

Rapidpoint™ Coag

Operator's Manual

All Rights Reserved

© 1999 Chiron Diagnostics Corporation, East Walpole, MA. Adapted from *TAS® Analyzer Operator Manual* with permission of the copyright holder.

This manual is copyrighted, and all rights reserved. No part of this manual or the products it describes may be reproduced by any means or in any form without prior consent in writing from Chiron Diagnostics.

The Rapidpoint Coag system is for *In Vitro* Diagnostic Use.

Rapidpoint is a trademark of Chiron Diagnostics Corporation, East Walpole, MA.

PT-NC is a trademark and PT-ONE and TAS are registered trademarks of Cardiovascular Diagnostics, Inc., Raleigh, NC.

The Rapidpoint Coag Analyzer is protected by U.S. patents 4,849,340; 5,110,727; 5,350,676.

The information in this manual was correct at the time of printing. However, Chiron Diagnostics continues to improve products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

Contents

1	Overview of the Rapidpoint™ Coag Analyzer	1-1
	Intended Use	1-1
	Principles of Operation	1-1
	About the Rapidpoint Coag Test Cards	1-1
	Running a Test	1-2
	Method of Detection	1-3
	Specifications	1-4
<hr/>		
2	Precautions and Limitations	2-1
	CLIA Complexity Categorization	2-1
	Hazards	2-1
	Biohazard	2-1
	Electrical Hazard	2-1
	Safety Standards	2-3
	North American	2-3
	European	2-3
	Environmental Operating Conditions	2-3
	Test Card Storage and Handling	2-4
	Storage	2-4
	Test Preparation	2-4
	Specimen Handling	2-5
	Quality Control Testing	2-5
<hr/>		
3	Setting Up the Rapidpoint Coag Analyzer	3-1
	Unpacking the Rapidpoint Coag Analyzer	3-1
	Operating for the First Time	3-1
	Operating with the AC Power Supply	3-2
	Operating with Battery Power	3-3
	Charging the Battery	3-4
	Low Battery Conditions	3-4
	Connecting a Serial Printer	3-4

4	General Operating Instructions	4-1
	Using the Keypad	4-1
	Data Entry Keys	4-2
	Cursor and Display Movement Keys	4-3
	Command Keys	4-4
	Confirmation Keys	4-4
	Reading the Display	4-4
	Working with Menus	4-4
	Display Symbols and Prompts	4-5
	Editing Keypad Entries	4-5
	Displaying the User Functions	4-6
	Setting the Date and Time	4-7
	Date Format	4-7
	Time Format	4-7
	Working with Stored Test Records	4-10
	Viewing Test Records	4-10
	Printing Test Records	4-18
	Viewing PT and aPTT Normal Values	4-20
	Viewing QC Lockout Settings	4-20
	Viewing Control Ranges	4-21
	Printing Control Ranges	4-22
<hr/>		
5	Basic Test Instructions	5-1
	Getting Ready	5-1
	Reading a Test Card	5-2
	Entering an Operator ID	5-2
	Inserting a Test Card	5-3
	Selecting the Sample Type	5-4
	Entering Patient Identification	5-5
	Adding a Sample Drop	5-6
	Reviewing Results	5-7
	Irregular Test Results	5-8
<hr/>		
6	Supervisory Functions	6-1
	Displaying Supervisory Functions	6-1
	Enabling/Disabling Operating Modes	6-2
	Operator ID Mode	6-2
	Auto Print Mode	6-3
	QC Lockout Mode	6-4

<i>Setting Control Ranges</i>	6-7
<i>Defining Number of Control Range Levels</i>	6-7
<i>Setting High/Low Values for Control Ranges</i>	6-9
<i>Setting the QC Printout Mode</i>	6-11
<i>Managing Operator IDs</i>	6-12
<i>Adding Operator IDs</i>	6-12
<i>Removing Operator IDs</i>	6-13
<i>Viewing Operator IDs</i>	6-14
<i>Printing Operator IDs</i>	6-15
<i>Clearing Stored Test Records</i>	6-16
<i>Setting the Date and Time Format</i>	6-17
<i>Defining PT and aPTT Normal Values</i>	6-19
<i>Entering a Custom Normal Value</i>	6-19
<i>Resetting a Mean Normal Value to Default</i>	6-21
<i>Enabling/Disabling the aPTT Ratio Mode</i>	6-22
<i>Selecting a Display Language</i>	6-23
<hr/>	
7 Troubleshooting and Service	7-1
<i>Addresses and Communication Numbers</i>	7-3
<hr/>	
8 Quality Control	8-1
<i>Calibration</i>	8-1
<i>Instrument Self-Tests</i>	8-1
<i>Diagnostic Messages</i>	8-2
<i>Operator Quality Control Procedures</i>	8-2
<i>Functional Quality Control</i>	8-5
<i>Reference Range Quality Control</i>	8-5
<hr/>	
Appendix A: Instrument Labels	A-1
<i>North American Version</i>	A-1
<i>European Version</i>	A-2
<hr/>	
Appendix B: Error Messages	B-1
<hr/>	
Appendix C: Protecting Yourself from Biohazards	C-1
<i>References</i>	C-2

1 Overview of the Rapidpoint™ Coag Analyzer

Intended Use

The Rapidpoint™ Coag Analyzer is a lightweight, portable instrument designed for *in vitro* diagnostic use in decentralized areas of a hospital. The Rapidpoint Coag Analyzer provides immediate, near-patient-care results using specially developed Rapidpoint Coag test cards to detect the onset of clot formation or lysis in citrated whole blood, non-citrated whole blood, or plasma samples. The Rapidpoint Coag Analyzer can also be used in traditional clinical laboratory settings.

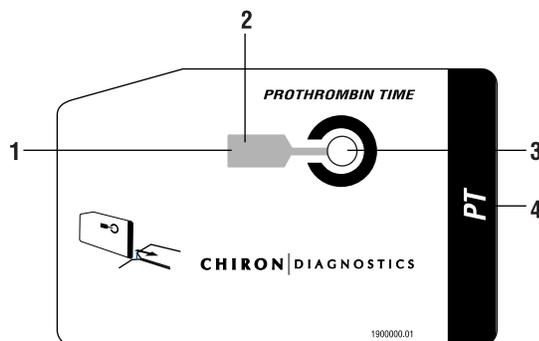
NOTE: Refer to test card package inserts for specific sample requirements.

Principles of Operation

About the Rapidpoint Coag Test Cards

Rapidpoint Coag test cards, which are the size of a credit card, have a reaction chamber containing paramagnetic iron oxide particles and the required reagents to perform a test using the Rapidpoint Coag Analyzer. The reagents have been freeze-dried, which provides extended stability.

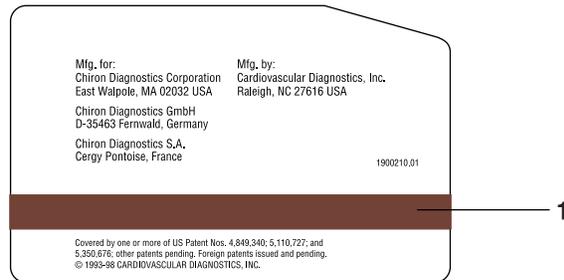
Front of Test Card



- 1 Reaction Chamber
- 2 Lyophilized Reagent
- 3 Sample Well
- 4 Test Name

The magnetic stripe on the back of the test card provides instructions to the instrument about the type of test, card lot characteristics (including lot number and expiration date), and other test parameters. This information is entered into the Rapidpoint Coag Analyzer by passing the card through the magnetic card reader at the beginning of a test.

Back of Test Card



1 Magnetic Stripe

The test cards are disposable and individually packaged in a pouch. They are ready for use and do not require any special preparation except warming them to room temperature and removing them from the packaging. An expiration date for the test card is encoded on the card and is also embossed on the seal of the foil pouch. This expiration date is valid only if the card is properly stored in a refrigerator at 2 to 8°C until used (see *Test Card Storage and Handling* in Section 2). Only one Rapidpoint Coag test card at a time can be used in the instrument.

Running a Test

Running a Rapidpoint Coag test involves entering the required test parameters by passing the Rapidpoint Coag test card through the magnetic card reader, selecting the appropriate sample type, entering patient information, inserting the test card into the analyzer, and adding a sample drop. Visual, step-by-step instructions and audible signals are provided throughout the operation of the Rapidpoint Coag Analyzer.

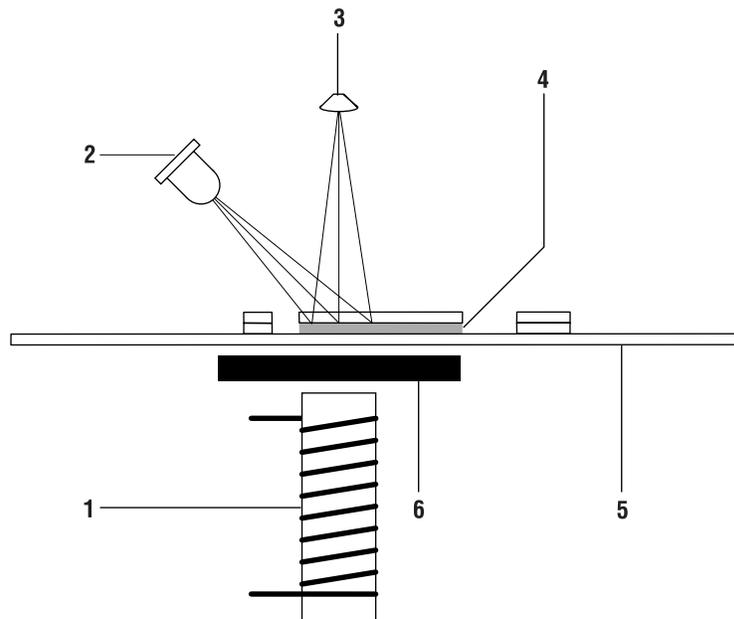
The Rapidpoint Coag Analyzer continuously monitors for conditions that could cause invalid results, and it can automatically stop a test. Warnings and other diagnostic messages can also be issued during a test.

Method of Detection

When a sample drop is added to the reaction chamber on a Rapidpoint Coag test card, the mixture of paramagnetic iron oxide particles and reagents is reconstituted. The Rapidpoint Coag Analyzer automatically begins the test when the photodetector in the instrument observes a light change from the added sample.

While a Rapidpoint Coag Analyzer test is in progress, an electromagnet turns on and off every second. The iron oxide particles on the test card stand up when the magnet is on, causing more light to pass to the photodetector. When the magnet is off, the particles fall down causing less light to be detected. The movement of these particles produces an optical signal which is processed by the analyzer. Clotting of the sample causes slowing and eventual cessation of the particle movement, and lysis causes the particles to resume movement. The analyzer monitors particle movement and records clotting and lysis times in seconds.

Method of Detection



- 1 Electromagnet
- 2 Light Emitter
- 3 Photodetector
- 4 Sample
- 5 Test Card
- 6 Bias Magnet

Specifications

<i>Characteristic</i>	<i>Measurement</i>
Width	152 mm (6 in)
Height	100 mm (3.9 in)
Length	265 mm (10.5 in)
Weight	1.9 kg (4.25 lb)
Internal Battery Power	6V, 5.0 AH, lead acid battery
External Power Supply (see Note)	North American: Input: 120 V AC, 60Hz Output: 7.1 V DC European: Input: 220-240 V AC, 48-52Hz Output: 7.1 V DC
Temperature Regulation	37±0.3°C (98.6±0.5°F)
Ambient Temperature Range	18–32°C (65–90°F)

NOTE: Dispose of the lead acid battery according to applicable federal, state, and local requirements. Do not discard the battery in trash that will be disposed of in a landfill. Send the battery to a recycling center if one is available to you and waste regulations allow.

NOTE: The Rapidpoint Coag Analyzer must only be operated with a power supply provided by Chiron Diagnostics – North American catalog number 118615, European catalog number 118870.

2 *Precautions and Limitations*

CLIA Complexity Categorization

The Rapidpoint Coag Analyzer has been jointly assessed by the Center for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in accordance with the Clinical Laboratories Improvement Amendments (CLIA) of 1988.

The analyzer has been given the following classification:

CLIA Complexity: Moderate

CDC Test System Identifier Code: 10257

Hazards



CAUTION: Any modifications to this device not expressly authorized by Chiron Diagnostics will void the user's warranty for the device.

Biohazard

- Always treat test samples as biohazardous and ensure proper handling and disposal of these materials.
- Once the analyzer has been run with a test sample, it is considered biohazardous and should be handled according to procedures for biohazardous materials.
- Wipe surface spills from the Rapidpoint Coag Analyzer using a mild detergent, followed by a disinfectant, or a fresh 10% chlorine bleach solution. Do **not** use any organic solvent other than alcohol.

Electrical Hazard

- The Rapidpoint Coag Analyzer is supplied with a properly grounded, external power supply cord for connection into a grounded power outlet. If an adapter is used, the grounding wire should be properly connected to a permanent ground.
- Do **not** attempt to charge the battery when the instrument is located in a small, airtight space – explosive gases can be generated.

- Do **not** attempt to operate the instrument in an explosive atmosphere. There is a risk of explosion if the Rapidpoint Coag Analyzer is used in the presence of flammable anesthetics.
- Do **not** immerse the instrument in water or other liquids.
- If the power supply is lost or damaged, replace it only with a power supply provided by Chiron Diagnostics. Contact Chiron Diagnostics for replacement power supplies (see *Troubleshooting and Service* in Section 7).

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy. If not installed in accordance with the *Rapidpoint Coag Operator's Manual*, it can cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference. If this occurs, the user will be required to correct the interference at his own expense.

NOTE FOR EUROPEAN ANALYZERS: (catalog numbers 118864, 118865, 118866, 118867, 118868, 118869) External equipment that will be connected to signal input and signal output parts or other connectors shall comply with relevant IEC standard (i.e., IEC 950 for IT equipment and IEC 601 series for medical electrical equipment). In addition, all such combinations (systems) shall comply with the standard IEC 601-1-1 (safety requirements for medical electrical systems).

Any person who connects external equipment to signal input and signal output parts or other connectors has formed a system and is, therefore, responsible for the compliance of that system with the requirements of IEC 601-1-1. If in doubt, contact a qualified technician or your local representative.

NOTE: Where the integrity of the external protective earth conductor arrangement is in doubt, the analyzer shall be operated from its internal power source.

Safety Standards

North American

The North American model (catalog number 118608) of the Rapidpoint Coag Analyzer complies with the following safety standard regulations:

- FCC Class A digital device, compliant with Part 15 of the FCC rules
- UL 544 (MET. Listing # ML1522)
- CSA C22.2 No. 125-M1984

European

The European models (catalog numbers 118864, 118865, 118866, 118867, 118868, 118869) of the Rapidpoint Coag Analyzer comply with the following safety standard regulations:

- EN 55011
- EN 50082-1
- IEC 601-1
- EN 60601-1-1
- EN 60601-1-2



Environmental Operating Conditions

WARNING Do **not** operate the Rapidpoint Coag Analyzer in the presence of flammable anesthetics to prevent the risk of explosion. See *Hazards* in Section 2.

Operate the Rapidpoint Coag Analyzer on a stable, level surface in an area where the room (ambient) temperature is between 18 and 32°C (65 and 90°F). Operating the instrument at room temperatures greater than 32°C can prevent the analyzer from properly controlling reaction temperatures. When this occurs, the analyzer will issue the message, Ambient Temp Too High. Turn off the Rapidpoint Coag Analyzer, move to a cooler area, and allow the analyzer to cool to less than 32°C (90°F) before using it again.

If the analyzer is too cold when turned on, it will issue the message, Heater Timeout. If the analyzer has been exposed to very low temperatures, allow it to return to room temperature between 18 and 25°C (65 and 77°F) before use.

Test Card Storage and Handling

Storage



CAUTION: Do **not** expose the Rapidpoint Coag test cards to magnetic objects or fields at any time. Magnetic exposure can corrupt the encoded information on the card and prevent the analyzer from starting a test.

Store the Rapidpoint Coag test cards in a refrigerator at a temperature between 2 and 8°C (36 and 46°F).

A Rapidpoint Coag test card will retain its viability under the following conditions:

- While sealed in its pouch and stored in a refrigerator at 2 to 8°C (36 to 46°F), the test card is usable until the expiration date embossed on its foil pouch.
- After warming to room temperature (20 to 25°C or 68 to 77°F), a test card in an *unopened* pouch is usable for 2 weeks.
- After warming to room temperature, a test card in an *opened* pouch must be used within 15 minutes.

NOTE: Do **not** repeatedly warm Rapidpoint Coag test cards and return them to the refrigerator.

NOTE: Be sure to record a new expiration date on any unopened pouches removed from refrigeration. The new expiration date on the test card pouch should be 2 weeks from the time the test card was removed from refrigeration.

