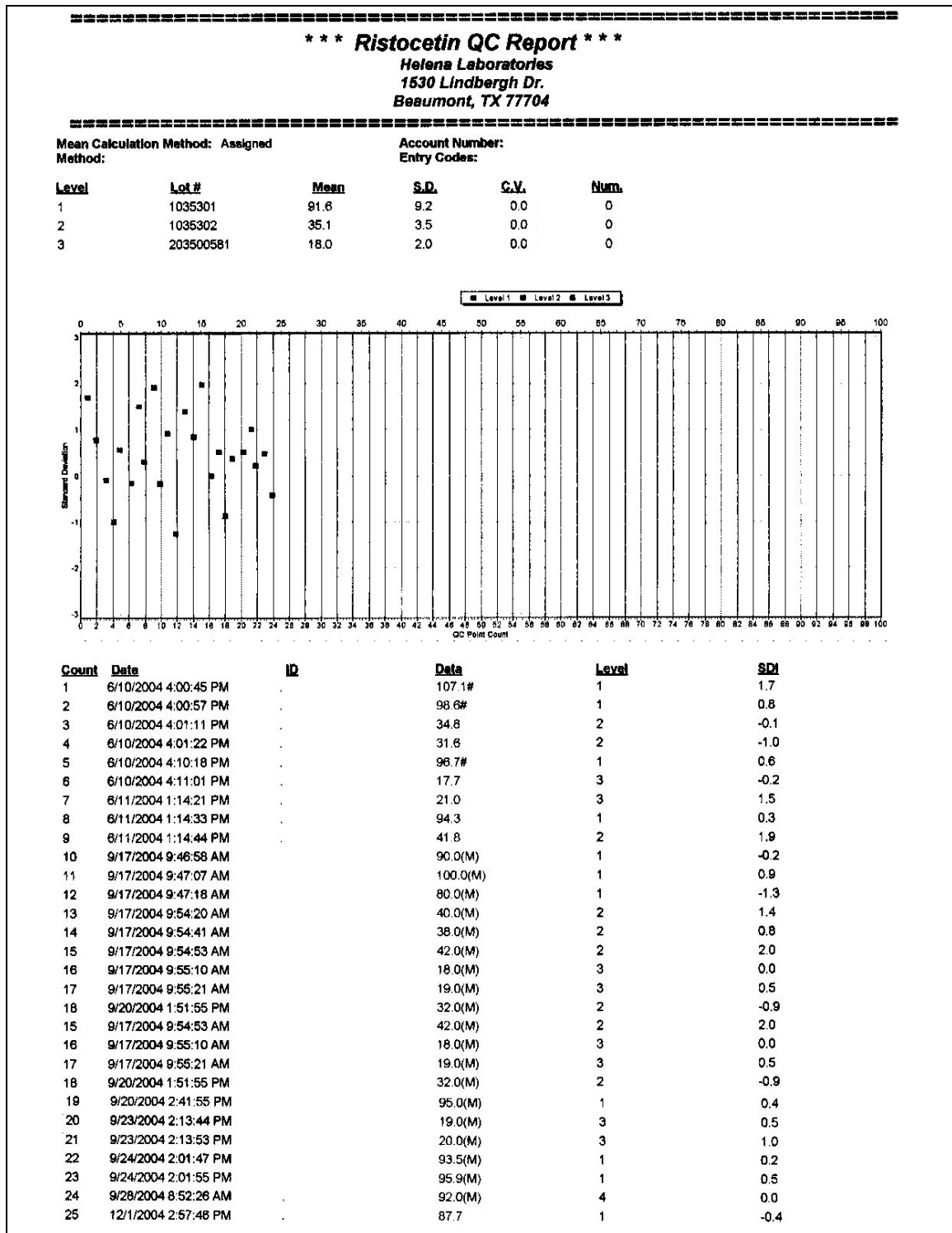


Figure 13-3. QC Report - Assigned

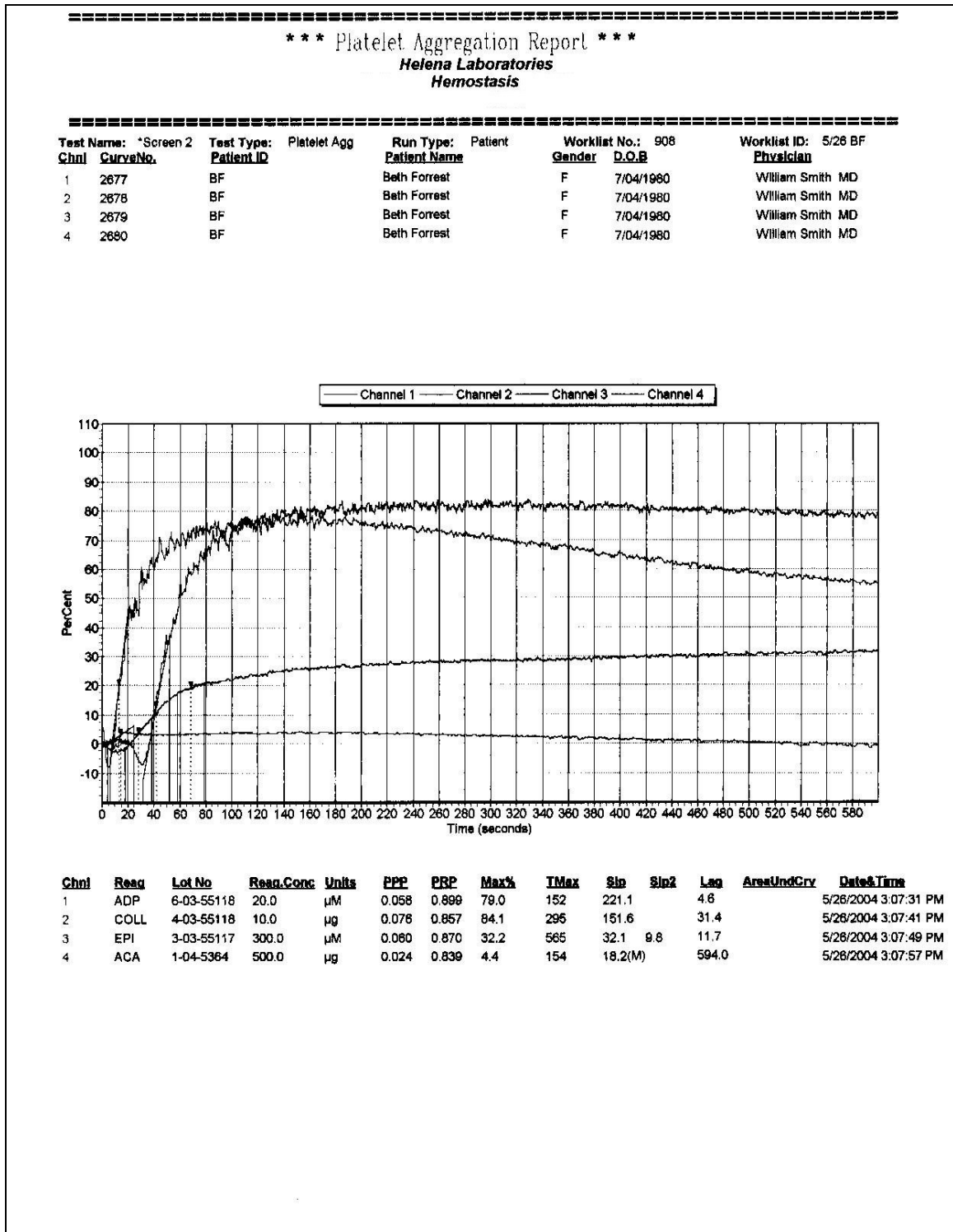


Figure 13-4. Platelet Aggregation Report

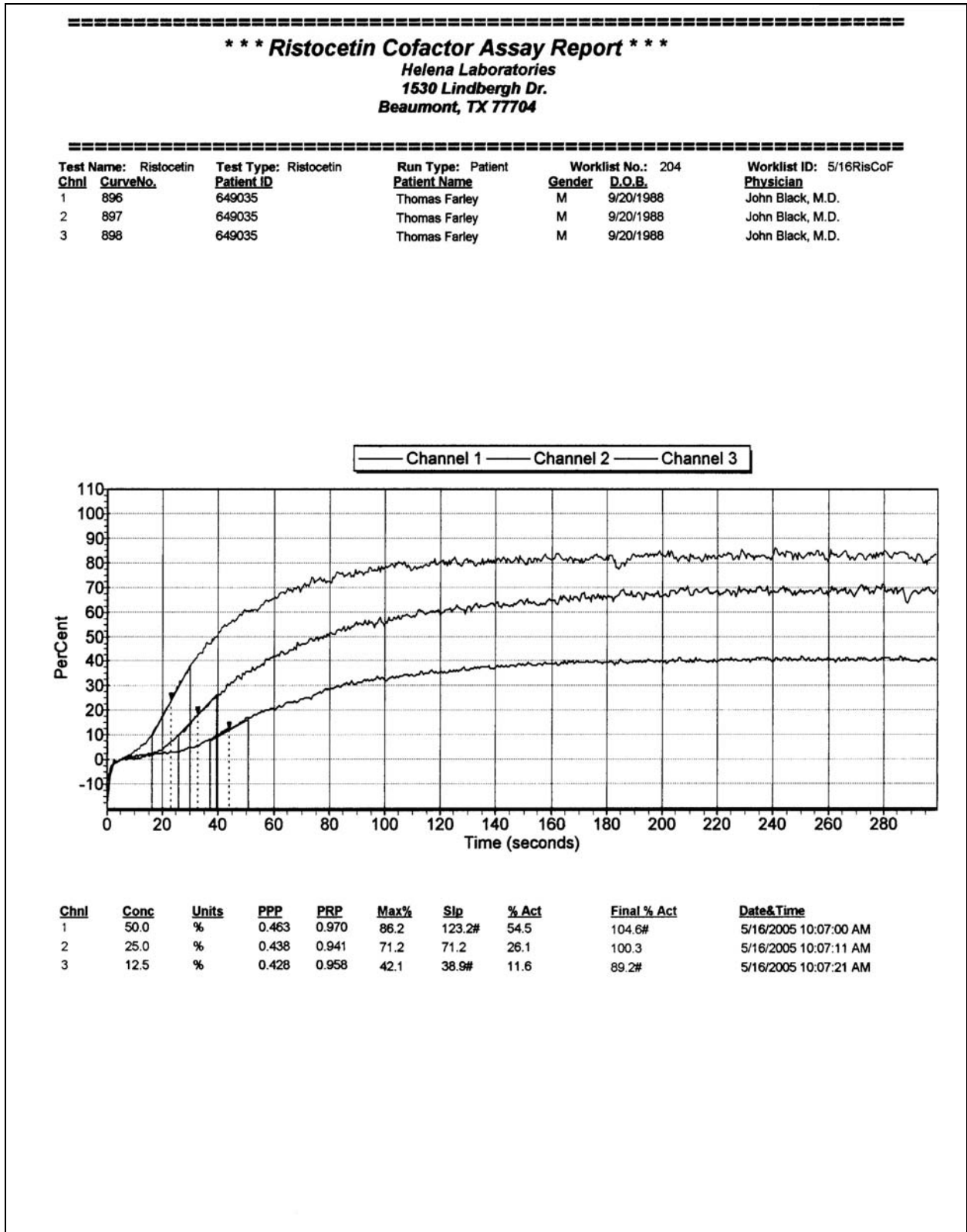


Figure 13-5. Ristocetin Cofactor Assay Report - Patient

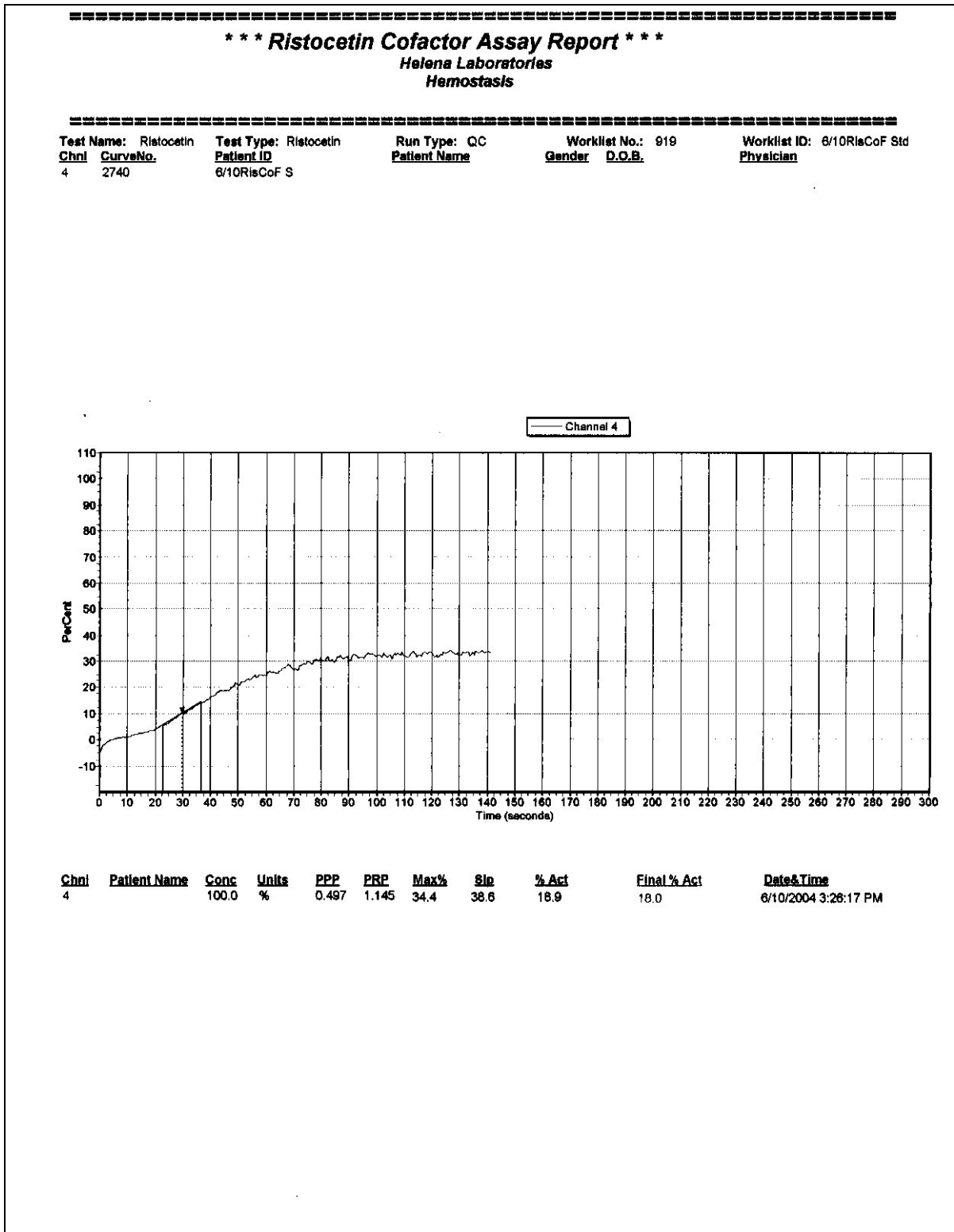


Figure 13-6. Ristocetin Cofactor Assay Report - QC

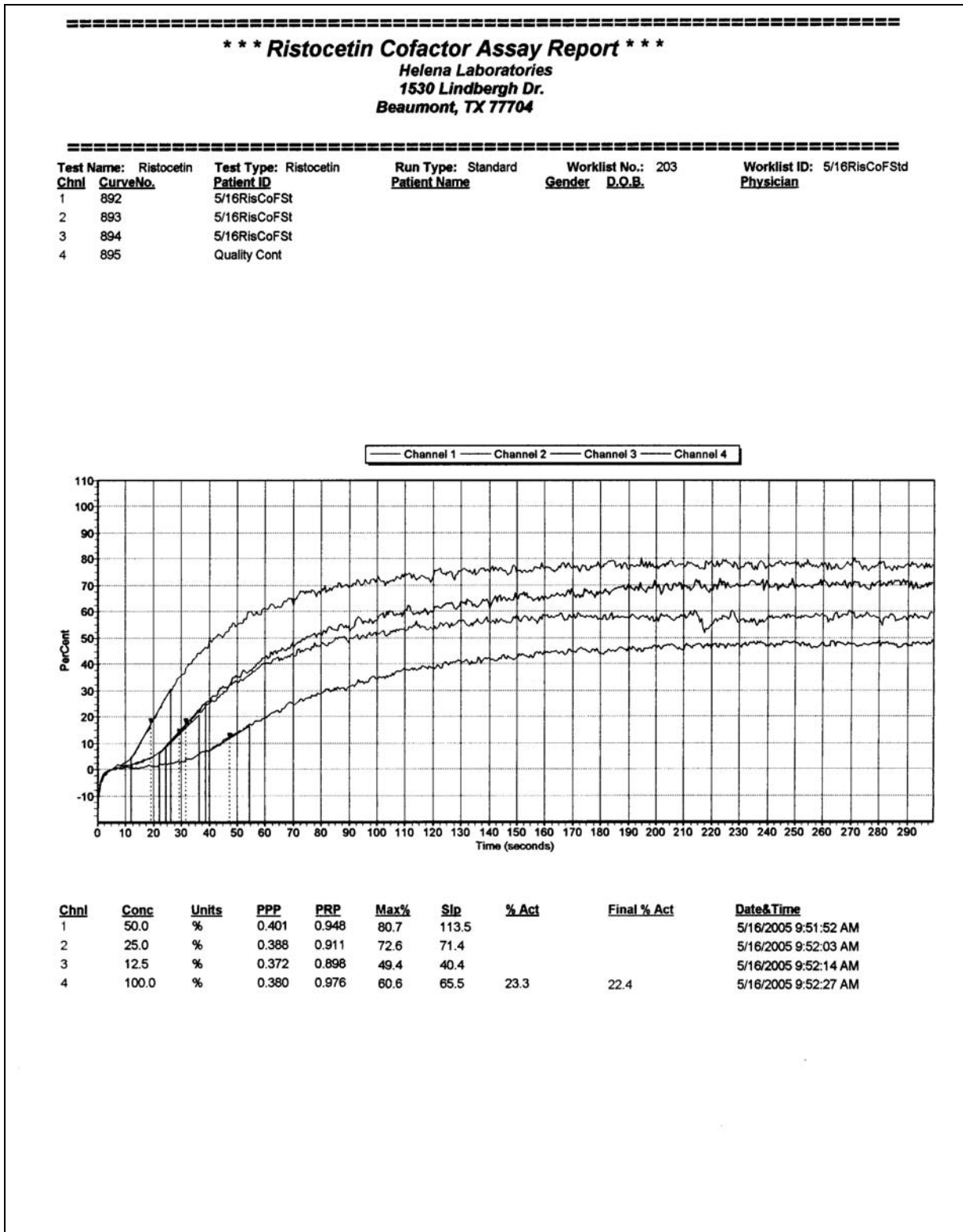


Figure 13-7. Ristocetin Cofactor Assay Report - Standard

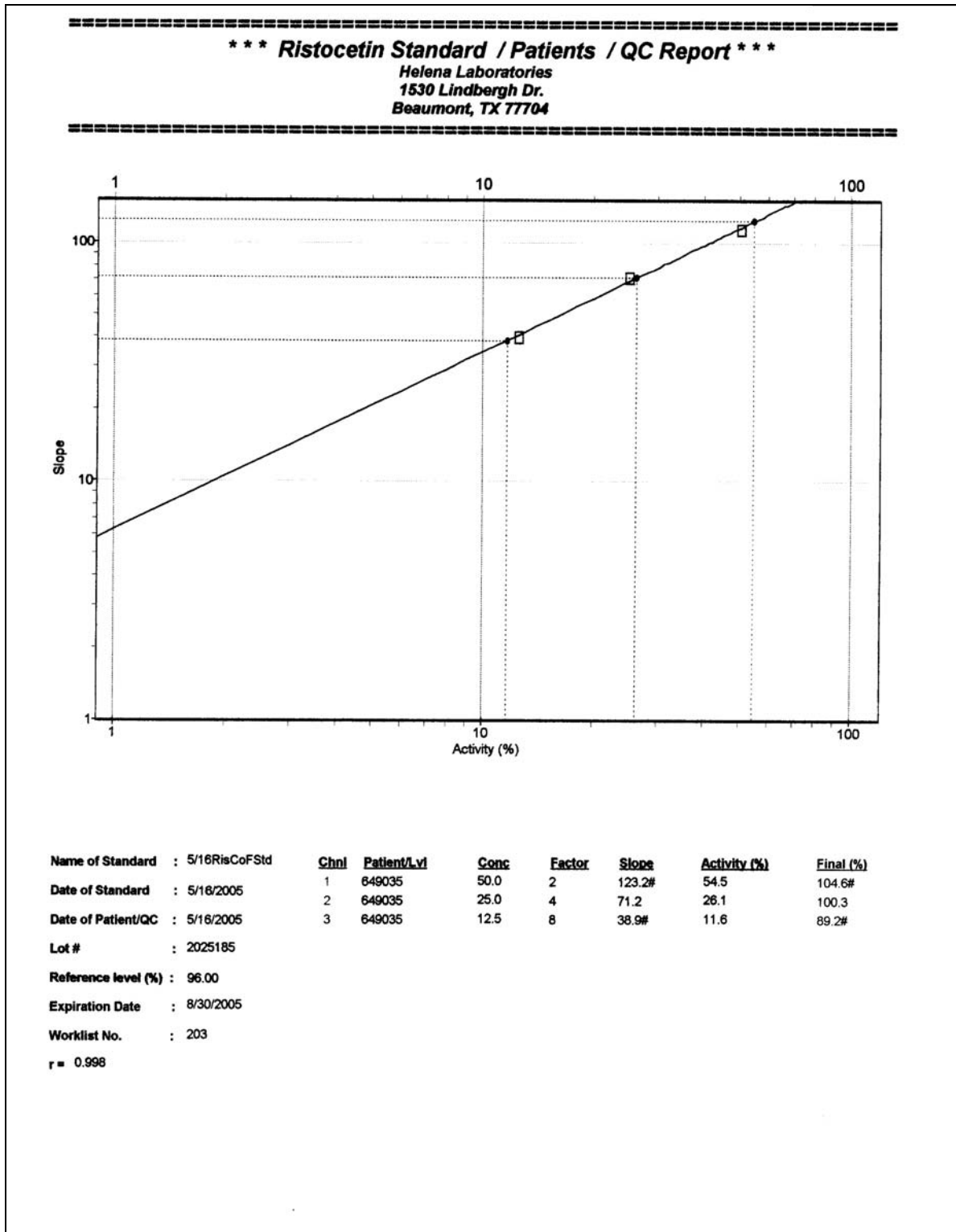


Figure 13-8. Ristocetin Standard / Patients / QC Report

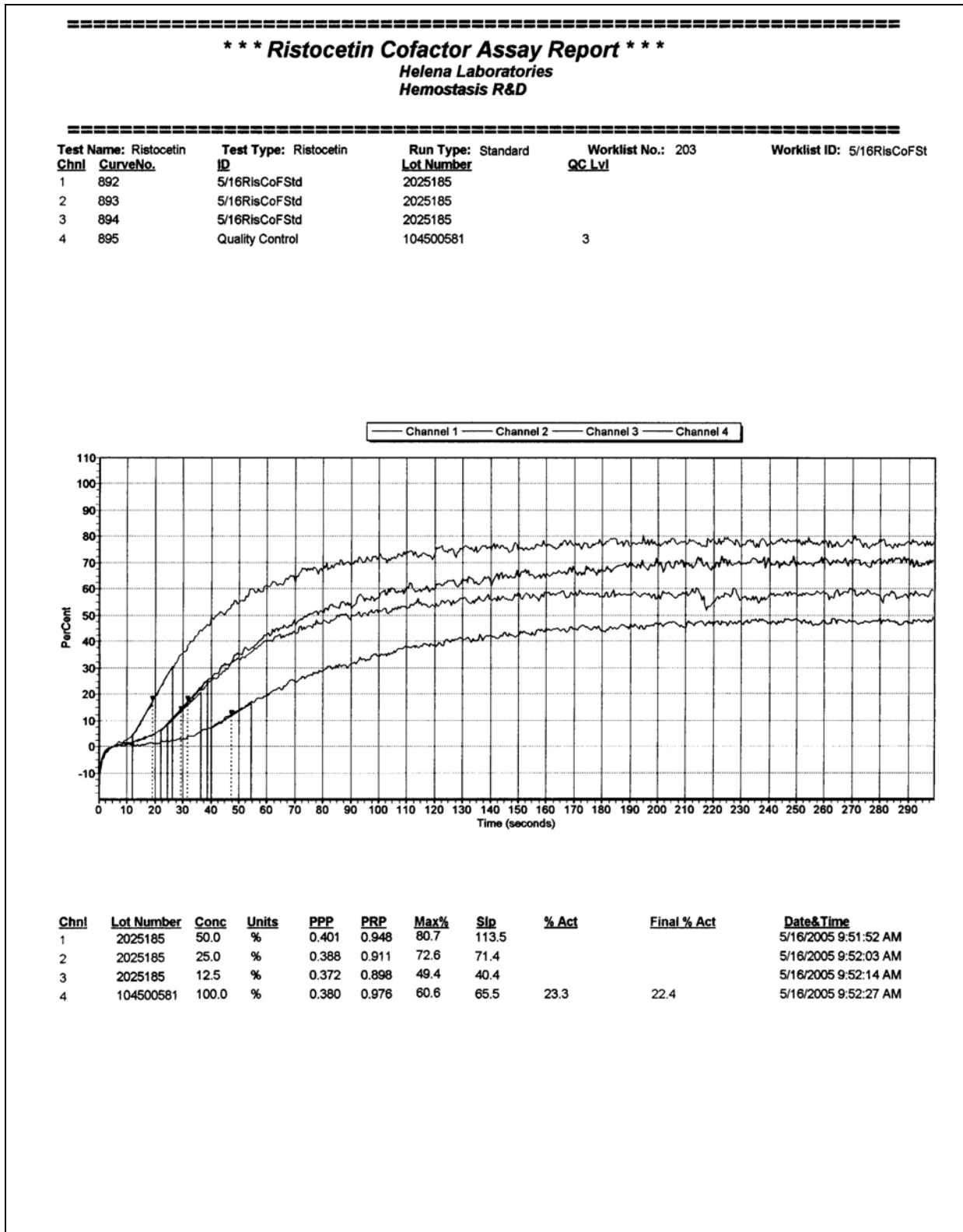


Figure 13-9. Ristocetin Cofactor Assay Report - Standard

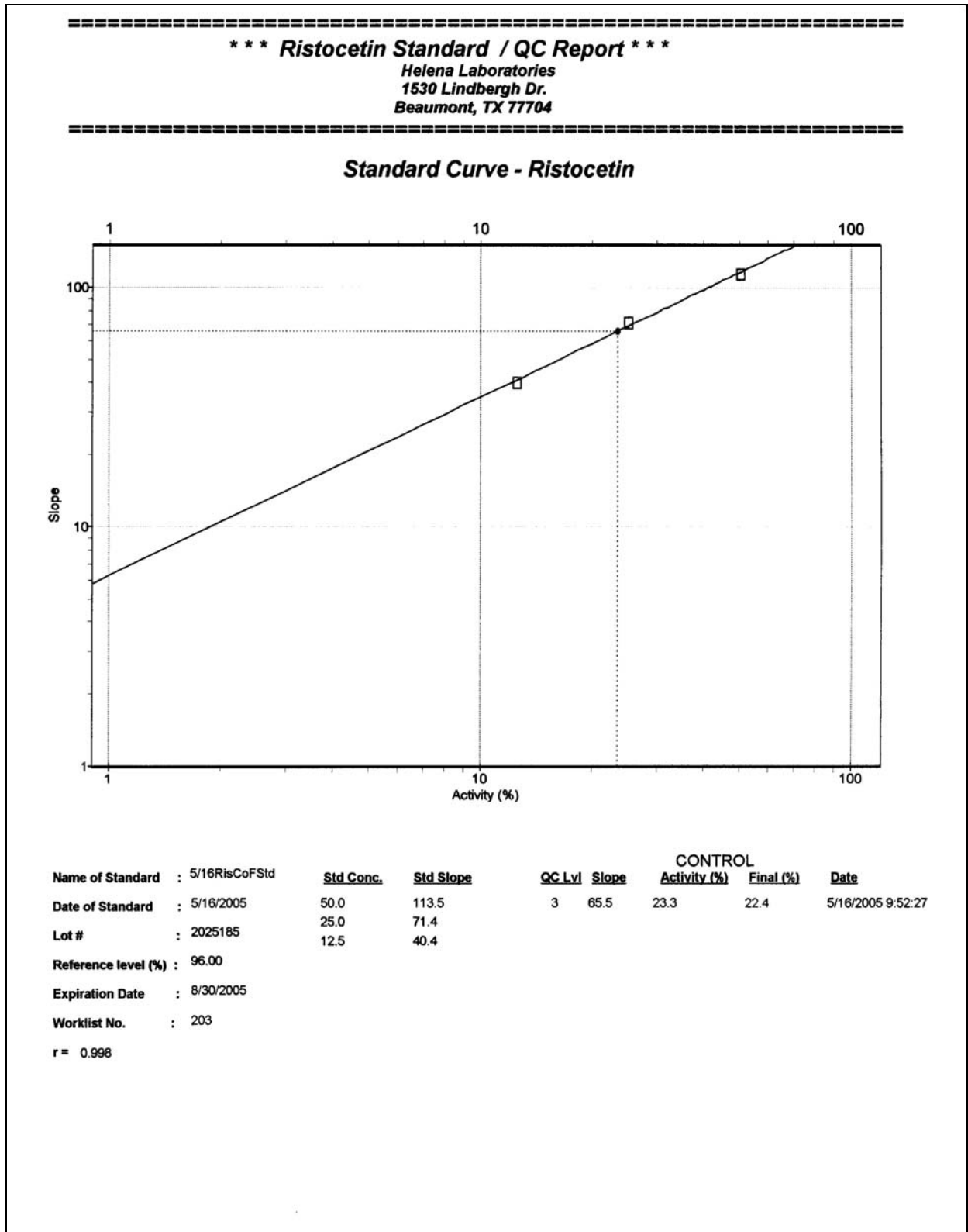


Figure 13-10. Ristocetin Standard / QC Report