Test Preparation

- The Rapidpoint Coag test cards are for *in vitro* diagnostic use only.
- To prepare a test card for testing, warm the card to room temperature at 20 to 25°C (68 to 77°F) before removing it from its foil pouch. The test card must be used within 15 minutes after the pouch is opened.
- Do not allow the test card to remain in the analyzer longer than 15 minutes before applying the sample. Prolonged warming of the test card can affect performance of the test.
- Be sure the test card is fully inserted into the Rapidpoint Coag Analyzer card slot and is seated against the slot retaining wall.

Specimen Handling

- Proper specimen handling prior to testing is essential in order to minimize sample deterioration. Non-citrated whole blood should be tested immediately. Citrated whole blood should be tested or processed to plasma within 15 minutes of collection. Plasma samples should be run within 2 hours of collection. See the package insert provided with the Rapidpoint Coag test cards for specific instructions on the test being performed.
- Always treat test samples as biohazardous, and handle and dispose of them accordingly. Refer to Appendix C, *Protecting Yourself from Biohazards*, for recommended precautions when working with biohazardous materials.

Quality Control Testing

Quality control testing for the Rapidpoint Coag Analyzer should be performed regularly by the Rapidpoint Coag operator.

- To ensure accurate results, routine quality control procedures should be followed by the operator each day a test is performed.
- Functional testing requirements vary by the test being performed. See the package insert provided with the Rapidpoint Coag test cards for specific instructions on the test being performed.
- The relationship of the results obtained by the Rapidpoint Coag Analyzer and results from any other methods used should be established by the operator whenever there is a change in test card lots, reference methods, or reagent lots.

An extensive level of quality control testing is performed automatically by the Rapidpoint Coag Analyzer at the time it is turned on and while the instrument is in use. These internal instrument quality controls do not, however, take the place of regular, operator performed, quality control testing.

Please see *Quality Control* in Section 8 for details about these quality control procedures.

3 *Setting Up the Rapidpoint Coag Analyzer*

Unpacking the Rapidpoint Coag Analyzer

The basic Rapidpoint Coag Analyzer is shipped with the following items:

- Rapidpoint Coag Analyzer
- External AC Power Supply (see Note)
- Rapidpoint Coag Operator's Manual
- Biohazard bag
- Two 35 μ L pipettes
- 100 35 μ L pipette tips

After unpacking the shipping carton, place the Rapidpoint Coag Analyzer on a stable, level surface in an area where the room (ambient) temperature remains between 18 and 32°C (65 and 90°F). See *Precautions and Limitations* in Section 2 for detailed information on electrical hazards and environmental operating conditions.

Additional accessories are available for the Rapidpoint Coag Analyzer, including a serial printer. Contact Chiron Diagnostics for more information on analyzer accessories.

NOTE: The Rapidpoint Coag Analyzer must only be operated with a power supply provided by Chiron Diagnostics – North American catalog number 118615.

Operating for the First Time

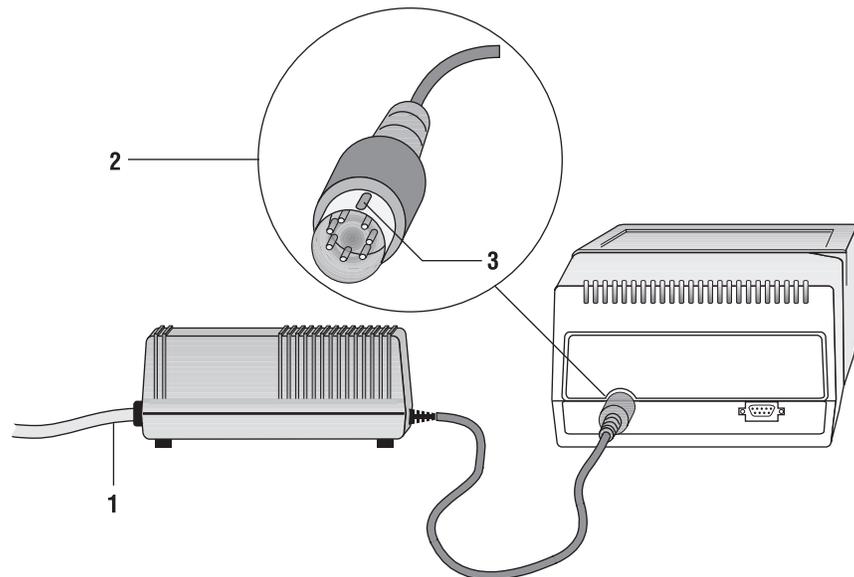
Before operating the Rapidpoint Coag Analyzer for the first time, be sure to read and understand all information contained in the *Rapidpoint Coag Operator's Manual*. Particular attention should be given to Section 2, *Precautions and Limitations*, where important information is provided regarding hazards, safety standards, environmental operating conditions, handling of test cards and specimens, and quality control measures.

Once unpacked from the shipping carton, the Rapidpoint Coag Analyzer requires minimal setup to become fully operational. The analyzer can be used immediately in the proper operating environment by connecting the external AC power supply provided with the instrument to an electrical outlet. If the analyzer will be operated with battery power, the battery must be charged before it can be used (see *Operating with Battery Power* in Section 3).

Operating with the AC Power Supply

1. Be sure the Rapidpoint Coag Analyzer power switch is in the OFF/RECHARGE position.
2. Connect the 7-pronged plug on the external power supply (see Note, below) into the receptacle on the back of the analyzer (see *Instrument Labels*, Appendix A).
The plug must be positioned to match the receptacle – a crimp on the plug indicates the part of the connector that should be facing up.

Power Supply Connection



- 1 To electrical outlet
- 2 Reverse detail
- 3 Crimp

3. Connect the three-pronged plug on the external power supply into a 120V, 60 Hz, AC, hospital grade receptacle (see *Electrical Hazard* in Section 2).
NOTE: The Rapidpoint Coag Analyzer must only be operated with a power supply provided by Chiron Diagnostics – North American catalog number 118615.
4. To turn the analyzer on, push the switch on the right side of the instrument to the ON position. The OFF/RECHARGE position indicates that the power is off.
The analyzer performs several self-tests.

```
Rapidpoint Coag
Performing
Self Test nn
```

1 Identifies self-test number

Once the self-tests are complete, a screen is briefly displayed which shows the software version installed on the analyzer.

```
Rapidpoint Coag
Analyzer
Software V x.xx
```

5. The analyzer is ready for operation when the Ready screen is displayed.

```
--READY-- 01/15/98
           10:44 AM

Pass card thru readr
or press enter
```

6. To ensure proper notification when attempting to use expired test cards and to maintain accuracy in patient test records, verify that the displayed date and time are correct.

NOTE: See *Setting the Date and Time* in Section 4 to correct the date and time and *Setting the Date and Time Format* in Section 6 to change the date and time format.

Operating with Battery Power

The Rapidpoint Coag Analyzer can be operated using either the external AC power supply (see Note) or internal battery power. Once the Rapidpoint Coag Analyzer battery is charged, the instrument can be operated continuously without any loss in overall performance for 8 hours on internal battery power alone.

NOTE: The Rapidpoint Coag Analyzer must only be operated with a power supply provided by Chiron Diagnostics – North American catalog number 118615.

Charging the Battery

Before the analyzer can be operated under battery power for the first time, the battery should be charged for at least 12 hours. The analyzer battery charges automatically while the instrument is connected to 120V AC, using the external power supply (see Note). The analyzer can be operated at any time using the external power supply (see Note).

Low Battery Conditions

As an internal quality control measure, the analyzer verifies that sufficient power is available for proper test performance when the instrument is turned on and each time a test is initiated. If battery power is low, the analyzer provides an audible warning and displays the following message:

```
BATTERY NEEDS  
RECHARGING  
PLEASE PLUG IN UNIT  
H01 03/21/98 10:20
```

To continue running tests, turn the analyzer off, connect it to the external power supply (see Note), and turn it back on. The battery will gradually recharge from the power supply while running. To recharge more efficiently, turn the analyzer off, connect it to the power supply, and allow it to recharge for at least 12 hours.



CAUTION: Do not allow the battery to become completely discharged. An excessively discharged battery can lose capacity when recharged.

If the battery power has become so low that the analyzer is unable to turn on or check the power level, the analyzer demonstrates noticeably erratic behavior with blank or incomplete displays and will not allow test initiation. Recharge the battery as described above.

NOTE: The Rapidpoint Coag Analyzer must only be operated with a power supply provided by Chiron Diagnostics – North American catalog number 118615.

Connecting a Serial Printer

The Rapidpoint Coag Analyzer can be operated with an optional serial printer connected to the RS-232 port on the back of the instrument. This enables the analyzer to print QC self-diagnostic results when the instrument is turned on (see *Enabling/Disabling Operating Modes* in Section 6), results at the end of each test, all stored test records, or groups of test records according to patient ID, test type, or sample type (see *Printing Test Records* in Section 4).

Though the analyzer can operate with any serial printer, the printer available from Chiron Diagnostics is highly recommended. The Chiron Diagnostics printer option includes a portable serial printer and a customized printer cable. If another serial printer is used with the analyzer, the printer switches must be set accordingly, and a custom printer cable obtained from a third party.

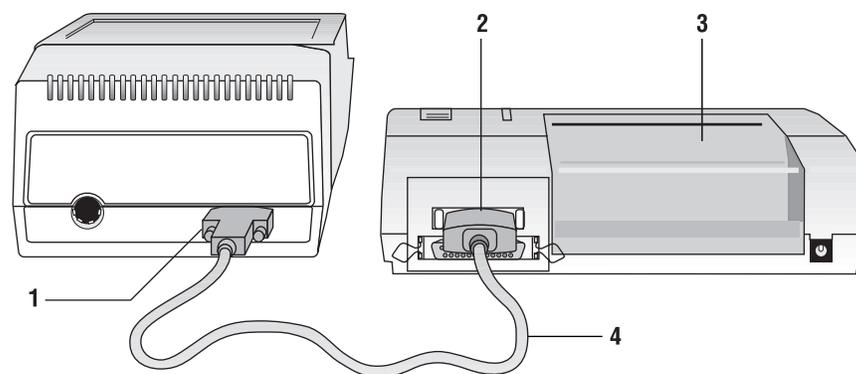
1. If using a serial printer other than the one available from Chiron Diagnostics, set the printer switches as follows (refer to the user's manual for your printer):

- Input Method = Serial
- Data Bit Length = 8 bits
- Baud Rate = 9600
- Parity = No bit
- Stop bit = One

The printer available through Chiron Diagnostics is delivered with the proper switch configuration.

2. Connect the 25-pin plug on the custom printer cable to the printer.
3. Connect the 9-pin male connector on the custom printer cable to the 9-pin female serial port on the back of the analyzer (see *Instrument Labels*, Appendix A).

Printer Connection



- 1 9-pin connector
- 2 25-pin connector
- 3 Serial printer
- 4 Custom printer cable

4. Connect the power supply cord on the printer to a 120V outlet.
5. Turn the serial printer on.

4 General Operating Instructions

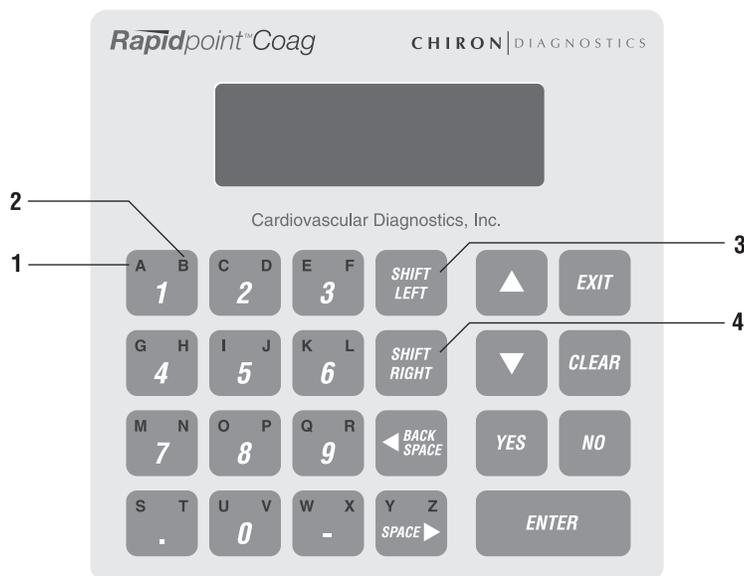
Using the Keypad

Use the Rapidpoint Coag Analyzer keypad to respond to visual instructions provided on the analyzer display. Symbols and other prompts are provided on the display to help you determine valid keypad responses (see *Reading the Display* in Section 4). The analyzer beeps once each time a valid keypad entry is made. Two beeps indicate an invalid keypad entry.

The Rapidpoint Coag Analyzer keypad has four key categories:

- Data Entry Keys
- Cursor and Display Movement Keys
- Command Keys
- Confirmation Keys

Rapidpoint Coag Analyzer Keypad



- 1 Green
- 2 Blue
- 3 Green, enables the left (green) alphabetic character on the keys
- 4 Blue, enables the right (blue) alphabetic character on the keys

Data Entry Keys

The Rapidpoint Coag Analyzer data entry keys consist of alphanumeric keys and shift keys. The alphanumeric keys contain color-coded alphabetic characters and numeric or special characters on the same key. The green and blue shift keys are used in combination with these alphanumeric keys to enter the alphabetic characters.

Key	Action
	Displays the “1” character in the cursor position on the display.
	Enables the entry of the alphabetic characters in the upper left corners of the alphanumeric keys.
	Enables the entry of the alphabetic characters in the upper right corners of the alphanumeric keys.
Press	Followed by Action
	 Displays the “A” character in the cursor position on the display.
	 Displays the “B” character in the cursor position on the display.

Entering Numeric or Special Characters

When the shift keys are disabled, numeric characters, or the period, hyphen, and space can be entered by pressing the alphanumeric key that contains that character.

Entering Alphabetic Characters Using the Shift Keys

You must use a shift key followed by an alphanumeric key to enter an alphabetic character. The shift keys enable the entry of one alphabetic character at a time. When a shift key is pressed and then released, the shift left or right function is enabled for the indicated cursor position only, and the alphabetic character corresponding to the enabled shift key can be entered. The cursor changes from a line to a blinking box to indicate a shift key is enabled.

Alphabetic characters are identified on the upper left and upper right corners of each alphanumeric key. The LEFT alphabetic character is green, and the RIGHT alphabetic character is blue. The color and location of the alphabetic character indicates the shift key that needs to be used with the alphanumeric key in order to enter the alphabetic character.

A shift key is only enabled for the current cursor position, so a shift key must always precede the entry of an alphabetic character. For example, to enter the patient name "Jones", press each of the following keys in sequence:

**SHIFT RIGHT – J SHIFT LEFT – O SHIFT RIGHT – N SHIFT LEFT – E
SHIFT LEFT – S**

To enter a left (green) alphabetic character:

1. Press and release the green, **SHIFT LEFT** toggle key.
The cursor changes to a blinking box on the display and the green or **LEFT** alphabetic characters are enabled for data entry.
2. Press and release the alphanumeric key containing the green or **LEFT** alphabetic character you want to enter.
The selected alphabetic character is entered in the cursor position on the display, and the shift key is disabled.

To enter a right (blue) alphabetic character:

1. Press and release the blue, **SHIFT RIGHT** toggle key.
The cursor changes to a blinking box on the display and the blue or **RIGHT** alphabetic characters are enabled for data entry.
2. Press and release the alphanumeric key containing the blue or **RIGHT** alphabetic character you want to enter.
The alphabetic character is entered in the cursor position on the display, and the shift key is disabled.

Cursor and Display Movement Keys

The Rapidpoint Coag Analyzer cursor and display movement keys are used to position the cursor for editing, to select a menu option, to move forward to the next display, or to move backward to the previous display.

Key	Action
	Deletes the character to the left of the cursor and moves the cursor backward, or to the left, on the display.
	Selects the option above the current option on a menu, or moves backward to the previous display.
	Selects the option below the current option on a menu, or moves forward to the next display.

Command Keys

The Rapidpoint Coag Analyzer command keys are used to send operation instructions to the analyzer.

<i>Key</i>	<i>Action</i>
	Cancels the current selection or operation.
	Accepts the selected option; displays the User Function menu if the --READY-- screen is displayed.
	Erases all characters on the display that were entered from the keypad.

Confirmation Keys

The Rapidpoint Coag Analyzer confirmation keys are used to respond positively or negatively when the analyzer issues a YES/NO prompt.

<i>Key</i>	<i>Action</i>
	Returns a YES response to an analyzer YES/NO prompt.
	Returns a NO response to an analyzer YES/NO prompt.

Reading the Display

The Rapidpoint Coag Analyzer provides visual instructions on the display for each step of an operation or test. Many of the analyzer options are presented on the display in the form of a menu or a list of options. Symbols and other prompts also are provided on the display to help you determine the valid keypad responses for a given screen.

Working with Menus

- To select a menu option, use one of the cursor and display movement keys indicated on the display to move between menu options.

The option that is selected appears in upper case characters on the Rapidpoint Coag Analyzer display. Other possible menu options appear in lower case characters.

- To activate the menu option that is selected, press **ENTER**.
- To cancel the current operation, press **EXIT**.