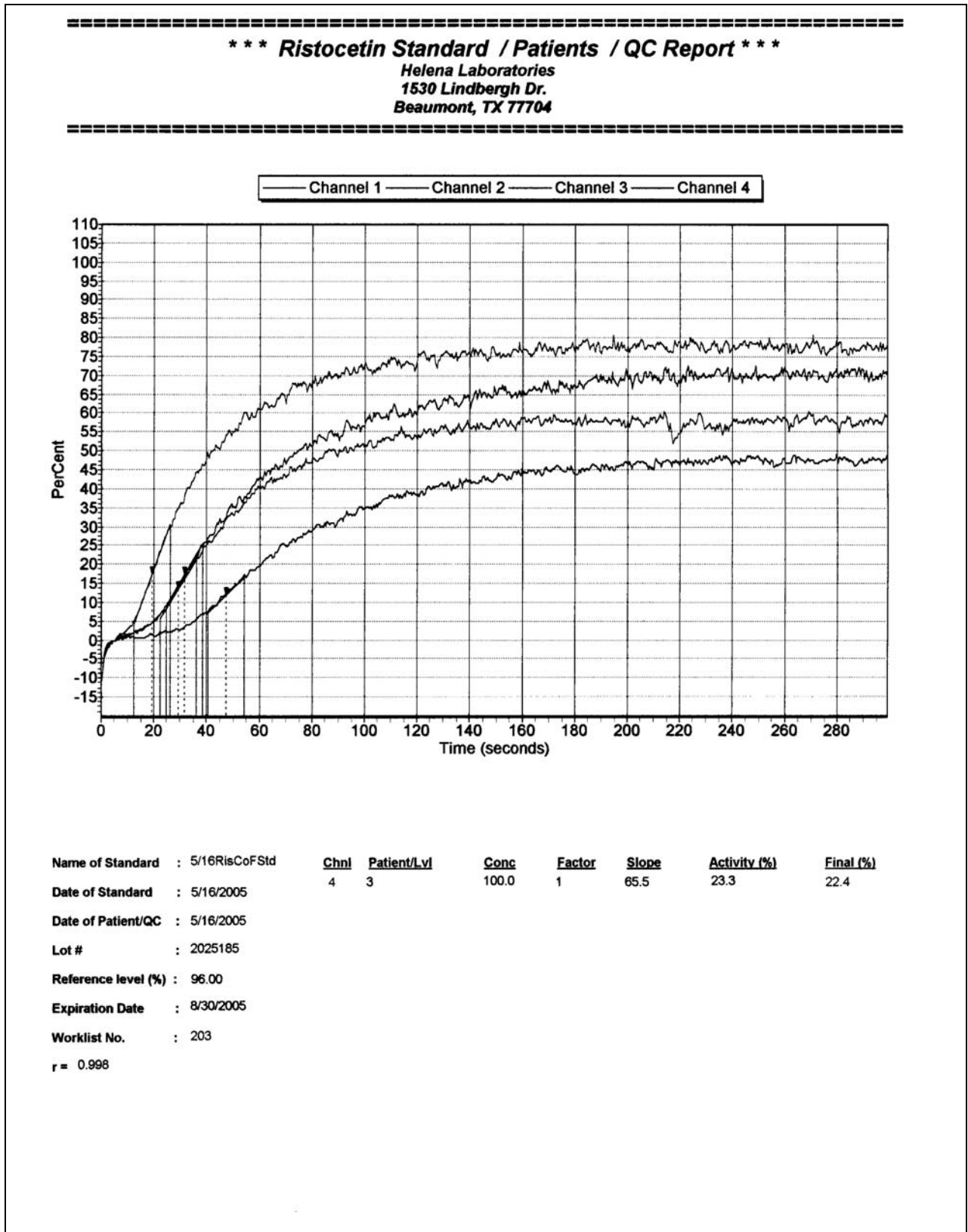


Figure 13-11. Ristocetin Standard / Patients / QC Report

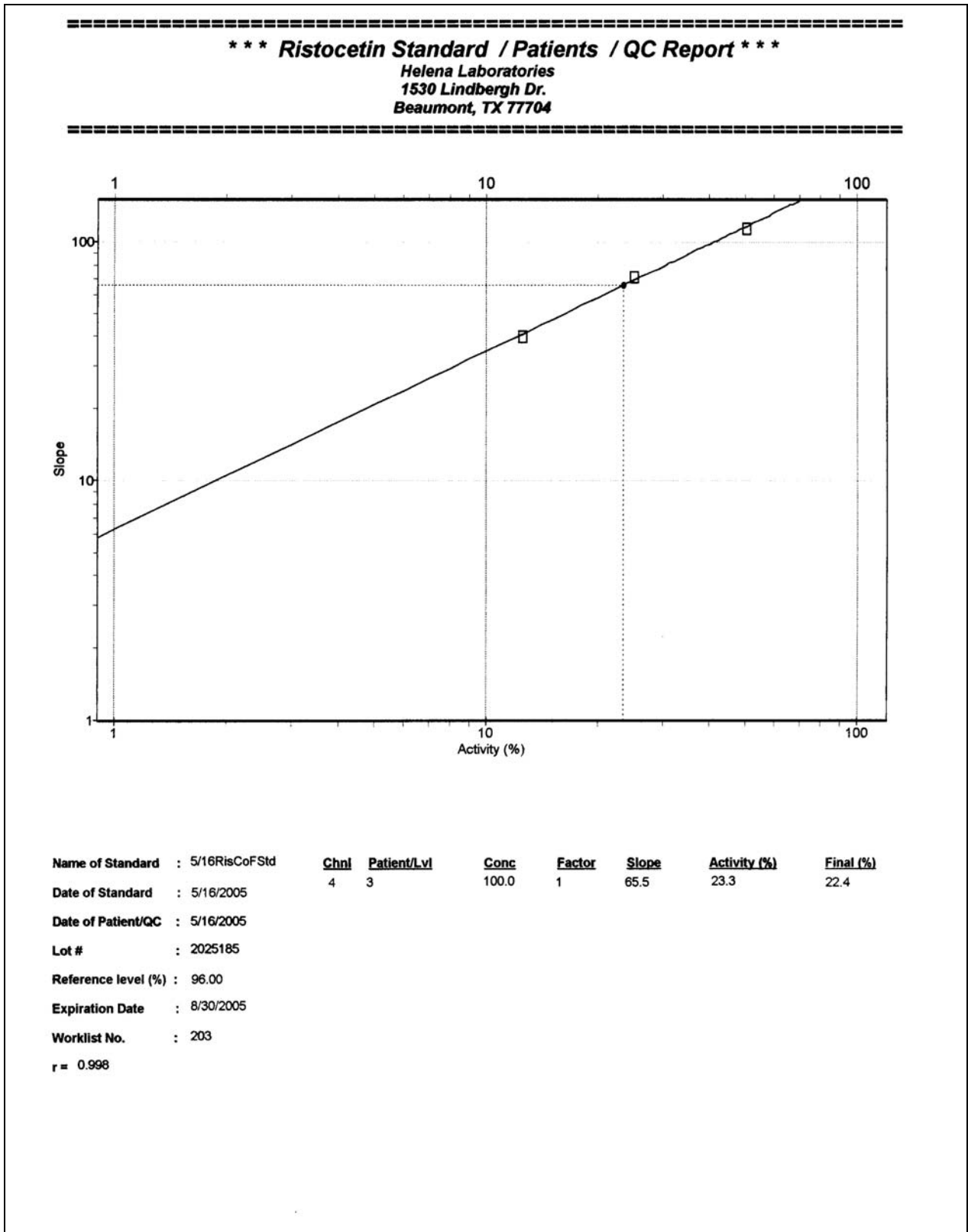


Figure 13-12. Ristocetin Standard / Patients / QC Report

Section 14 - Index

A

abort, 7-1, 7-3, 7-4, 7-9, 7-10
absorbance, 1-1, 2-1, 9-1, 10-2
access level, 6-1, 6-6, 7-1, 7-20
agglutination, 2-1, 2-2
aggregation, 1-1, 2-1, 2-2, 3-1, 7-1, 7-2, 7-3, 7-4, 7-5, 7-11, 7-12
archive, 7-20
area under curve, 6-2, 6-3
assigned, 6-5, 6-6
asterisk, 6-2
ASTM, 6-6, 12-1, 12-3, 12-4
auto import, 6-6
auto-output, 6-7

B

backup, 7-20
baseline, 2-1, 7-2
baud rate, 6-6, 12-1
begin run, 7-1, 7-3, 7-4, 7-9
blank, 7-1, 7-2, 7-3, 7-4, 7-5, 7-11
block temperature, 6-2, 6-3, 10-3

C

calibration, 2-2, 7-16, 10-1, 13-1
channels, 6-2, 6-3, 7-15
chart, 7-15
cleaning, 3-1, 4-1, 10-2, 10-3
comments, 7-13
computer, 2-1, 2-2, 5-2, 5-3, 6-1, 6-6, 7-1, 10-9, 12-1, 12-2, 12-3, 12-5
concentration, 2-1, 6-2
controls, 6-3, 7-1, 7-2, 7-4, 8-1
correlation coefficient, 13-1
cuvette, 2-2, 6-4, 7-1, 7-2, 7-3, 7-4, 7-5, 9-1, 10-1, 10-2, 10-3

D

data bits, 6-6, 12-1
date, 7-14, 7-19