Display Symbols and Prompts

The following table shows the relationship between the symbols that can appear on the display and the associated keypad options that are available:

<i>Symbol</i>	<i>Valid Keypad Option</i>
Cursor or Blank Line	Any data entry key
	
	
	
	

Editing Keypad Entries

Use the **BACK SPACE** key or the **CLEAR** key to edit the data entered on the display. The **BACK SPACE** key erases characters one at a time as it moves the cursor backward, while the **CLEAR** key erases all characters that have been entered.

1. Do one of the following:
 - Press **BACK SPACE** to position the cursor under the character to be edited.
The entered characters are erased one at a time as the cursor moves backward with each entry of the backspace key.
 - Press **CLEAR** to erase all characters that have been entered.
All entered characters are erased, and the cursor is positioned at the beginning of the data entry field.
2. Reenter the correct character or group of characters at the cursor position.

3. When all characters appear correctly on the display, press **ENTER** to accept the changes.

NOTE: To save keystrokes, verify each of the keypad entries on the display as they are made. If an entry needs to be edited, the backspace key can be used to make the correction.

Displaying the User Functions

The Rapidpoint Coag Analyzer has two sets of functions: Supervisory Functions and User Functions. The Supervisory Functions allow an operator to perform certain setup operations (see *Supervisory Functions*, Section 6). The User Functions allow the operator to perform the following analyzer operations:

- Set the date and time
 - View or print test records
 - View the PT and aPTT normal values
 - View QC Lockout settings
 - View or print control ranges
1. From the Ready screen, press **ENTER**.

```
--READY--    01/15/98
              10:44 AM
Pass card thru readr
or press enter
```

The User Function menu is displayed showing the available user functions. In the following example, “VIEW PATIENT RECS” is in uppercase characters and would be the option selected if you pressed **ENTER**.

```
Select Function ← ↓ ↗
VIEW PATIENT RECS
set date/time
view pt normal
```

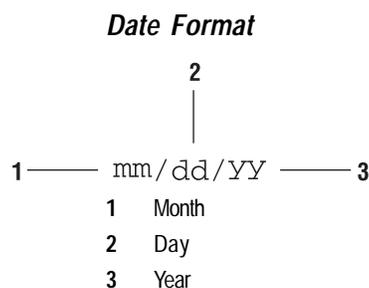
2. To return to the Ready screen, press **EXIT**.

Setting the Date and Time

The Rapidpoint Coag Analyzer notifies the operator when a test card has expired. The analyzer also records the time and date on each test record. Each time the analyzer is used, verify that the system time and date are accurate. The system date and time are displayed on the analyzer Ready screen.

Date Format

The analyzer default system date is entered in the following format:

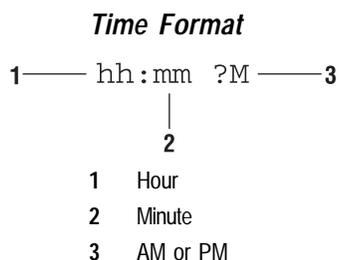


A number must be entered for each of the data entry fields shown on the display; any months or days represented by a single digit must be preceded by a zero (0). For example, the month of August is represented as 08. The analyzer issues an error message if an invalid date is entered, and returns to the Set Date screen so it can be reentered.

The analyzer can be configured to use the alternative date formats, *dd.mm.yy* or *yy.mm.dd*, using the supervisory functions to change the date and time setting (see *Setting the Date and Time Format* in Section 6).

Time Format

The analyzer default system time is entered in the following format:



A number must be entered for each of the characters shown on the display, and an A or a P must be entered for AM or PM. The analyzer issues an error message if an invalid time is entered, and returns to the Set Time screen so it can be reentered.

The analyzer can be configured to use the alternative international 24-hour time format, hh:mm, using the supervisory functions to change the date and time setting (see *Setting the Date and Time Format* in Section 6). An A or P is not required for the 24-hour time format.

1. From the Ready screen, press **ENTER**.

```

--READY--    01/15/98
              10:44 AM

Pass card thru readr
or press enter
  
```

The Select Function menu is displayed showing available user functions.

2. Choose the **Set Date/Time** option, using the cursor movement keys.
The SET DATE/TIME option is displayed in uppercase characters.

```

Select Function ←↑↓↗
view patient recs
SET DATE/TIME
view pt normal
  
```

3. Press **ENTER**.

The Set Date screen is displayed with the cursor positioned under the first *m*.

```

      SET DATE
      mm/dd/yy
Enter digits. Press
ENTER when done.
  
```

4. Enter the two numbers representing the current month.
The entered numbers replace the two *m*'s, and the cursor moves below the first *d*.
5. Enter the two numbers representing the current day.
The entered numbers replace the two *d*'s, and the cursor moves below the first *y*.
6. Enter the last two numbers representing the current year.
The entered numbers replace the two *y*'s.
7. Press **ENTER**.

- If the entered date is invalid, an error message is displayed. Press any key to return to the Set Date screen.

```
Date is invalid.  
Re-enter date.  
  
Hit any key to cont.
```

If ENTER is pressed before specifying a number for every available data entry field, the Set Date screen remains on the display.

- If the entered date is valid, the Set Time screen is displayed, and the cursor is positioned under the first *h*.

```
SET TIME  
hh:mm ?M  
Enter digit for HH &  
MM, A or P for "?".
```

8. Enter the two numbers representing the current hour.

The entered numbers replace the two *h*'s, and the cursor moves below the *m*.

9. Enter the two numbers representing the current minute.

The entered numbers replace the two *m*'s, and the cursor moves below the question mark symbol.

10. Enter an A or a P to indicate the time of day as AM or PM.

The question mark is replaced by the entered character, and AM or PM is displayed.

11. Press **ENTER**.

- If the entered time is invalid, an error message is displayed. Press any key to return to the Set Time screen.

```
Time is invalid.  
Re-enter time.  
  
Hit any key to cont.
```

If ENTER is pressed before specifying a number for every available data entry field, the Set Time screen remains on the display.

- If the entered time is valid, the Ready screen is displayed.

The date and time are displayed in the upper right corner of the screen.

NOTE: The date and time cannot be updated independently. Values for both the date and time must be entered in order for the date selection to be accepted.

NOTE: EXIT can be pressed at any time from the Set Date and Set Time screens to cancel the selections and return to the Ready screen.

Working with Stored Test Records

The Rapidpoint Coag Analyzer can store up to 1000 test records. These records can be viewed or printed by the operator using the basic User Functions provided by the analyzer. When the analyzer memory is full, it issues the following message:

```
PATIENT RECORD  
MEMORY FULL  
Press enter to cont.  
Press EXIT to cancel
```

If testing continues, the oldest test record contained in memory is overwritten and cannot be recovered.

NOTE: To avoid the warning message, PATIENT RECORD MEMORY FULL, and overwriting stored test records that have not been saved to a permanent record, an operator with supervisory access should periodically print all test records before the 1000 test record limit is reached. After the records have been printed, the memory should be cleared (see *Supervisory Functions* in Section 6).

Viewing Test Records

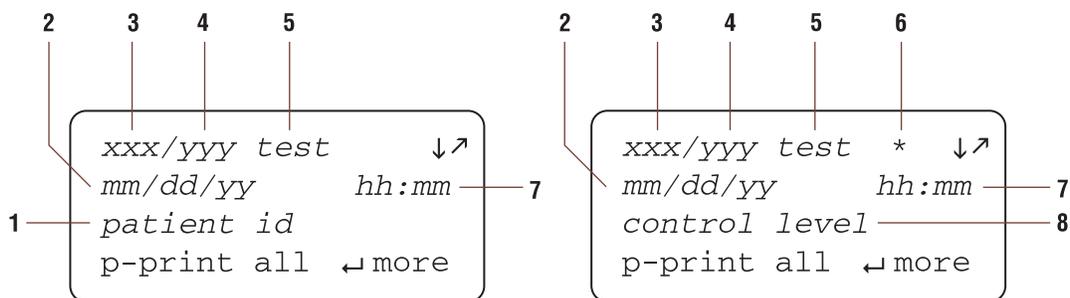
Using the View Patient Recs option on the user Select Function menu, test records can be viewed in four ways:

- All test records stored in the analyzer
- All test records stored for a specified patient
- All test records stored by a specific test type
- All test records stored by a specific sample type

With each of the above viewing options, the most recent test record is displayed first. Each test record has two information screens. The first screen displays the record counter, test name, patient identification (or control level number), and the date and time the test was performed. The second screen displays the sample type and the test result.

The variables in the first screen are defined as follows:

First Screen of Test Records



- 1 Identifies the patient identification
- 2 Identifies the date the test was performed
- 3 Identifies the test record number
- 4 Identifies the total number of test records stored in the analyzer
- 5 Identifies the test name
- 6 Identifies a control sample result that is out of range
- 7 Identifies the time the test was performed
- 8 Identifies the control level number

Second Screen of Test Records

```

Sample Type:      ↗
      control plasma
      result=37.4 sec.
Press p to print rec
    
```

The number of test records stored in the analyzer for the selected viewing option is indicated by the record counter on the first screen of the test record in the form, xxx of yyy. The record counter displays the number of the current test record being viewed out of the total number of possible records available for display. Additional test records can be viewed by using the display movement key indicated in the upper right corner of the screen display.

Viewing All Stored Test Records

Every test record currently stored in the Rapidpoint Coag Analyzer can be viewed through the All Records option. Stored test records can also be printed if the analyzer printer option is enabled (see *Printing Test Records* in Section 4).

1. From the Ready screen, press **ENTER**.

```

--READY--    01/15/98
              10:44 AM

Pass card thru readr
or press enter
  
```

The Select Function menu is displayed showing the available user functions.

2. From the Select Function menu, choose the **View Patient Recs** option.
The VIEW PATIENT RECS option is displayed in uppercase characters.

```

Select Function ← ↓ ↗
VIEW PATIENT RECS
set date/time
view pt normal
  
```

3. Press **ENTER**.

The View By menu is displayed.

```

--View By--    ← ↓ ↗
ALL RECORDS
patient id
test name
  
```

4. Choose the **All Records** option.
The ALL RECORDS option is displayed in uppercase characters.
5. Press **ENTER**.
The first screen of the most recent test record is displayed.

```

xxx/yyy test    ↓ ↗
mm/dd/yy       hh:mm
               patient id
p-print all    ← more
  
```

6. Press the required key:

<i>Key</i>	<i>Action</i>
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT	
RIGHT-P	To print all test records stored in the analyzer.
EXIT	To return to the Ready screen.

Viewing All Test Records for a Specific Patient

The Patient ID option of the View Patient Records user function is used to display (or print) all test records stored in the Rapidpoint Coag Analyzer for a specific patient ID. Stored test records can be printed if the analyzer printer option is enabled (see *Printing Test Records* in Section 4).

1. From the Ready screen, press **ENTER**.

```

--READY--    01/15/98
              10:44 AM

Pass card thru readr
or press enter

```

The Select Function menu is displayed showing available user functions.

2. From the Select Function menu, choose the **View Patient Recs** option.

The VIEW PATIENT RECS option is displayed in uppercase characters.

```

Select Function ← ↓ ↗
VIEW PATIENT RECS
set date/time
view pt normal

```

3. Press **ENTER**.

The View By menu is displayed.

```

--View By--    ← ↑ ↓ ↗
all records
PATIENT ID
test name

```

4. Choose the **Patient ID** option.
The PATIENT ID option is displayed in uppercase characters.
5. Press **ENTER**.
The Enter Patient ID screen is displayed.

```

Enter Patient ID
_____

```

6. Enter the name or identification of the patient whose records you want to display.
The entered identification is displayed in the cursor position.
7. Press **ENTER**.
The first screen of the most recent test record is displayed.

```

xxx/yyy test      ↓↗
mm/dd/yy         hh:mm
                patient id
p-print all     ←more

```

8. Press the required key:

Key	Action
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT	
RIGHT-P	To print all test records for the specified patient ID stored in the analyzer.
EXIT	To return to the Ready screen.

Viewing All Test Records for a Selected Test Type

The Test Name option of the View Patient Records user function is used to display (or print) all records stored in the Rapidpoint Coag Analyzer for a certain test category. Test records can be printed if the analyzer printer option is enabled (see *Printing Test Records* in Section 4).

1. From the Ready screen, press **ENTER**.

```
--READY--    01/15/98
              10:44 AM
Pass card thru readr
or press enter
```

The Select Function menu is displayed showing available user functions.

2. From the Select Function menu, choose the **View Patient Recs** option.

The VIEW PATIENT RECS option is displayed in uppercase characters.

```
Select Function ← ↓ ↗
VIEW PATIENT RECS
set date/time
view pt normal
```

3. Press **ENTER**.

The View By menu is displayed.

```
--View By--    ←↑↓↗
all records
patient id
TEST NAME
```

4. Choose the **Test Name** option.

The TEST NAME option is displayed in uppercase characters.

5. Press **ENTER**.

The Select Test menu is displayed. This menu lists all of the test types currently stored in the analyzer memory.

```
-Select Test- ←↑ ↗
APTT
hmt
pt
```

6. Choose the name of a test type.

The selected TEST NAME is displayed in uppercase characters.

7. Press **ENTER**.

The first screen of the most recent test recorded for the specified test name is displayed.

```
xxx/yyy test      ↓↗
mm/dd/yy         hh:mm
                patient id
p-print all     ←more
```

8. Press the required key:

Key	Action
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT	
RIGHT-P	To print all test records for a specified test name stored in the analyzer.
EXIT	To return to the Ready screen.

Viewing All Records for a Selected Sample Type

The Sample Type option under View Patient Records is used to display (or print) all records stored in the Rapidpoint Coag Analyzer for a certain sample type. Test records can be printed if the analyzer printer option is enabled (see *Printing Test Records* in Section 4).

1. From the Ready screen, press **ENTER**.

```
--READY--      01/15/98
                10:44 AM
Pass card thru readr
or press enter
```

The Select Function menu displays available user functions.

2. From the Select Function menu, choose the **View Patient Recs** option.
The VIEW PATIENT RECS option is displayed in uppercase characters.

```
Select Function ←↑↓↗
VIEW PATIENT RECS
set date/time
view pt normal
```

3. Press **ENTER**.

The View By menu is displayed.

4. Choose the **Sample Type** option.

The SAMPLE TYPE option is displayed in uppercase characters.

```
--View By--      ←↑↓↵
patient id
test name
SAMPLE TYPE
```

5. Press **ENTER**.

The Sample Type menu is displayed. This menu lists all of the sample types recognized by the analyzer.

```
-Sample Type- ←↑↓↵
CITRATED PLASMA
citrated wh. blood
control plasma
```

6. Choose the name of a sample type.

The selected SAMPLE TYPE is displayed in uppercase characters.

7. Press **ENTER**.

The first screen of the most recent test recorded for the specified sample type is displayed.

```
xxx/yy test      ↓↵
mm/dd/yy        hh:mm
                patient id
p-print all     ← more
```

8. Press the required key:

Key	Action
ENTER	To display the second screen of the test record.
▼	To display the previous test record.
SHIFT RIGHT-P	To print all test records for the specified sample type stored in the analyzer.
EXIT	To return to the Ready screen.

Printing Test Records

Test records can be printed to an externally attached serial printer from the Rapidpoint Coag Analyzer (see *Setting Up the Rapidpoint Coag Analyzer* in Section 3). Test records are automatically stored in the analyzer memory each time a test is performed. These records remain in memory until overwritten or erased (see *Clearing Stored Test Records* in Section 6).

Individual test records can be printed automatically upon test completion if the Auto Print Mode is enabled (see *Enabling/Disabling Operating Modes* in Section 6). Individual test records, or groups of test records categorized by patient ID, test type, or sample type can be printed using the View Patient Records user function.

To print every test record stored in memory:

1. From View Patient Records, choose **All Records**.
The most recent test record in the analyzer memory is displayed.
2. Enter **P** to print all of the records in the viewing category.
The message, PRINTING...PRESS EXIT TO STOP, is displayed as the records are sent to the printer. If **EXIT** is pressed, the printer will continue to print until the printer buffer is empty.

To print all stored test records in a particular viewing category:

1. From View Patient Records, select either Patient ID, Test Name, or Sample Type to print stored test records in that category. Press **ENTER**.
The most recent test record from the selected viewing category is displayed.
2. Enter **P** to print all of the records in the selected option.
The message, PRINTING...PRESS EXIT TO STOP, is displayed as the records are sent to the printer. If **EXIT** is pressed, the printer will continue to print until the printer buffer is empty.

To print individually stored test records from a particular viewing category:

1. From View Patient Records, select the test record category to be printed. Press **ENTER**.
The most recent test record from the selected category is displayed.
2. Use the display movement keys to scroll through the available records to the test record to be printed.
The first screen of the test record is displayed.
3. Press **ENTER**.
The second screen of the test record is displayed.

4. Enter **P** to print the selected test record.

The message, PRINTING...PRESS EXIT TO STOP, is displayed as the records are sent to the printer. If **EXIT** is pressed, the printer will continue to print until the printer buffer is empty.