delete, 6-2, 6-3, 6-7, 7-6, 7-7, 7-8, 7-16, 7-17, 7-18, 7-20
demographics, 7-5, 7-15
determination time, 6-4
display parameters, 6-2, 6-4, 7-15

E

edit, 6-3, 7-10, 7-11, 7-12, 7-13, 7-16, 13-1
error messages, 7-21
exit, 6-2, 6-4, 6-5, 6-6, 6-7, 7-6, 7-7, 7-8, 7-9, 7-13, 7-14, 7-16, 7-17, 7-19, 7-20, 7-21, 10-1, 10-3
export, 6-6, 7-11, 12-1
external computer, 2-1, 2-2, 6-6

F

filter, 10-3

H

help, 7-21
HemoRAM software, 5-3, 6-1, 7-1, 12-1, 12-2, 12-3, 12-4, 12-5

I

import, 6-6, 7-5, 7-6, 12-1
import/export parameters, 6-6
incubate, 2-1, 7-1, 7-3, 7-5
index, 7-20
installation, 5-1
installation verification report, 5-4

L

Levey-Jennings Chart, 7-18, 8-1
limit days, 7-17
login, 6-1, 7-1, 7-20
log-log, 6-3, 7-18
lot-to-date, 6-5, 7-19
lyophilized platelets, 2-1