PT Test Result Sample Report

```
RAPIDPOINT COAG ANALYZER PATIENT RECORDS PRINTOUT
SERIAL #000001      11/11/98      11:13 AM

Patient ID: 12345678901234567890
Test Name   :PT
Test Result:= 9.7 sec.
ratio = 0.8
Calculated inr = 0.72
Sample Type:citrated plasma
Test Date   :11/11/98
Test Time   :11:11 AM
Card Lot    :124040
Operator    :
```

NOTE: Be sure to check the printed record for accuracy.

NOTE: Though the analyzer can operate with any serial printer, the printer available from Chiron Diagnostics is highly recommended. The Chiron Diagnostics printer option includes a portable serial printer and a customized printer cable. If another serial printer is used with the analyzer, the printer switches must be set accordingly, and a custom printer cable obtained from a third party.

NOTE: To avoid the warning message, PATIENT RECORD MEMORY FULL, and the possible overwriting of previously stored test records that have not been saved to a permanent record, an operator with supervisory access should periodically print all test records before the 1000 test record limit is reached. After the records have been printed, the memory should be cleared (see *Supervisory Functions* in Section 6).

NOTE: If a record has a control sample test result that is out of range, the message, *** RESULT OUT OF RANGE ***, will be printed immediately following the "Test Result" line.

NOTE: Pressing the EXIT key will discontinue the printing function. However, the printer will continue to print more records until all the records in its internal buffer memory are printed.

Viewing PT and aPTT Normal Values

The geometric mean of the normal range is used to calculate results for certain Rapidpoint Coag tests. Test specific means are encoded on each Rapidpoint Coag test card. The mean value can be read from the test card, or it can be customized for each valid sample type by an operator with supervisory access (see *Supervisory Functions* in Section 6). If the mean of the normal range is not entered in the Rapidpoint Coag Analyzer by an operator, the encoded mean value from the Rapidpoint Coag test card is used as the default.

The setting for the PT or aPTT Normal can be viewed from the User Functions. If a custom mean value has been set using the Set PT or Set aPTT Normals Supervisory Function, the analyzer displays the custom value. If a custom mean value has not been set, the analyzer displays “card”.

1. From the Select Function menu, choose the **View (test) Normal** option.

The VIEW (test) NORMAL option is displayed in uppercase characters.

```
Select Function ←↑↓↵
view patient recs
set date/time
VIEW PT NORMAL
```

2. Press **ENTER**.

```
Sample           Norm ↗
non-cit blood    15.9
citratd blood    card
citratd plasma   card
```

NOTE: Non-Citratd Blood is available only when View PT Normal is selected.

- If the analyzer is customized with a mean normal range value, the analyzer displays that value in seconds.
- If the analyzer is configured to read the mean normal range value from the Rapidpoint Coag test card, the analyzer displays “card”.

Viewing QC Lockout Settings

The QC Lockout time period ensures that a control sample is run within an operator defined time period of 1 to 24 hours.

The setting for QC Lockout can be viewed from the User Functions. If a time period has been defined, the analyzer will show that time period and the QC Lockout setting.

1. From the Select Function menu, choose the **View QC Lockout** option.
The VIEW QC LOCKOUT option is displayed in uppercase characters.

```
Select Function ←↑↓↵
set date/time
view pt normal
VIEW QC LOCKOUT
```

2. Press **ENTER**.

```
QC #hrs between ↵
control samples
hrs: 12
Level: WARNING
```

- The value for hours ranges from 1 to 24; 0 indicates the value has not been set.
- The possible options for QC Lockout are: DISABLE, WARNING, or LOCKOUT. (See *QC Lockout Mode* in Section 6 for a detailed explanation of these options.)

Viewing Control Ranges

Control ranges are used to monitor whether a control test result falls within the parameters set by the operator for a specific Rapidpoint Coag test.

The settings for control ranges can be viewed from the User Functions. If a control range has been defined, the analyzer will show each level number and its associated high/low values.

1. From the Select Function menu, choose the **View Control Ranges** option.
VIEW CONTROL RANGES is displayed in uppercase characters.

```
Select Function ←↑↓↵
view aptt normal
view qc lockout
VIEW CONTROL RANGES
```

2. Press **ENTER**.
The Test Selection menu is displayed showing the available test types.

```

Select Test  ←↑↓↵
APTT
hmt
pt

```

3. Do one of the following:

- Select the first test.
- Use the down and up arrows to scroll through the test selection list.
- Press the first letter of the desired test to skip through the test selection list to the assays beginning with that letter.

The selected test is displayed in uppercase characters.

4. Press **ENTER**.

```

LEVEL LOW      HIGH
I          xxxx.x xxxx.x
II         xxxx.x xxxx.x
III        xxxx.x xxxx.x

```

If high and low values for a Level I, II, or III control range have been set, the analyzer displays those values in seconds.

Printing Control Ranges

Settings for control ranges can be printed to an externally attached serial printer from the User Functions.

When a printer is properly attached (see *Setting Up the Rapidpoint Coag Analyzer* in Section 3), the analyzer can print the levels and associated high/low range values for every control sample test type.

1. From the Select Function menu, choose the **Print Control Ranges** option.

PRINT CONTROL RANGES is displayed in uppercase characters.

```

Select Function ←↑↓↵
view qc lockout
view control ranges
PRINT CONTROL RANGES

```

2. Press **ENTER**.

A printout is generated, by test type, for the associated high and low range values of each defined control sample level.

Sample Report of Control Ranges

<TEST NAME>		
LEVEL	LOW	HIGH
I	XXXX.X	XXXX.X
II	XXXX.X	XXXX.X
III	XXXX.X	XXXX.X

5 Basic Test Instructions

The same basic procedure is used to initiate and perform all Rapidpoint Coag tests. Differences in the Rapidpoint Coag tests can be found in specimen collection and preparation, quality control, limitations, results, and expected values. Test-specific procedures in the test card package insert should be consulted when running tests.

Getting Ready

Refer to the package insert instructions provided with the test cards for test-specific information and quality control procedures.

1. Turn the Rapidpoint Coag Analyzer on. The analyzer will perform a series of self-diagnostic tests.
2. If the self-diagnostic tests are successfully completed, the Ready screen is displayed.

```
--READY--  01/15/98  
           10:44 AM  
  
Pass card thru readr  
or press enter
```

3. If the QC Printout mode is enabled, the analyzer is connected to a serial printer, and the analyzer has successfully completed all self-diagnostic tests, a summary of self-test results is printed. If a printer is not attached to the analyzer, the following error message appears briefly.

```
Warning!!  
No Printer Attached  
QC self-test results  
are unavailable
```

4. Follow package insert quality control procedures for the specific test being run.
5. Allow the test card to warm to room temperature while still sealed in its foil pouch.
6. Collect a blood sample as instructed in the test card package insert.
7. Remove the test card from its pouch.

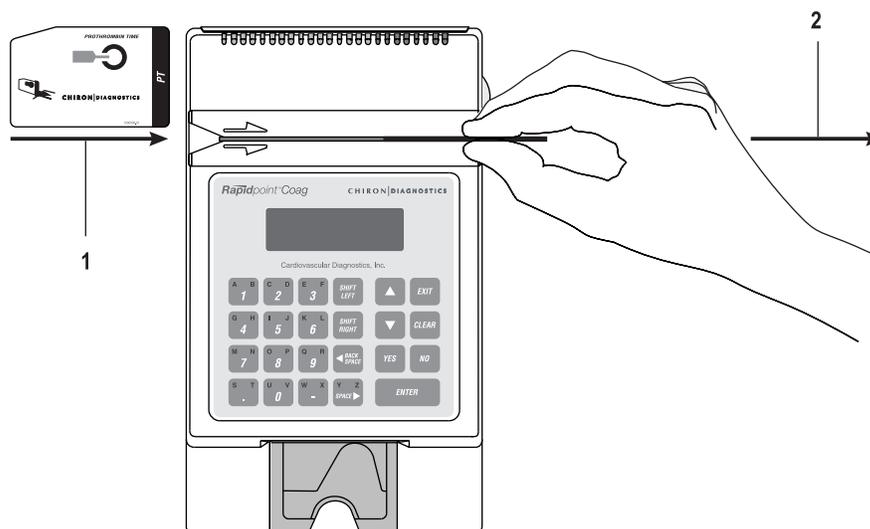
Reading a Test Card

Calibration information for each test card lot is encoded on the magnetic stripe on the back of the Rapidpoint Coag test card. This information is transferred to the analyzer microprocessor when the card is passed through the card reader slot during test initiation.

1. Hold the test card face-forward, with the magnetic stripe toward the back of the analyzer.
2. Pass the card at a steady rate from left to right through the card reader.

If the card has been successfully read, the analyzer emits an audible beep. If the QC Lockout mode is enabled, and a control sample has not been run within the QC Lockout time period, a warning message is displayed (see *QC Lockout Mode* in Section 6).

Reading a Test Card

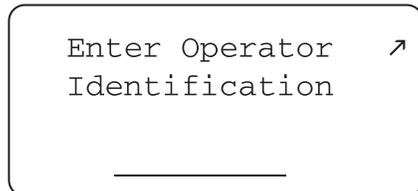


- 1 Pass through reader slot in this direction.
- 2 Pull card through reader slot in this direction.

Entering an Operator ID

When the Operator ID mode is enabled (see *Supervisory Functions* in Section 6), the Rapidpoint Coag Analyzer requires the operator to enter a personal access code (two to six characters) before running a test. After reading a test card, the analyzer prompts you to enter your operator identification.

1. On the Operator Identification screen, enter a valid access code.

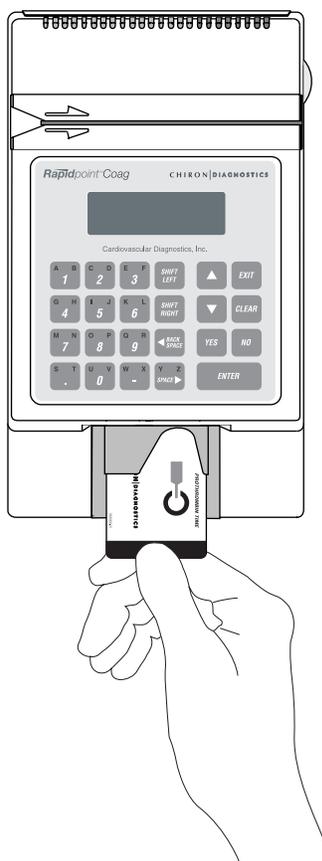


The entered code is displayed in the operator identification field.

2. Press **ENTER**.

When a valid access code is entered, the analyzer displays the prompt, **INSERT TEST CARD**. If an invalid access code is entered, the analyzer displays the message, **UNKNOWN OPERATOR ID**.

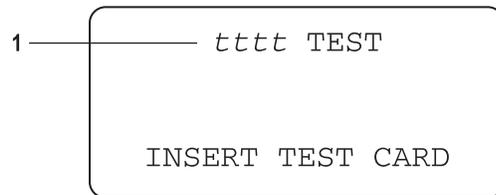
Inserting a Test Card



The Rapidpoint Coag Analyzer prompts the operator to insert the test card either after entry of the operator identification code (when required) or after reading a test card. Do not insert the test card until prompted to do so.

It is important to position the test card correctly into the Rapidpoint Coag Analyzer to properly perform a test.

1. When the prompt, Insert Test Card, is displayed, hold the test card face up, leading with the angled corner on the right side of the card.



1 Identifies the test name

2. Slide the test card completely into the card holder making sure the outside edge of the card rests against the card slot retaining wall.

NOTE: If the test card is inserted prematurely into the card slot while the Ready screen is displayed, the message, PLEASE REMOVE CARD, is displayed.

NOTE: Do not remove the test card until prompted to do so by the analyzer, or the test will be stopped.

Selecting the Sample Type

After the test card is inserted, the Rapidpoint Coag Analyzer prompts the operator to select the sample type being used with the test card. Accurate selection of the sample type is essential to obtain correct test results. Calibration factors can be different for the various sample types available for a test; therefore, invalid test results can be reported if the sample type is incorrectly selected. In addition, using a sample type other than those indicated for a given test is likely to produce invalid results. Data encoded on the back of each test card controls which sample types are available in the sample type menu.

The possible sample type choices are:

- Citrated Plasma
- Citrated Whole Blood
- Control Plasma
- Non-Citrated Whole Blood

1. On the Sample Type screen, select the appropriate test sample type.

The selected sample type will be displayed in capital letters. Scroll through the menu for additional options.

```

-SAMPLE TYPE-  ←↑↓↵
CITRATED PLASMA
citrated wh. blood
control plasma

```

2. Press **ENTER**.
3. One of the following will occur:
 - If a test sample type other than a control is selected, the analyzer prompts the operator to enter the patient identification before running the test (see *Entering Patient Identification* in Section 5).
 - If a control sample is selected and if only one control level has been set, a prompt will appear instructing the operator to add a sample drop. If more than one control level has been set, the operator must select a control level from the Level Select menu before running the test.

```

Select Level  ←↑↓↵
Level I
Level II
Level III

```

NOTE: If QC Lockout is set to Lockout and the conditions necessary to prevent a Lockout have not been met, the only sample type available will be Control Plasma (see *QC Lockout* in Section 6).

Entering Patient Identification

After a sample type is selected for a test, the Rapidpoint Coag Analyzer prompts the operator to enter up to 20 alphanumeric key characters to identify the patient on whom the test is being run.

1. On the Patient Identification screen, enter the patient's name or a unique identifier for the patient.

1 ——— tttt TEST ↗
 Enter Patient ID

 ↑ Previous ID

1 Identifies the test name

The entered identifier is displayed in the patient identification field.

After a test has been performed and stored, and if it was not a control sample, the ↑ symbol will be displayed. Pressing the s key enters the Patient ID from the previous test in the current test's patient identification field.

2. Press **ENTER**.

The patient identification is accepted, and the analyzer displays the message, **WARMING CARD...PLEASE WAIT**.

NOTE: The analyzer warms the test card for 20 seconds before it is ready for the sample to be added. If more than 20 seconds have elapsed between inserting the card and entering the patient identification and sample type, the message, **Warming Card ... Please Wait**, is not displayed.

Adding a Sample Drop



Add a sample drop to the sample well on the Rapidpoint Coag test card when prompted to do so by the analyzer. The sample drop automatically enters the reaction chamber on the test card, and the analyzer detects its presence and begins testing.

NOTE: One of the following methods is recommended to withdraw the sample.

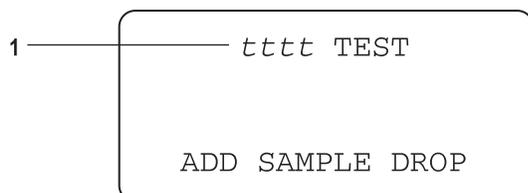
- Carefully remove the rubber stopper from the collection tube, using a device designed to minimize the formation of aerosols. Use a transfer pipette or other device capable of dispensing a drop of approximately 30 to 35 μL (0.03 to 0.035cc).
- Pierce the stopper of the collection tube, using a tuberculin needle with attached syringe. Slowly aspirate 0.1 mL or more of the sample into the syringe. Carefully disconnect the syringe from the needle hub with a twisting motion without removing the needle from the stopper. Press the plunger to dispense a drop of sample. This method is **not** recommended for use with plasma samples.

1. If a whole blood sample is being tested, invert the sample several times.



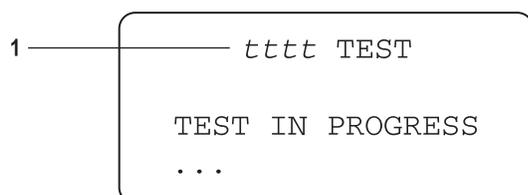
CAUTION: Do not touch the test card with the device used to add the sample.

2. When the analyzer displays Add Sample Drop, add approximately 30 to 35 μL (0.03 to 0.035cc) of sample to the sample well on the test card.



1 Identifies the test name

The analyzer automatically detects the presence of the sample and emits an audible beep when the testing begins.



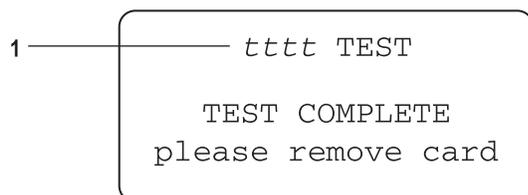
1 Identifies the test name

A moving ■ is displayed beneath the message, TEST IN PROGRESS, while the test is being performed.

Reviewing Results

When the appropriate endpoint of a test is reached, the analyzer prompts the user to remove the test card from the instrument. If a problem is encountered in determining the test result, a diagnostic message is displayed (see *Irregular Test Results* in Section 5).

1. When prompted by the analyzer, remove the test card from the instrument.

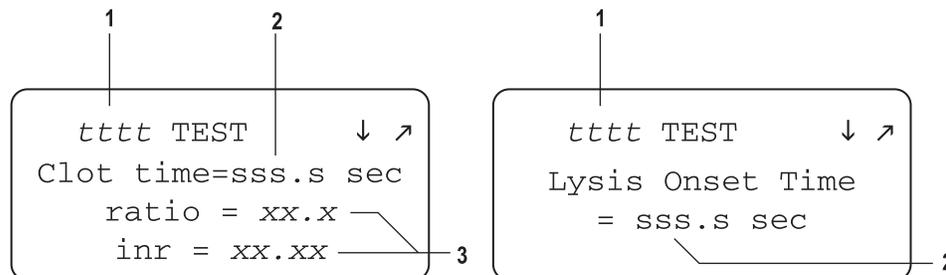


1 Identifies the test name

- Verify that a sufficient amount of sample was added to the card.

The entire gray area of the reaction chamber on the analyzer test card should be covered by the sample. If the reaction chamber has not been completely covered by the sample, repeat the test, using a new test card (see *Testing Method Quality Control* in Section 8).

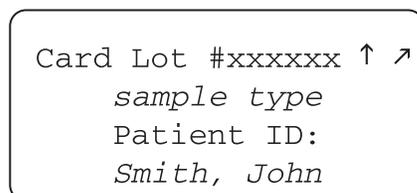
Test results are displayed on one of the following the analyzer screens:



- Identifies the test name
- Identifies the time in seconds
- Identifies the numerical value

NOTE: Ratio is displayed for the PT, PT-ONE®, PT-NC™, and aPTT tests. An INR is displayed for the PT, PT-ONE, and PT-NC tests.

- Use the cursor and display movement keys to review additional information about the test performed, such as test card lot number, sample type selected, patient ID, and the control level number if a control test has been run.



If the Auto Print mode is enabled and the analyzer is properly connected to a printer, the analyzer automatically prints the test record.

- After reviewing the information and ensuring that the patient ID and sample type have been accurately recorded, press **EXIT**.

The analyzer returns to the Ready screen.

Irregular Test Results

Irregular test results are sometimes encountered when endpoints are outside the expected limits for a test. If this occurs, a diagnostic message is displayed on the analyzer screen. The operator should repeat the test to verify the result.

Irregular Result

If a test endpoint is found to be outside the defined range, the message, IRREGULAR RESULT, is displayed.

```

IRREGULAR RESULT.
  REPEAT TEST.

Hit any key to cont.
  
```

After pressing any key, one of the following results screens is displayed:

```

1 2
  tttt TEST ↓ ↗
  Clot time < ss.s sec
  RATIO = ***.*
  INR = **.**. 3
  
```

```

1
  tttt TEST ↓ ↗
  Lysis Onset Time
  < ss.s sec 2
  
```

- 1 Identifies the test name
- 2 Identifies a time in seconds
- 3 Identifies a numerical value out of range

Use the cursor to scroll through irregular results information. The operator should repeat the test to verify the result.

NOTE: Ratio is displayed for the PT, PT-ONE, PT-NC, and aPTT tests. An INR is displayed for the PT, PT-ONE, and PT-NC tests.

No Clot Found

If the sample has insufficient intact fibrinogen to form a detectable clot, the message, NO CLOT FOUND, is displayed in tests whose endpoint is the onset of clot lysis.

```

NO CLOT FOUND ↗
NO RESULT TO REPORT.
  
```

After pressing any key, the analyzer returns to the Ready screen. Repeat the test to verify the result.

Possible Error

If no test endpoint is found and the test time has exceeded the defined range of the test, the message, POSSIBLE ERROR, is displayed.

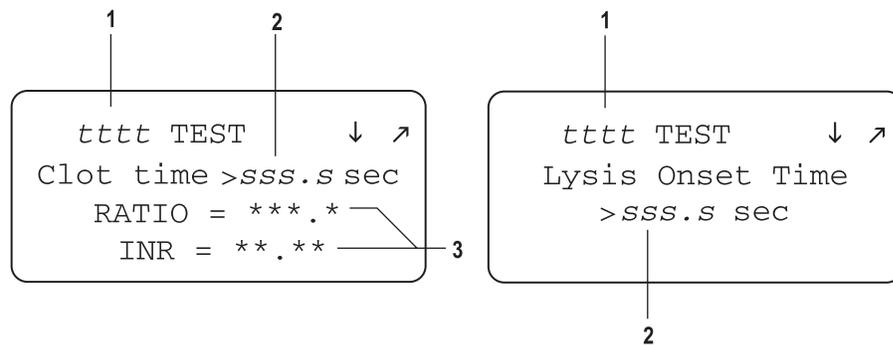
```

POSSIBLE ERROR.
REPEAT TO VERIFY.

Hit any key to cont.

```

After pressing any key, one of the following results screens is displayed:



- 1 Identifies the test name
- 2 Identifies a time in seconds
- 3 Identifies a numerical value out of range

Use the cursor to scroll through irregular results information. Repeat the test to verify results.

NOTE: Ratio is displayed for the PT, PT-ONE, PT-NC, and aPTT tests only. An INR is displayed for PT, PT-ONE, PT-NC.

Control Sample Out of Range:

If the results of a control sample fall outside the expected range, the message, RESULT NOT IN RANGE, is displayed.

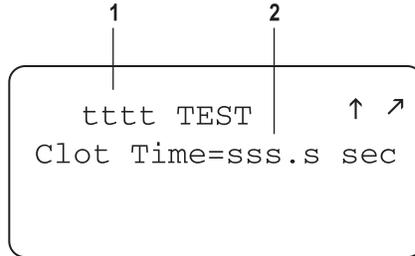
```

Control Level X ——— 1
Result not in range
xxxx.x to xxxx.x ——— 2
Hit any key to cont.

```

- 1 Identifies Control Level I, II, or III
- 2 Identifies high and low values for the control range

After pressing any key, the following results screen is displayed:



- 1 Identifies the test name
- 2 Identifies a time in seconds

Use the cursor to scroll through irregular results information. Repeat the test to verify the result.

6 *Supervisory Functions*

The Rapidpoint Coag Analyzer has two sets of functions, User Functions and Supervisory Functions. The User Functions allow the operator to perform basic analyzer operations (see *General Operating Instructions* in Section 4), and the Supervisory Functions allow an operator with access to a supervisor's code to perform the following operations:

- Set operating modes
- Set control ranges
- Set QC printout mode
- Manage operator IDs
- Clear stored test records
- Set the date and time format
- Define custom PT and aPTT normal values
- Set aPTT ratio mode
- Select display language

Supervisory Functions are used to change the analyzer default settings. These settings are retained in the analyzer memory until the Supervisory Functions are used to modify them.

The Supervisory Functions menu is displayed on multiple analyzer screens. Use the cursor and display movement keys to display additional menu options. Follow the display symbols on the screen to perform the indicated functions.

Displaying Supervisory Functions

1. From the Ready screen, press the key sequence of the supervisor's code in rapid succession.

```
  --READY--   01/15/98  
                10:44 AM  
  
Pass card thru readr  
or press enter
```

The Supervisory Functions menu is displayed after successful entry of the supervisor's code.

NOTE: The supervisor's code is provided under separate cover.

```
--Select one-- ← ↓↗
SET OPERATOR ID ON
set auto print on
set qc printout on
```

2. Use the cursor and display movement keys indicated by the symbols on the analyzer screen to scroll through menu options.
3. To return to the Ready screen, press **EXIT**.

Enabling/Disabling Operating Modes

An operator with supervisory access can enable the Rapidpoint Coag Analyzer to run in one or all three of the following operating modes:

- Operator ID
- Auto Print
- QC Lockout

Operator ID Mode

When the Operator ID mode is enabled, the Rapidpoint Coag Analyzer requires entry of a valid operator identification code before beginning a test. Operator identification codes can be assigned to operators who have been trained and are authorized to perform tests using the Rapidpoint Coag Analyzer, preventing access to test functions by unauthorized operators. An **O** appears on the second line of the analyzer Ready screen, indicating the Operator ID mode is on.

```
1 --- --READY--   01/15/98
      O           10:44 AM
      Pass card thru readr
      or press enter
```

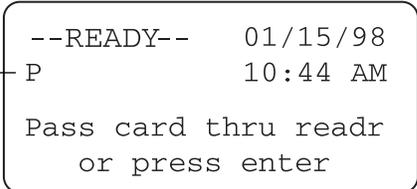
1 Indicates Operator ID mode is enabled

1. From the Supervisory Functions menu, do one of the following:
 - To enable the Operator ID mode, choose the **set operator id on** option.
 - To disable the Operator ID mode, choose the **set operator id off** option.The selected option is displayed in uppercase characters.
2. Press **ENTER**.
 - If the Operator ID mode is enabled, the analyzer displays the message, operator id mode is now on, and returns to the Supervisory Functions menu. The menu option now displays the message, SET OPERATOR ID OFF.
 - If the Operator ID mode is disabled, the analyzer displays the message, operator id mode is now off, and returns to the Supervisory Functions menu. The menu option now displays the message, SET OPERATOR ID ON.

NOTE: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, set operator id on, the Operator ID mode is currently off (disabled). When the menu option displays the message, set operator id off, the Operator ID mode is currently on (enabled).

Auto Print Mode

When the Auto Print mode is enabled and the Rapidpoint Coag Analyzer is connected to a printer, the analyzer automatically prints a report at the end of a test. The character **P** appears on the second line of the analyzer **Ready** screen indicating the Auto Print mode is on.

1 — The screenshot shows a terminal window with the following text: --READY-- 01/15/98, P 10:44 AM, Pass card thru readr, or press enter. A line with the number '1' points to the 'P' character on the second line.

1 Indicates Auto Print mode is enabled

NOTE: The Auto Print mode requires installation of the Rapidpoint Coag Analyzer printer option (see *Connecting a Serial Printer* in Section 3).

To enable or disable the Auto Print mode:

1. From the Supervisory Functions menu, do one of the following:
 - To enable the Auto Print mode, choose the **set auto print on** option.
 - To disable the Auto Print mode, choose the **set auto print off** option.The selected option is displayed in uppercase characters.

2. Press **ENTER**.

- If the Auto Print mode is enabled, the analyzer displays the message, auto print mode is now on, and returns to the Supervisory Functions menu. The menu option now displays the message, SET AUTO PRINT OFF.
- If the Auto Print mode is disabled, the analyzer displays the message, auto print mode is now off, and returns to the Supervisory Functions menu. The menu option now displays the message, SET AUTO PRINT ON.

QC Lockout Mode

The Rapidpoint Coag Analyzer operates with the QC Lockout mode in the Warning, Lockout, or Disabled state. If QC Lockout is set to Warning or Lockout, the analyzer requires that a control sample(s) for each level be run within a specified interval of time. An operator with access to Supervisory Functions can set these time intervals from 1 to 24 hours within which control samples must be run. Once set, if control samples are not run before the end of this time period, the user will be alerted that time has expired.

The three QC Lockout states are:

- **Disable**
The QC time period is ignored. No warning messages are supplied to the user.
- **Warning**
When the QC time period has expired, the analyzer displays a warning message. The operator can, however, continue to run all blood sample types for any tests. The warning messages will continue until the required control samples are run.
- **Lockout**
When the QC time period has expired, the analyzer displays a message instructing the operator to either exit to the Ready screen or continue. If the operator continues, the only sample type available is CONTROL SAMPLE.

NOTE: The QC Lockout mode options, Warning and Lockout, operate in a dependent relationship with the control range settings. If either of the QC Lockout options, Warning or Lockout, is selected, acceptable ranges for control samples **must** be defined and set for one or more of the three control range levels. (See *Setting Control Ranges* in Section 6.)

1. From the Supervisory Functions menu, scroll down to **SET QC LOCKOUT**.

The SET QC LOCKOUT option is displayed in uppercase characters.

2. Press **ENTER**.

The following menu options are displayed.

```
--Select One-- ← ↓↗
DISABLE
warning
lockout
```

3. Do one of the following:

- Choose the **DISABLE** option.

All QC Lockout functions will be disabled.

- Choose the **WARNING** option.

This selection displays a data entry field into which the desired number of hours between QC samples is entered. When this option is enabled, a **W** appears on the second line of the analyzer Ready screen indicating that QC Lockout is in WARNING mode.

- Choose the **LOCKOUT** option.

This selection displays a data entry field into which the desired number of hours between QC samples is entered. When this option is enabled an **L** appears on the second line of the analyzer Ready screen indicating that QC Lockout is in LOCKOUT mode.

4. Press **ENTER**.

- If the **DISABLE** option is chosen, the analyzer returns to the Supervisory Functions menu.
- If the **WARNING** or **LOCKOUT** option is chosen, the QC Time Period screen is displayed.

```
Max interval between
control samples
hours: _ _
Select: 01 to 24
```

5. Enter a two-digit value from 1 to 24 to set the maximum number of hours between QC samples. For time periods between 1 and 9 hours, place a zero in front of the number; for example, enter 06 for 6 hours.

```

Max interval between
control samples:
  hours: 06
Select: 01 to 24

```

6. Press **ENTER**.

The defined QC time period is accepted, and the analyzer returns to the Supervisory Functions menu.

NOTE: To avoid lockout, run all defined control levels for a test type during the 60 minutes immediately prior to expiration of the QC Lockout time period. All defined control level results **must** fall within the ranges defined for each level in SET CONTROL RANGES. (See *Setting Control Ranges* in Section 6.)

EXAMPLE: The following table shows a hypothetical schedule for running controls. This schedule is set up to avoid lockout. In this example, the analyzer has the following settings:

- PT Control Levels I, II, and III defined and set.
- QC Lockout enabled. Lockout option ON.
- QC Lockout time period: 9 hours.
- Time and date: U.S. 24-hour clock.

	<i>Time First Controls Run</i>	<i>Time Second Controls Run</i>	<i>Time Third Controls Run</i>	<i>Time Fourth Controls Run</i>
Level I	Monday, 0700 hrs.	Monday, 1500 – 1600 hrs.	Monday, 2300 – 2400 hrs.	Tuesday, 0700 – 0800 hrs.
Level II	Monday, 0705 hrs.	Monday, 1500 – 1600 hrs.	Monday, 2300 – 2400 hrs.	Tuesday, 0700 – 0800 hrs.
Level III	Monday, 0710 hrs.	Monday, 1500 – 1600 hrs	Monday, 2300 – 2400 hrs.	Tuesday, 0700 – 0800 hrs.

Setting Control Ranges

Control ranges are used to monitor whether a control test result falls within the parameters set by the supervisor for a specific Rapidpoint Coag test. Expected ranges for control test results can be defined for both normal and abnormal control samples.

Up to three levels of control ranges can be set for each test type by an operator with supervisory access, using the Set Control Ranges option on the Supervisory Functions menu.

If a control range for a specific test is not defined in Supervisory Functions, a broad default Level I range for normal control samples is provided by the Rapidpoint Coag Analyzer.

There are no default range settings for abnormal control samples. Level II and Level III ranges for abnormal control samples must be defined and set with the Set Control Ranges option.

Once expected control ranges for a test have been defined in the Set Control Ranges Supervisory Functions, these ranges are used for all controls defined for that test type until the ranges are reset, using the Supervisory Functions.

Defining Number of Control Range Levels

Up to three levels of expected ranges for control test results can be entered for each test type, using the Set Control Ranges option.

1. From the Supervisory Functions menu, choose the **Set Control Ranges** option.

The SET CONTROL RANGES option is displayed in uppercase characters.

```
--Select One-- ←↑ ↗
select language
set QC lockout
SET CONTROL RANGES
```

2. Press **ENTER**.

From the Test Selection menu, do one of the following:

```

Select Test  ←↑↓↵
APTT
hmt
pt
  
```

- Select the first test.
- Use the down and up arrows to scroll through the test selection list.
- Using the keypad, press the first letter of the desired test to skip through the test selection list to the test names beginning with that letter.

The selected option is displayed in uppercase characters.

3. Press **ENTER**.

The Set Levels/Ranges menu is displayed for the selected test type.

```

--Select One-- ← ↓ ↵
SET NUMBER OF LEVELS
set high/low ranges
  
```

SET NUMBER OF LEVELS is displayed in uppercase characters.

4. Press **ENTER**.

The Set Number of Levels menu is displayed for selection of the number of control range levels to be set and checked.

```

--Select one-- ← ↓ ↵
ONE LEVEL
two levels
three levels
  
```

5. Do one of the following:

- Choose ONE LEVEL to select one control range to be set and checked.
- Choose TWO LEVELS to select both Level I and Level II control ranges to be set and checked.
- Choose THREE LEVELS to select Level I, Level II, and Level III control ranges to be set and checked.

The selected option is displayed in uppercase characters.

6. Press **ENTER**.

The selected number of levels is accepted, and the analyzer automatically displays the Set High/Low Ranges screen (See *Setting High/Low Values for Control Ranges*, in Section 6). If, however, the number of levels selected is the same number currently set in the analyzer, the analyzer will return to the Test Selection menu.

NOTE: If more than one control level is selected and defined for a specific test type, controls for each level must be run within a 60-minute time period to prevent QC Lockout. Control results must fall within the ranges set in the Rapidpoint Coag Analyzer.