M

M (manually modified), 7-12, 7-13
maintenance, 10-1, 10-2, 10-3
manual slope, 7-12
mean calculation method, 6-5, 7-19
measurement, 2-1, 2-2
micro volumes, 6-1, 6-3, 7-1, 7-2, 7-4
module, 1-1, 2-2, 5-2, 5-3, 5-4, 6-1, 6-2, 6-3, 7-1, 7-2, 7-3, 7-4, 7-9, 9-1, 10-1, 10-2, 10-3
monitor, 5-3, 6-1, 7-1
month-to-date, 6-5, 7-19

N

new standard, 7-4

O

optical calibration check, 10-1
optical chambers, 2-2, 9-1, 10-2
overlay, 7-7, 7-17
overlay reference, 7-17

P

pan, 7-19
parity, 6-6, 12-1
password, 6-1, 6-6, 7-1, 7-20
patient, 2-1, 2-2, 6-3, 6-4, 7-1, 7-2, 7-4, 7-5, 7-6, 7-7, 7-8, 7-13, 7-14, 7-15, 7-16, 7-17, 8-1, 12-4, 12-5, 13-1
patient demographics, 7-5, 7-6
pipette, 7-1, 7-2, 7-3, 7-4, 7-5
platelet aggregation, 1-1, 2-1, 6-1, 7-1, 7-2, 7-6, 7-11, 7-12, 7-13, 7-17, 9-1
platelet count, 3-1, 7-16, 13-1
platelet solution, 7-11
PPP, 2-1, 2-2, 7-1, 7-2, 7-3, 7-5, 7-11
printer, 5-2, 5-3, 6-1, 6-7, 7-1, 7-10, 7-20, 7-21
printer driver, 5-3
printout, 6-7, 10-1, 10-3
protocol, 6-6, 12-1
PRP, 2-1, 3-1, 7-1, 7-2, 7-3, 7-5, 7-11, 7-16, 13-1

Q

QC, 6-4, 6-5, 7-4, 7-5, 7-8, 7-9, 7-11, 7-13, 7-16, 7-17, 7-18, 7-19, 8-1, 13-1
QC parameters, 6-5, 6-6
quality control, 7-8, 8-1

R

raw data, 7-12
reagent, 1-1, 2-1, 2-2, 6-2, 6-3, 6-4, 6-5, 7-1, 7-2, 7-4, 7-6, 7-7, 7-10, 7-11, 7-21, 8-1
reference, 2-2, 7-6, 7-8, 7-16, 7-17
report, 6-7, 7-11, 7-12, 7-16, 7-17, 7-18, 13-1
report parameters, 6-7
restore, 7-20
results, 2-1, 2-2, 6-5, 7-2, 7-4, 7-5, 7-9, 7-10, 7-11, 7-13, 7-17, 7-21, 10-1, 10-2, 10-3, 12-5
ristocetin cofactor, 2-1, 6-3, 6-5, 7-2, 7-4, 7-7, 7-8, 7-11, 7-12, 7-13, 7-17, 7-18, 9-1
run, 7-1, 7-2, 7-4, 7-5, 7-6, 7-9
RunType, 6-4, 6-7, 7-3, 7-4, 7-7, 7-8, 7-14, 7-16, 7-17

S

sample, 2-1, 2-2, 7-1, 7-2, 7-3, 7-5, 7-11, 8-1
scale set, 10-2, 10-3
search, 7-14
semi-log, 6-3, 7-18
setup, 6-1, 6-2, 6-3, 6-4, 6-5, 6-6, 6-7, 7-6, 7-7, 7-8, 7-20
single channel, 7-14, 7-15
slope, 2-2, 7-12, 7-13, 7-16, 7-17, 13-1
slope II, 6-2, 6-3
slope location, 7-12
slope window, 7-12, 7-13
smooth, 7-10, 7-13
software, 6-6, 7-12, 7-13, 7-14, 7-18, 7-20, 7-21, 8-1, 9-1, 10-9, 12-1, 12-3, 12-4

spills, 10-2
standard, 2-1, 2-2, 6-3, 6-4, 7-3, 7-8, 7-16, 7-17, 7-18, 8-1, 13-1
standard curve, 6-3, 7-2, 7-4, 7-11, 7-12, 7-13, 7-17
standard volumes, 6-1, 6-3, 7-1, 7-2, 7-4
step identification, 6-4
step time, 6-4, 7-11
steps, 7-1, 7-2, 7-3, 7-4, 7-5, 7-9, 7-10
stir bar, 7-1, 7-3, 7-4, 7-5, 9-1, 10-2
stir speed, 6-2, 6-3, 7-6, 7-7, 7-8
stop, 7-10
stop bits, 6-6, 12-1

T

temperature, 5-2, 6-2, 6-3, 7-9, 9-1, 10-2, 10-3
test, 2-1, 2-2, 6-2, 6-3, 6-7, 7-2, 7-3, 7-4, 7-5, 7-6, 7-7, 7-8, 7-9, 7-10, 7-18, 7-19, 8-1, 9-1
test parameters, 6-2, 6-3, 6-4, 7-9
test sequence, 6-2, 6-3, 6-4
TestType, 6-2, 6-3, 6-4, 6-5, 7-6, 7-7, 7-8, 7-14, 7-16, 7-17, 7-19
time, 2-1, 2-2, 6-4, 7-2, 7-3, 7-5, 7-11, 7-12, 7-13, 7-14, 7-19, 9-1

U

unit of measure, 6-2, 6-3, 7-7, 7-10
user ID, 6-1, 6-6, 7-1, 7-20
utilities, 7-20

V

view, 6-3, 7-9, 7-10, 7-11, 7-14, 7-15, 7-17, 7-19, 7-21
volume, 6-1, 6-3, 6-4, 7-1, 7-11, 7-21, 9-1
von Willebrand, 2-1

W

warranty, 10-9
wavelength, 9-1
Westgard, 6-5, 7-4, 7-5, 7-16, 7-18, 7-19, 8-1, 13-1
window seconds, 6-2, 6-3
worklist, 7-1, 7-2, 7-3, 7-4, 7-5, 7-6, 7-7, 7-8, 7-9, 7-14, 7-15, 7-16, 7-17

Z

zoom, 7-19



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Operator's Manual

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