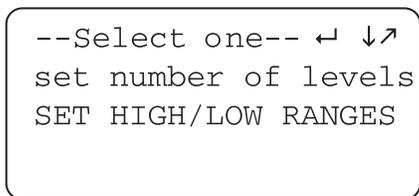
Setting High/Low Values for Control Ranges

In order for the Rapidpoint Coag Analyzer to monitor whether a control test result falls within the correct parameters for a normal or abnormal control sample, an expected range for control test results must be defined and entered as Level I, II, or III.

Once a control range is entered, it is used for all controls defined for that test type until the high and/or low value is changed again, using the Supervisory Functions.

1. From the Set Levels/Ranges menu, choose the **Set High/Low Ranges** option.

The SET HIGH/LOW RANGES action is displayed in uppercase characters.



2. Press **ENTER**.

The Set High/Low Ranges screen is displayed. The cursor is positioned in the LOW value field of Level I. Previously set values are displayed. Only the selected number of levels will appear on the screen.

LEVEL	LOW	HIGH
I	█	15.0
II	0.0	0.0
III	0.0	0.0

1 Indicates three levels of control defined

3. Enter a value between 0.0 and 9999.9 to define the low value for Level I.

4. Press **ENTER**.

The defined **LOW** value for the Level I control range is accepted, and the cursor advances to the **HIGH** value field for the Level I control range.

5. Enter a value between 0.0 and 9999.9 to define the **HIGH** value for the Level I control range.

The **HIGH** value must be greater than the **LOW** value or the analyzer will not accept it.

LEVEL	LOW	HIGH
I	10.0	13.0
II	45.0	█
III	0.0	0.0

6. Press **ENTER**.

The defined **HIGH** value for the Level I control range is accepted. If more than one level was selected, the cursor skips to the next line and is positioned in the low value field for Level II. When all selected levels have been entered, the analyzer returns to the Test Select menu.

7. Define high/low values for Level II and Level III control ranges by repeating steps 3 through 6.

LEVEL	LOW	HIGH
I	5.0	15.0
II	45.0	90.0
III	200.0	300.█

8. To save high/low values and return to the Test Select menu, advance the cursor to the last data entry position and press **ENTER**.
9. Use the arrows to select another test or press **EXIT** to return to the Supervisory Functions menu.

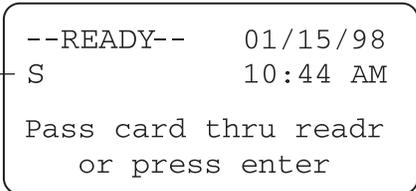
NOTE: To clear values in the currently selected field and reenter, press **CLEAR**. To change values previously entered and accepted by the analyzer, it is necessary to finish entering values for all selected levels, then repeat steps 1 through 6. To recover the value previously entered in the currently selected field, press the up arrow key.

Setting the QC Printout Mode

When the QC Printout mode is enabled, the Rapidpoint Coag Analyzer automatically prints a report verifying that the following QC diagnostic self-tests were successful:

- Boot ROM self-test
- Flash Memory self-test
- Static RAM self-test
- Dynamic RAM self-test
- Temperature Regulation

An **S** appears on the second line of the analyzer ready screen, indicating that the QC Printout option is on.

1 — The screenshot shows a terminal window with the following text: --READY-- 01/15/98, S 10:44 AM, Pass card thru readr, or press enter. A line with the number 1 points to the 'S' character on the second line.

1 Indicates QC Printout option is enabled

NOTE: The QC Printout option requires installation of the Rapidpoint Coag Analyzer printer. (See *Connecting a Serial Printer* in Section 3.)

1. From the Supervisory Functions menu, do one of the following:
 - To turn the QC Printout mode on, choose **set qc printout on**.
 - To turn the QC Printout mode off, choose **set qc printout off**.The selected setting is displayed in uppercase characters.
2. Press **ENTER**.
 - If the QC Printout mode is turned on, the analyzer briefly displays the message, qc printout mode is now on, and then returns to the Supervisory Functions menu. The menu option now displays the message, SET QC PRINTOUT OFF.
 - If the QC Printout option is turned off, the analyzer briefly displays the message, qc printout mode is now off, and then returns to the Supervisory Functions menu. The menu option now displays the message, SET QC PRINTOUT ON.

Managing Operator IDs

The Rapidpoint Coag Analyzer can store up to 100 unique operator identification codes. An operator with supervisory access can:

- Add a new ID
- Delete an existing ID
- View stored IDs
- Print stored IDs

Adding Operator IDs

When the Operator ID mode is enabled, only operators assigned an ID can initiate a test. Adding an operator ID involves defining a code and assigning it to an operator.

The operator ID is made up of 2 to 6 unique characters. These characters can be any of the alphanumeric keys, including the decimal, hyphen, or space. In addition to the 2 to 6 character code, assign a description of 2 to 16 characters to the code to identify the operator (for example, the operator's name or employee number).

A new operator ID can be added to the Rapidpoint Coag Analyzer if fewer than 100 IDs are stored and an identical ID does not already exist in the instrument. An error message is displayed if these conditions are not satisfied.

1. From the Supervisory Functions menu, choose **Add Operator Id**.

The ADD OPERATOR ID option is displayed in uppercase characters.

```

--Select one-- ←↑↓↵
set auto print off
set qc printout off
ADD OPERATOR ID
  
```

2. Press **ENTER**.

The New operator id prompt is displayed, and the cursor is placed in the first character position of the operator ID field.

```

New operator id: ↵
_____
Assign to:
  
```

3. Enter 2 to 6 unique alphanumeric key characters to define the new operator ID.
The entered characters are displayed in the New Operator ID field.
4. Press **ENTER**.
The operator ID is accepted, and the cursor moves to the first position of the 16-character field displayed under the prompt, Assign to.
5. Enter 2 to 16 alphanumeric key characters to describe the operator (for example, the operator's name or employee number).
The description is displayed under the prompt, Assign to.
6. Press **ENTER**.
The entered code and description are accepted, and the analyzer returns to the Supervisory Functions menu.

NOTE: Press **EXIT** at any time to cancel the add operator ID function and return to the Supervisory Functions menu.

NOTE: The message, OPERATOR ID ALREADY EXISTS, is displayed if the entered code matches an existing operator ID. The newly entered code is not accepted.

NOTE: The message, OPERATOR MEMORY IS FULL, is displayed when the memory limit of 100 operator IDs has been reached. An operator ID must be removed before a new ID can be added (see *Removing Operator IDs* in Section 6).

Removing Operator IDs

Existing operator IDs can be removed from the Rapidpoint Coag Analyzer using the Delete Operator ID option on the Supervisory Functions menu. If 100 operator IDs have already been entered into the analyzer, an operator ID must be removed before a new ID can be added.

1. From the Supervisory Functions menu, choose the **Delete Operator ID** option.
The DELETE OPERATOR ID option is displayed in uppercase characters.

```
--Select one--  ←↑↓↵
set qc printout off
add operator id
DELETE OPERATOR ID
```

2. Press **ENTER**.

The message, Enter operator id to delete, is displayed, and the cursor is placed at the first character position of the six character code.

```

Enter operator id ↗
to delete
_____

```

3. Enter the characters of the operator ID to be removed.

The entered characters are displayed in the code field.

4. Press **ENTER**.

The operator ID is removed from the list, and the analyzer returns to the Supervisory Functions menu.

NOTE: If the operator ID has been entered incorrectly or does not exist, the analyzer displays the message, UNKNOWN OPERATOR ID, and returns to the Supervisory Functions menu. Go to the View Operator IDs option to verify an Operator ID.

Viewing Operator IDs

Existing operator IDs in the Rapidpoint Coag Analyzer memory can be viewed using the View Operator IDs option on the Supervisory Functions menu. The first column on the screen displays the ID code, and the second column displays the name or description assigned to that ID.

Operator IDs are displayed in the order in which they are entered into the analyzer memory so the last operator ID entered appears at the end of the operator ID list. Use the cursor and display movement function keys as indicated by the symbols on the analyzer screen to display additional operator ID entries.

1. From the Supervisory Functions menu, choose the **View Operator Ids** option.

The VIEW OPERATOR IDS option is displayed in uppercase characters.

```

--Select one-- ←↑↓↗
add operator id
delete operator id
VIEW OPERATOR IDS

```

2. Press **ENTER**.

The list of operator IDs is displayed in the order in which they were entered into the analyzer.

```

id:      name:      ↑↓↗
123456 JONES, BOB
121212 DAVIS, RUTH
1AC56L  HERNDON, JANE

```

3. Press ▼ or ▲ as indicated by the symbols on the analyzer screen to scroll down or up through the list of operator ID entries.
4. To return to the Supervisory Functions menu, press **EXIT**.

Printing Operator IDs

Existing operator IDs in the Rapidpoint Coag Analyzer memory can be printed using the Print Operator IDs option on the Supervisory Functions menu.

Operator IDs are printed in the order in which they were entered into analyzer memory.

1. From the Supervisory Functions menu, choose the **Print Operator IDs** option. The PRINT OPERATOR IDS option is displayed in uppercase characters.

```

--Select one-- ←↑↓↗
delete operator id
view operator ids
PRINT OPERATOR IDS

```

2. Press **ENTER**.

The list of operator IDs is printed in the order in which they were entered into the analyzer. The first column on the printout lists the ID code, and the second column lists the name or description assigned to that ID.

The message, PRINTING...PRESS EXIT TO STOP, is displayed briefly as the records are sent to the printer. If the EXIT key is pressed, the printer will continue printing records until the printer buffer is empty.

3. To return to the Supervisory Functions menu, press **EXIT**.

If a printer is not attached to the analyzer, the following error message will briefly appear on the screen. The analyzer will then return to the Supervisory Functions menu.

```
Warning!!  
No Printer Attached  
Operator IDs are  
Unavailable
```

Clearing Stored Test Records

The Rapidpoint Coag Analyzer can store a total of 1000 test records. Once the limit of 1000 stored test records is reached, additional test results cannot be stored in the analyzer without overwriting existing records.

When test record storage reaches 1000, the analyzer displays the following message when a test is initiated:

```
PATIENT RECORD  
MEMORY FULL  
Press enter to cont.  
Press EXIT to cancel
```

If testing continues, the oldest test record is overwritten and cannot be recovered. To avoid this loss of data and to remove the memory full condition, test records should be printed or otherwise documented, and then cleared from the analyzer.

The Clear Patient Recs. option on the Supervisory Functions menu can be used to delete every test record stored in the Rapidpoint Coag Analyzer memory so that new test results can be stored. The Clear Patient Recs. option removes all stored test results. *Stored test results cannot be deleted individually.*

CAUTION: Cleared test results cannot be recovered from the analyzer. Therefore, it is important to print or otherwise document stored results prior to clearing them from the analyzer memory (see *Printing Test Records* in Section 4).

1. From the Supervisory Functions menu, choose the **Clear Patient Recs.** option. The CLEAR PATIENT RECS. option is displayed in uppercase characters.

```
--Select one-- ←↑↓↵  
view operator ids  
print operator ids  
CLEAR PATIENT RECS.
```

2. Press **ENTER**.
A prompt is displayed to confirm the decision to clear memory.

```
Clear All Patient  
Records?  
Press yes or no
```

3. Do one of the following:
 - To clear all stored test results from memory, press **YES**.
All stored test results are removed from analyzer memory and the analyzer returns to the Supervisory Functions menu.
 - To cancel the clear function, press **NO**.
All stored test results remain in analyzer memory and the analyzer returns to the Supervisory Functions menu.

Setting the Date and Time Format

The Rapidpoint Coag Analyzer supports multiple date and time formats which can be set from the Supervisory Functions menu using the Format Date/Time option. The Format Date/Time option provides a choice of four date and time combinations and supports both 12-hour and 24-hour time formats. The date and time formats cannot be selected individually.

Once the default format is changed with the Supervisory Functions, the analyzer retains that format setting each time the analyzer is turned on.

1. From the Supervisory Functions menu, choose the **Format Date/Time** option.
The **FORMAT DATE/TIME** option is displayed in uppercase characters.

```
--Select one-- ←↑↓↵
print operator ids
clear patient recs.
FORMAT DATE/TIME
```

2. Press **ENTER**.
The Select Format screen is displayed.

```
-Select Format- ← ↓↵
MM/DD/YY HH:MM 12HR
mm/dd/yy hh:mm 24hr
dd.mm.yy hh:mm 24hr
```

3. Do one of the following:
 - Choose the **MM/DD/YY HH:MM 12HR** option.
The selected option is displayed in uppercase characters, and the analyzer time will be displayed as AM or PM, U.S. format.
 - Choose the **MM/DD/YY HH:MM 24HR** option.
The selected option is displayed in uppercase characters, and the analyzer time will be displayed in 24-hour, U.S. format.
 - Choose the **DD.MM.YY HH.MM 24HR** option.
The selected option is displayed in uppercase characters, and the analyzer time will be displayed in 24-hour, international format.
 - Choose the **YY.MM.DD HH.MM 24HR** option.
The selected option is displayed in uppercase characters, and the analyzer time will be displayed in 24-hour, international format.
4. Press **ENTER**.
The selected date and time format combination is accepted, and the analyzer returns to the Supervisory Functions menu. The new date and time format is displayed on the Ready screen.

Defining PT and aPTT Normal Values

A mean normal value is used to calculate results for certain Rapidpoint Coag tests (see individual test package inserts). Test-specific mean normal values are encoded on each Rapidpoint Coag test card. The value can be read from the test card, or it can be customized for each valid sample type using the Set (*test*) Normals options on the Supervisory Functions menu.

If a mean normal value is not defined using the Rapidpoint Coag Analyzer Supervisory Functions, the value is read from the Rapidpoint Coag test card and appears on the screen as “card”. Settings for mean normal values can be viewed by using the User Functions (see *Viewing PT and aPTT Normal Values* in Section 4).

If a custom mean normal value has been set using the Supervisory Function, that value is used for all tests of that type until Supervisory Functions are used to change the value or reset it to the default.

Entering a Custom Normal Value

A custom, mean normal value can be entered into the Rapidpoint Coag Analyzer for each valid sample type, using the Set (*test*) Normals options on the Supervisory Functions menu to override the default value read from the test card.

Once a custom, mean normal value is entered for a test, it is used for all tests of that type until the value is changed, using the Supervisory Functions.

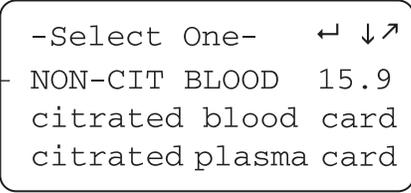
1. From the Supervisory Functions menu, choose the **Set (*test*) Normals** option for a specific test.

The SET (*TEST*) NORMALS option is displayed in uppercase characters.

```
-Select One-  ←↑↓↗  
clear patient recs.  
format date/time  
SET PT NORMALS
```

2. Press **ENTER**.

The Sample Type menu is displayed for selection of the sample type to be defined with a custom, mean normal value.

1 — 

```

-Select One-   ← ↓ ↗
NON-CIT BLOOD  15.9
citrated blood card
citrated plasma card

```

1 Non-Citrated Blood is available only when Set PT Normals is selected.

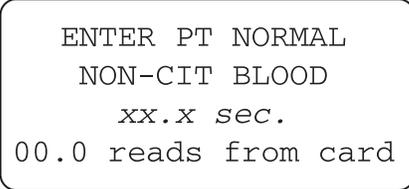
3. Do one of the following:

- Choose **NON-CITRATED BLOOD** to define a mean normal value for Non-Citrated Blood samples.
- Choose **CITRATED BLOOD** to define a mean normal value for Citrated Blood samples.
- Choose **CITRATED PLASMA** to define a mean normal value for Citrated Plasma samples.

The selected option is displayed in uppercase characters.

4. Press **ENTER**.

The ENTER (TEST) NORMAL screen is displayed for the selected sample type, and the cursor is positioned under the first digit.



```

ENTER PT NORMAL
NON-CIT BLOOD
  xx.x sec.
00.0 reads from card

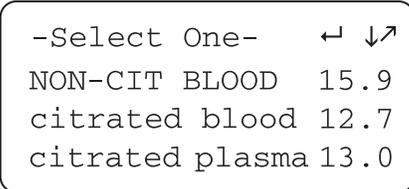
```

5. Enter three numbers to define the mean normal value, where the third number represents tenths of a second.

The cursor moves to the next position in the mean normal value field each time a number is entered.

6. Press **ENTER**.

The defined mean normal value is accepted, and the analyzer returns to the Sample Type menu where the new value is displayed.



```

-Select One-   ← ↓ ↗
NON-CIT BLOOD  15.9
citrated blood  12.7
citrated plasma 13.0

```

7. Do one of the following:
 - To define another mean normal value, choose a sample type and repeat Steps 4 through 6.
 - To return to the Supervisory Functions menu, press **EXIT**.

Resetting a Mean Normal Value to Default

In order for the Rapidpoint Coag Analyzer to use default mean normal values encoded on a test card once a custom, mean normal value has been defined, the mean normal value must be reset in the analyzer using the Set (*test*) Normals Supervisory Function.

1. From the Supervisory Functions menu, choose the **Set (test) Normals** option for a specific test.

The SET (*TEST*) NORMALS option is displayed in uppercase characters.

```
--Select One--  ←↑↓↗
clear patient recs.
format date/time
SET PT NORMALS
```

2. Press **ENTER**.

The Sample Type menu is displayed for selection of the sample type to be defined or reset.

```
-Select One-    ← ↓↗
non-cit blood   15.9
CITRATED BLOOD 12.7
citratd plasma 13.0
```

3. Choose the sample type whose mean normal value is to be reset to read from the test card.

The selected option is displayed in uppercase characters.

NOTE: Non-Citrated Blood is available only when Set PT Normals is selected.

4. Press **ENTER**.

The Enter (Test) Normal screen is displayed for the selected sample type, and the cursor is positioned under the first digit.

```

ENTER PT NORMAL ↗
CITRATED BLOOD
  xx.x sec.
00.0 reads from card

```

5. Enter three zeroes in the field for the mean normal value.

The cursor moves to the next position in the mean normal value field each time a number is entered.

```

ENTER PT NORMAL ↗
CITRATED BLOOD
  00.0 sec.
00.0 reads from card

```

6. Press **ENTER**.

The defined mean normal value is reset to be read from the test card, and the analyzer returns to the Sample Type menu where CARD is displayed.

```

-Select One- ← ↓ ↗
non-cit blood 15.9
CITRATED BLOOD CARD
citrated plasma 13.0

```

7. Do one of the following:

- To define or reset another mean normal value, choose a sample type.
- To return to the Supervisory Functions menu, press **EXIT**.

Enabling/Disabling the aPTT Ratio Mode

An operator with supervisory access can enable the Rapidpoint Coag Analyzer to report activated Partial Thromboplastin Time (aPTT) ratio values. When the aPTT Ratio mode is enabled, the analyzer uses aPTT test results from a sample of citrated plasma or citrated whole blood to automatically calculate the aPTT ratio for that sample. The aPTT ratio is calculated as follows:

$$\text{aPTT ratio} = \text{aPTT Clot Time} / \text{aPTT Mean Normal}$$

When the aPTT ratio is enabled, the aPTT ratio value is displayed at the end of each aPTT test and stored in memory with the test result.

The menu option to enable or disable the aPTT ratio mode displays either **set aptt ratio on** or **set aptt ratio off**. Depending upon the current setting, the displayed option alternates between the On and Off settings.

```
--Select One-- ←↑↓↵  
format date/time  
set pt normal  
SET APTT RATIO OFF
```

1. From the Supervisory Functions menu, do one of the following:
 - To enable the aPTT Ratio mode, choose **Set APTT Ratio On**.
 - To disable the aPTT Ratio mode, choose **Set APTT Ratio Off**.
The selected option is displayed in uppercase characters.
2. Press **ENTER**.
 - If the aPTT Ratio mode is enabled, the analyzer displays the message, aptt ratio mode is now on, and returns to the Supervisory Functions menu. The menu option now displays the message, SET APTT RATIO OFF.
 - If the aPTT Ratio mode is disabled, the analyzer displays the message, aptt ratio mode is now off, and returns to the Supervisory Functions menu. The menu option now displays the message, SET APTT RATIO ON.

NOTE: The menu option indicates the available setting – not the current setting. For example, if the menu option displays the message, set aptt ratio on, the aPTT Ratio mode is currently off, or disabled. When the menu option displays the message, set aptt ratio off, the aPTT Ratio mode is currently on, or enabled.

Selecting a Display Language

The Rapidpoint Coag Analyzer is capable of displaying all operator messages in the following languages:

- English
- German
- French
- Italian
- Spanish

The language option is selected from the Supervisory Functions menu, using the SELECT LANGUAGE option.

The default language is English. Once the default language is changed, the analyzer retains that language setting until changed again, using the Supervisory Functions.

1. From the Supervisory Functions menu, choose the **SELECT LANGUAGE** option.

The SELECT LANGUAGE option is displayed in uppercase characters.

2. Press **ENTER**.

The SELECT LANGUAGE screen is displayed.

```
--Select one-- ← ↓↗  
ENGLISH  
french  
german
```

3. Select the language.

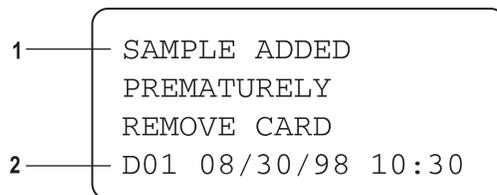
4. Press **ENTER**.

The selected language is accepted, and the analyzer returns to the Supervisory Functions menu. The display will now show all operator messages in the selected language.

7 Troubleshooting and Service

The Rapidpoint Coag Analyzer notifies the operator both visually and audibly if a problem occurs while operating the instrument. The analyzer continuously monitors for conditions that can cause invalid results and will stop a test, if necessary.

Diagnostic messages are provided on the analyzer display. If an error code is associated with the message, it is displayed in the lower left corner of the screen as three alphanumeric characters.



- 1 Diagnostic message
2 Error Code
-

If the analyzer displays a diagnostic message, note the error code and see *Error Messages*, Appendix B for a description of the message and possible actions to resolve the error condition. If the prescribed actions do not resolve the problem, or the diagnostic message continues to occur, note any error codes and call for technical assistance.

For service and repair information within the United States, call Chiron Diagnostics (toll free) at 1-800-255-2121. For customers outside the United States, contact your authorized Chiron Diagnostics service representative.

NOTE: The error messages in Appendix B are arranged alphabetically by error code.

There are no operator serviceable components in the Rapidpoint Coag Analyzer. If prescribed actions for an error message fail to correct the problem (see *Error Messages* in Appendix B), call for technical assistance.

To expedite handling of your Rapidpoint Coag Analyzer problem, have the following information available when calling for technical assistance:

- Any error code and message.
See *Error Messages*, Appendix B.
- Analyzer catalog and serial numbers.

The Rapidpoint Coag Analyzer catalog and serial numbers are located on the bottom of the instrument, as shown in the following figures:

North American Labels



CAUTION
TO REDUCE THE RISK OF ELECTRICAL SHOCK
DO NOT OPEN CASE.

NO USER SERVICEABLE PARTS.
REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.



REFER TO THE OPERATOR'S MANUAL BEFORE USING OR CONNECTING TO ACCESSORIES.

This equipment is intended for *in vitro* diagnostic use only.

POWER REQUIREMENTS
7.1VDC 1.5A 12W
Power may only be provided by the power supply provided with the unit.
Cat. No. **118615**

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.


Listing # ML1522

COMPLIES WITH
UL 544


C22.2 No. 125

US Patent Nos. 5,110,727; 4,849,340; and 5,350,676; other patents pending.
Foreign patents issued and pending.

Manufactured for:
Chiron Diagnostics Corporation
East Walpole, MA 02032 USA



Manufactured by:
Cardiovascular Diagnostics, Inc.
Raleigh, NC 27616 USA

Rapidpoint is a trademark of Chiron Diagnostics Corporation
East Walpole, MA 02032 USA.
Cat. No. **118608** 1900037.01

1900038.01

Serial No.: XXXX

Rapidpoint™ Coag

- 1 Catalog number
- 2 Serial number

• Analyzer software version.

The Rapidpoint Coag Analyzer software version is displayed on the screen after the self-tests are completed when the instrument is turned on (see *Operating for the First Time* in Section 3).

Rapidpoint Coag
Analyzer
Software V x.xx

- 1 Indicates the software version

Addresses and Communication Numbers

Chiron Healthcare Pty. Ltd.
2 Keith Campbell Court
Scoresby, Victoria 3179, Australia
61.3.9212.8444
Fax 61.3.9212.8445

Chiron GmbH
Petersbrunnstrasse 6 a
5020 Salzburg, Austria
43.662.840822
Fax 43.662.840822.9

Chiron N.V./S.A.
Excelsiorlaan 49
B-1930 Zaventem, Belgium
32.2/715.01.70
Fax 32.2/721.12.12

Chiron Brasil Ltda.
Av. Prof. Vicente Rao, 90
04706-900 Sao Paulo - SP,
Brazil
55.11.532.7797
Fax 55.11.543.5020

Chiron Inc.
90 Gough Road, Unit #1
Markham, Ontario L3R 5V5,
Canada
905.475.2220
Fax 905.475.2145

Chiron A/S
Slotsmarken 18 st.tv.
DK-2970 Hørsholm, Denmark
45.45.16.03.66
Fax 45.45.16.03.65

Chiron Diagnostics S.A.
Avenue du Gros ChÉne
B.P. 109 Eragny
95613 Cergy Pontoise Cedex, France
33.01.34.40.40.00
Fax 33.01.34.40.40.91

Chiron Diagnostics GmbH
Siemensstrasse 3
D-35463 Fernwald, Germany
49.641.4003.0
Fax 49.641.4003111

Chiron Ltd.
20/F Gee Chang Hong Centre
65 Wong Chuk Hang Road,
Hong Kong
852.2814.7337
Fax 852.2873.4245

Chiron Diagnostics S.p.A.
Via Roma, 108-Palazzo E
20060 Cassina de+ Pecchi (MI),
Italy
39.02.954551
Fax 39.02.95300419

Chiron KK
Unosawa Tokyu Building 3F
1-19-15, Ebisu
Shibuya-Ku
Tokyo 150, Japan
81.3.3440.4881
Fax 81.3.3440.6999

Chiron Ltd.
Kye Myung Building (4F)
Myungil Dong 48-7
Kangdong-Gu
Seoul 134 070, Korea
82.2.428.5980/8
Fax 82.2.428.5989

Chiron, S.A. de C.V.
PerifÁrico Sur 6677 PB
Col. Ejidos de Tepepan
C.P. 16018 Delegacion
Xochimilco, MÁxico D.F.
52.5.641.3815
Fax 52.5.641.3440

Chiron N.V.
Peppelkade 64 D/E
Postbus 111, 3990 DC Houten,
The Netherlands
31.30.6350750
Fax 31.30.6351041

Chiron Norway A.S.
Gladengveien 3B
Ensjø, 0661 Oslo, Norway
47.22.57.66.06
Fax 47.22.57.66.05

Chiron Sp. z o.o.
UL. Wiktorii Wiedenskiej 17/2
02-954 Warsaw, Poland
48.22.642.45.65
Fax 48.22.642.89.59

Ciba Corning Diagnostics, Lda.
Edificio Infante D. Henrique
R. Joao Chagas, 53 - CO5
1495 Alges, Portugal
351.1.4146010
Fax 351.1.4140933

Chiron Diagnostics Ltd.
6/3 Sechenovskiy per,
Moscow, 119034, Russia
7095.201.34.45
Fax 7095.201.24.18

Chiron España, S.A.
Edificio Dublin - 1a Planta
Parque Empresarial San Fernando
28831 Madrid, Spain
34.91.660.07.42
Fax 34.91.677.68.71

Chiron Diagnostics Ltd.
Pyramidbacken 6
14175 Huddinge, Sweden
46.08-740.15.50
Fax 46.08-740.08.90

Chiron Diagnostics AG
Neue Winterthurerstrasse 15
CH-8305 Dietlikon, Switzerland
41.1.835.27.27
Fax 41.1.835.27.47

Chiron Taiwan Co., Ltd.
8/F., No. 109, Sec. 2
Keelung Road
Taipei, Taiwan, R.O.C.
886.2.3777520
Fax 886.2.7390608

Chiron Diagnostics Ltd.
Colchester Road
Halstead, Essex, CO9 2DX U.K.
44.1787.472461
Fax 44.1787.475088

Corporate Headquarters:
Chiron Diagnostics Corporation
333 Coney Street
East Walpole, MA 02032 USA
508.668.5000
Fax 508.660.4591

US Commercial Operations:
Chiron Diagnostics Corporation
115 Norwood Park South
Norwood, MA 02062-4658 USA
1.800.255.3232 (ordering)
1.800.255.2121
(24-hour technical assistance)
Fax 781.551.7779

8 Quality Control

Calibration

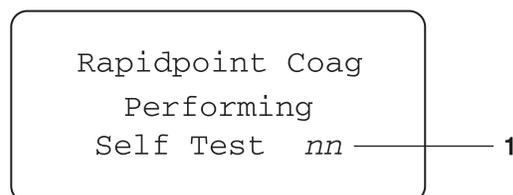
The Rapidpoint Coag Analyzer is calibrated at the factory to maintain a constant card slot temperature and optimum sensitivity and performance for the clot detection module inside the instrument.

Other calibration settings vary by test card lot and selected sample type. These lot-specific calibration parameters are encoded on the magnetic stripe on the back of each test card. The parameters are read from the test card and automatically set within the instrument when a test is initiated.

The only calibration procedure required by an operator is to set the correct date and time when necessary.

Instrument Self-Tests

When the Rapidpoint Coag Analyzer is turned on, it automatically performs a series of self-tests to verify hardware integrity. The Self Test screen increments the test number (*nn*) as it successfully completes each test.



1 Identifies the self-test number

After completion of the instrument self-tests, a screen with the analyzer software version appears briefly before the Ready screen is displayed. If an instrument self-test fails, an error message is displayed (see *Troubleshooting and Service*, Section 7 and *Error Messages*, Appendix B).

NOTE: If the analyzer is kept on continuously, the operator should periodically turn it off and on again as part of routine quality control procedures to ensure that the instrument self-tests are performed regularly. This should also be done if analyzer performance problems are suspected.

Diagnostic Messages

While the Rapidpoint Coag Analyzer is in use, it continuously monitors certain conditions and issues error messages when these conditions are abnormal (see *Troubleshooting and Service*, Section 7 and *Error Messages*, Appendix B).

The following aspects of operation are examples of some of the conditions the analyzer monitors while in use:

- Ambient temperature
- Sensor head temperature (temperature in the card slot)
- Low battery condition (when operating on battery power)
- Presence or absence of a test card in the instrument
- Presence of a sample in the reaction space of the test card

Operator Quality Control Procedures

Quality control testing for the Rapidpoint Coag Analyzer should be performed regularly by the Rapidpoint Coag operator. An extensive level of quality control testing is also performed automatically by the Rapidpoint Coag Analyzer when it is turned on and while the instrument is in use. These internal instrument quality controls do not, however, take the place of regular, operator performed, quality control testing.

Quality Control Timetable

<i>Quality Control Procedure</i>	<i>Schedule</i>
Test Card Validation	Each Test.
Date and Time Verification	Each Test.
Sufficient Sample Verification	Each Test.
Sample Type Verification	Each Test.
Functional testing with Control Plasma	Every 24 hours (minimum). See the package inserts provided with the Rapidpoint Coag test cards for test-specific instructions.
Reference Range Establishment	Change in test card lots. See the package inserts provided with the Rapidpoint Coag test cards for test-specific instructions.

Test Method Quality Control

Routine quality control procedures should be followed by the operator each time a test is performed to ensure that the proper test methodology is used.

These routine procedures include:

- Test Card Validation
- Date and Time Verification
- Sufficient Sample Verification
- Sample Type Verification

Test Card Validation

Before using a test card, be sure the card has been stored in acceptable conditions. Verify that the card has not passed its expiration for the conditions in which it was stored (see *Test Card Storage and Handling* in Section 2).

The expiration date encoded on the test card is verified against the date on the Rapidpoint Coag Analyzer when a test is performed. This verification is valid only if the test card has been refrigerated at 2 to 8°C (36 to 46°F) and the analyzer system date is correct.

NOTE: If the test card has been stored at room temperature, the encoded expiration date and the date embossed on the foil pouch are no longer valid.

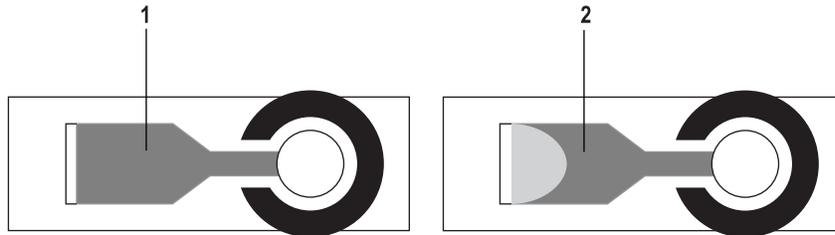
Date and Time Verification

Before beginning a Rapidpoint Coag test, verify that the correct date and time are displayed on the Ready screen. An accurate system date and time are necessary to validate the test card expiration and to properly record test records. To change the analyzer date and time, see *Setting the Date and Time* in Section 4.

Sufficient Sample Verification

After each test is performed, verify that the entire colored area of the reaction chamber on the test card is covered by the sample. If the reaction chamber has not been covered completely by the sample, repeat the test using a new test card (see the following figure).

Sufficient and Insufficient Samples



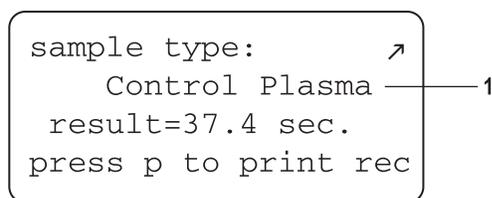
- 1 Sufficient sample
- 2 Insufficient sample

Rapidpoint Coag test cards do not require as much precision in sample dispensing as conventional methods – the reaction chamber is self-filling and self-limiting. One large drop (approximately 30 to 35 μL) of sample should be sufficient to fill the reaction chamber.

Sample Type Verification

After each test is performed, verify that the correct sample type was selected. Calibration settings are read from the test card according to the sample type selected by the operator (see *Selecting the Sample Type*, Section 5). Selection of the proper sample type is critical to valid test results.

The sample type is displayed on the second screen of the patient test result.



- 1 Identifies the selected sample type

Functional Quality Control

Generally, at least one normal and one abnormal level of control should be tested each day of use on each analyzer for each type of test card used.

Functional testing requirements vary according to the test being performed. See the package insert provided with the Rapidpoint Coag test cards for specific instructions on the test being performed.

Reference Range Quality Control

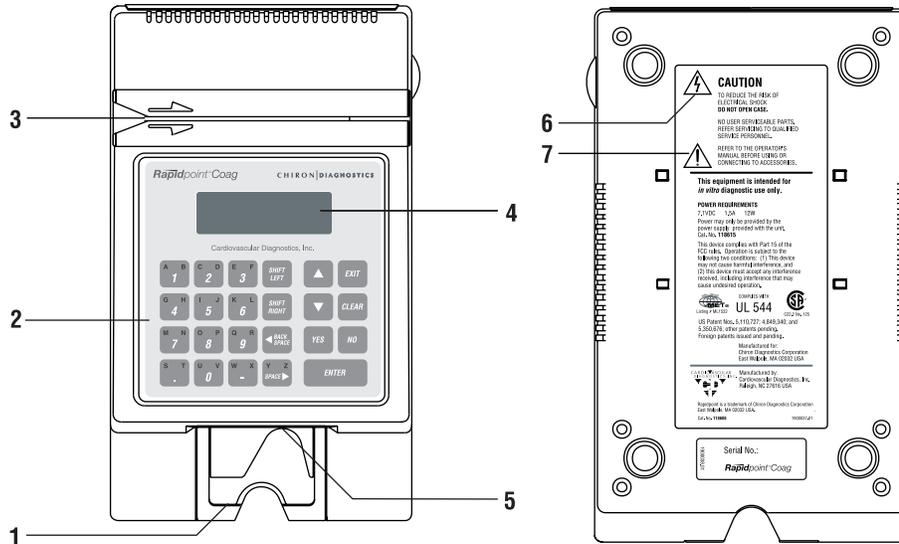
The relationship between the results obtained by the Rapidpoint Coag Analyzer and the results obtained by any other test methods used should be established by the operator when changes in test card lots, reference methods, or reagent lots occur.

Establishment of reference ranges vary by the test being performed. See the package insert provided with the Rapidpoint Coag test cards for specific instructions on the test being performed.

Appendix A: Instrument Labels

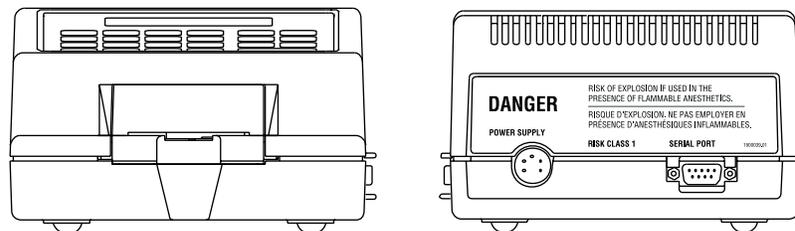
North American Version

Top and Bottom Views

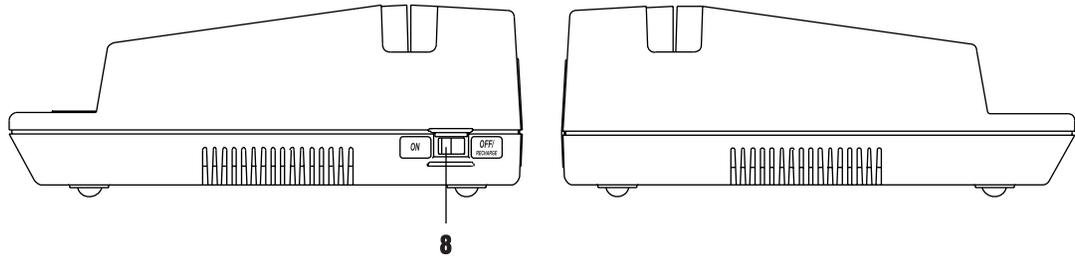


- 1 Card Slot Retaining Wall
- 2 Keypad
- 3 Card Reader Slot
- 4 Display
- 5 Optical Sensor Head
- 6 Caution: Danger of Electrical Shock
- 7 Attention

Front and Back Views



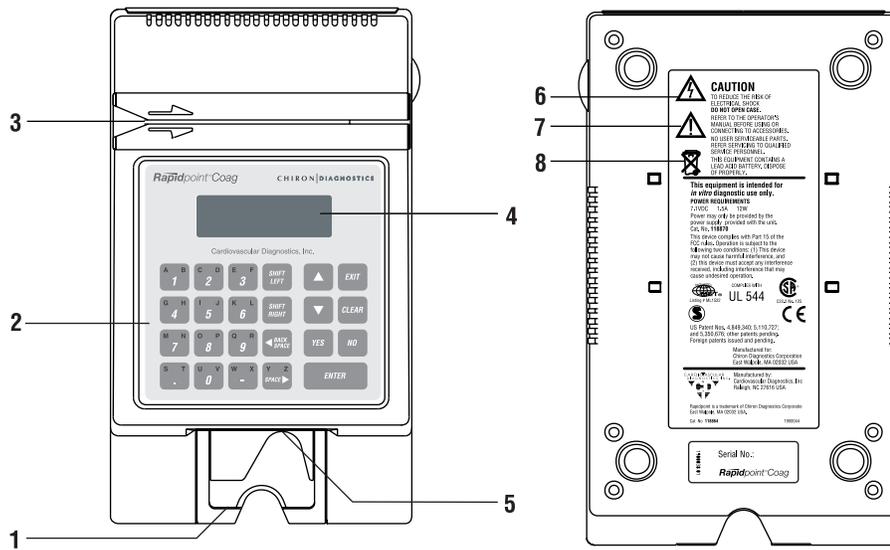
Side Views



8 On/Off Switch

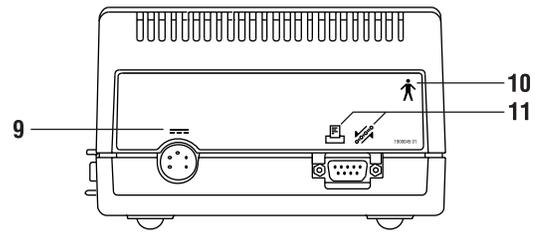
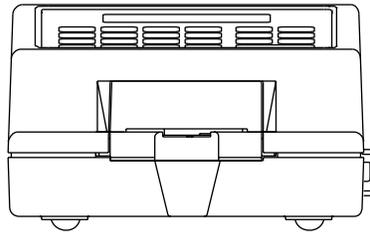
European Version

Top and Bottom Views



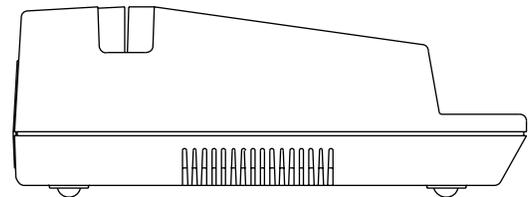
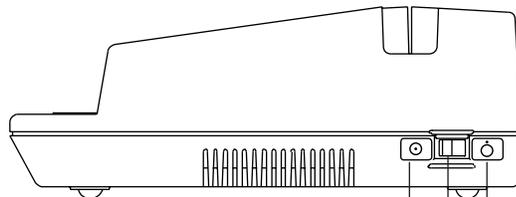
- 1 Card Slot Retaining Wall
- 2 Keypad
- 3 Card Reader Slot
- 4 Display
- 5 Optical Sensor Head
- 6 Caution: Danger of Electrical Shock
- 7 Attention
- 8 Lead Acid Battery – Dispose of Properly

Front and Back Views



- 9 D. C. Voltage Input
- 10 Type B Medical Device
- 11 Printer/Serial Port Connection

Side Views



- 12 On
- 13 On/Off Switch
- 14 Off

- 12 On
- 13 On/Off Switch
- 14 Off

Appendix B: Error Messages

<i>Message</i>	<i>Action</i>
B02 System Failure. Call Distributor.	Note error code and contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
B03 System Failure. Call Distributor.	Note error code and contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
B04 System Failure. Call Distributor.	Note error code and contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
B10 System Failure. Call Distributor.	Note error code and contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
C01 Invalid Card Data. Hit any key to continue.	<ul style="list-style-type: none">• The inserted card is not recognized as a valid Rapidpoint Coag test card.• Press any key to continue.• Repeat test, using a new card.• If error continues, contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
C02 Invalid Card Data. Hit any key to continue.	<ul style="list-style-type: none">• The title of the Rapidpoint Coag test card could not be read.• Press any key to continue.• Attempt to re-read the test card or replace with a new card.• If error continues, contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
C03 Invalid Card Data. Hit any key to continue.	<ul style="list-style-type: none">• The Rapidpoint Coag test card contains an unknown title.• Press any key to continue.• Repeat test, using a new card.• If error continues, contact your authorized distributor. (see <i>Troubleshooting and Service</i>).

<i>Message</i>	<i>Action</i>
C04 Warning! Card Expired on mm/dd/yy. Hit any Key to Continue.	<ul style="list-style-type: none"> • The Rapidpoint Coag test card has passed its usable date. • Press any key to continue. • Verify the system date and time. • Remove the test card and repeat the test, using a new card from a lot that has not expired.
C05 Invalid Card Data. Hit any Key to Continue.	<ul style="list-style-type: none"> • The Rapidpoint Coag test card contains invalid data. • Press any key to continue • Repeat test, using a new card. • If error continues, contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
C06 Please Remove Card.	<ul style="list-style-type: none"> • A Rapidpoint Coag test card was inserted into the sensor head before it was passed through the reader. • Remove the card from the analyzer and re-insert when prompted by the analyzer.
D01 Sample Added Prematurely. Hit Any Key to Continue.	<ul style="list-style-type: none"> • A sample was added to the Rapidpoint Coag test card before the analyzer issued the ADD SAMPLE DROP prompt. • Press any key to continue. • Repeat the test using any new card, and add the sample when prompted by the analyzer.
D02 Card Has Been Removed. Hit Any Key to Cont.	<ul style="list-style-type: none"> • A Rapidpoint Coag test card was removed from the instrument before the analyzer completed the test. • Press any key to continue. • Repeat test, using a new card.
D03 Test Aborted. Card Removed. Hit Any Key to Cont.	<ul style="list-style-type: none"> • A Rapidpoint Coag test card was removed from the instrument before the analyzer completed the test. • Press any key to continue. • Repeat test, using the same card.
G01 No Signal From Sample. Remove Card to Cont.	<ul style="list-style-type: none"> • The analyzer received a false “start test” signal before the sample was applied (usually caused by bumping the analyzer or moving the test card prior to adding the sample). • Remove the test card to continue. • Repeat test, using the same card.

<i>Message</i>	<i>Action</i>
G02 Signal Too Large. Test Aborted. Remove Card to Cont.	<ul style="list-style-type: none"> • The analyzer signal is larger than the predetermined threshold. • Although rare, this condition could occur for samples with unexpected physical properties or unusual chemical components. • Remove the test card to continue. • Repeat test using a new card and the same sample. • If repeat test fails, obtain new sample and repeat test using a new card.
G03 Could Not Set Gain. Remove Card to Continue.	<ul style="list-style-type: none"> • Remove test card. • Repeat test, using a new card. • If error continues, contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
H01 Battery Needs Recharging. Please Plug in Unit.	<ul style="list-style-type: none"> • Turn off the analyzer and connect the instrument to the external power supply. • Connect the power supply to a 120V AC wall outlet for 10 hours to completely recharge (see <i>Operating Under Battery Power</i>).
Inn* System Failure. Call Distributor. *(nn =01-18)	Note error code and contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
Irregular Result. Repeat Test. Hit any key to continue.	<ul style="list-style-type: none"> • A test endpoint is found to be outside of the expected test limits (see <i>Irregular Test Results</i>). • Press any key to display the results screen. • Repeat the test to verify the result.
K01 System Failure. Call Distributor.	Note error code and contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
No Clot Found. No Result to Report. Hit any key to continue.	<ul style="list-style-type: none"> • Encountered in tests whose endpoint is the onset of clot lysis, when the sample has insufficient intact fibrinogen to form a detectable clot (see <i>Irregular Test Results</i>). • Press any key to return to the Ready screen. • Repeat the test to verify the result.

<i>Message</i>	<i>Action</i>
Possible Error. Repeat to Verify. Hit any key to continue.	<ul style="list-style-type: none"> • Atest endpoint is found within the maximum test time limit (see <i>Irregular Test Results</i>). • Press any key to display the results screen. • Repeat the test to verify the result.
Q03 System Failure. Call Distributor.	Note error code and contact your authorized distributor. (see <i>Troubleshooting and Service</i>).
T01 Ambient Temp Too High. Turn Rapidpoint Coag Off Then On.	<ul style="list-style-type: none"> • The ambient temperature is too high for analyzer operation. • Turn the analyzer off, move to a cooler area (see <i>Environmental Operating Conditions</i>), and turn the analyzer back on. • It may be necessary to allow the analyzer to cool for a short time before it can be used again.
T02 Heater Malfunction. Turn TAS Off Then On.	<ul style="list-style-type: none"> • Turn the analyzer off then on. • If error message continues, turn off the analyzer and call your authorized distributor.
T03 Heater Timeout. Turn TAS Off Then On.	<ul style="list-style-type: none"> • The ambient temperature is too low for analyzer operation. Turn the analyzer off, move to a warmer area (see <i>Environmental Operating Conditions</i>), and turn the analyzer back on. • It may be necessary to allow the analyzer to warm for a short time before it can be used again.
U02 Serial Port Failure. Call Distributor.	<ul style="list-style-type: none"> • A hardware failure has occurred on the analyzer serial port. • Note error code and contact your authorized distributor (see <i>Service</i>).
U03 Serial Port Failure. Call Distributor.	<ul style="list-style-type: none"> • A hardware failure has occurred on the analyzer serial port. • Note error code and contact your authorized distributor (see <i>Service</i>).

Appendix C: Protecting Yourself from Biohazards

This information summarizes the established guidelines for handling laboratory biohazards. This summary is based on the guidelines developed by the National Institutes of Health (NIH), the Centers for Disease Control (CDC), the NCCLS Document M29, *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue*, and the Occupational Safety and Health Administration's Bloodborne Pathogens Standard.¹⁻³

Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

By definition, a biohazardous condition is a situation involving infectious agents biological in nature, such as the hepatitis B virus, the human immunodeficiency virus (HIV), and the tuberculosis bacterium. These infectious agents may be present in human blood and blood products and in other body fluids.

The following are the major sources of contamination when handling potentially infectious agents:

- needlesticks
- hand-to-mouth contact
- hand-to-eye contact
- direct contact with superficial cuts, open wounds, and other skin conditions that may permit absorption into subcutaneous skin layers
- splashes or aerosol contact with skin and eyes

To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- Wear gloves while servicing parts of the instrument that have contact with body fluids such as serum, plasma, urine, or whole blood.
- Wash your hands before going from a contaminated area to a noncontaminated area, or when you remove or change gloves.
- Perform procedures carefully to minimize aerosol formation.
- Wear facial protection when splatter or aerosol formation are possible.
- Wear personal protective equipment such as safety glasses, gloves, lab coats or aprons when working with possible biohazard contaminants.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds before starting any work.
- Dispose of contaminated materials according to your laboratory's biohazard control procedures.

- Keep your work area disinfected.
- Disinfect tools and other items that have been near any part of the instrument sample path or waste area with 10% v/v bleach.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipet any liquid, including water.
- Do not place tools or any other items in your mouth.
- Do not use the biohazard sink for personal cleaning such as rinsing coffee cups or washing hands.

To prevent needlestick injuries, needles should not be recapped, purposely bent, cut, broken, removed from disposable syringes, or otherwise manipulated by hand.

References

1. Centers for Disease Control. 1988. Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in healthcare settings. *MMWR*, 37:377–382, 387, 388.
2. National Committee for Clinical Laboratory Standards. Protection of laboratory workers from instrument biohazards and infectious disease transmitted by blood, body fluids, and tissue. Approved Guideline. NCCLS publication M29-A. Wayne, PA: NCCLS; 1997 Dec. 90p.
3. Federal Occupational Safety and Health Administration, Bloodborne Pathogens Standard, 29 CFR 1910.1030.