USER OPERATION MANUAL

QUICKSLIDE™ HEMAPRO | HARDY DIAGNOSTICS A Culture of Service™

D61316

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Congratulations!

You have made an excellent choice for your Lab. Hardy Diagnostics thanks you for the trust you have placed in our products and services.

This operating manual has been designed to help you gain an understanding of the operation and application of our HemaPRO. For optimal utilization of all functions, we recommend that you thoroughly study this manual prior to beginning operation.

This manual has been prepared as an aid for all operations and maintenance, which can be carried out in your facility.

The QuickSlide™ Quality Management System

Our devices for the medical laboratory are developed, produced, and distributed according to the requirements of ISO 9001:2008.

Unpacking and Inspecting

Carefully unpack the HemaPRO and accessories. Check for damage incurred during transit. Keep all packing material until you are sure the unit operates properly. Any damage to the shipping box should be reported to the responsible carrier. These instructions must be followed for us to guarantee our full support of your claim for protecting against loss from concealed damage.

Important: Keep this operating manual for future use.

QuickSlide™, a Division of Hardy Diagnostics
800-266-2222
www.HardyDiagnostics.com
www.QuickSlide.com
Sales@HardyDiagnostics.com

SPECIFICATIONS

Dimensions/Weight
Width 30.48 cm (12 in.)
Height 26.67 cm (10.5 in.)
Depth 27.94 cm (11 in.)
Weight 4.5 kg (10.00 lbs.)

Power Requirements
Input 100-240V, 50-60 Hz, 0.8 A

Standard power cords are supplied to meet local standards.

Temperature, Ambient Operation
16-32 Degrees C (60-90 Degrees F)

Humidity
0 to 95%, without condensation

Operator Adjustments
Individual adjustable stain times on both blood and marrow stain cycles
Adjustable audible sound volume control

Operator Entry
Moisture proof

Standards
IEC-61010-1:2010 (Third Edition)
EN55022; CISPR 22 Ed. 6.0:2008 Class A
CFR 47, Part 15, Subpart B, Class A, 2011
ICES-003 Issue 4, 2004 CAN/CSA-CIE/IEC CISPR 22;02 Class A
EN61326-1: 2010

Warranty
One Year Standard

1.0 INTRODUCTION

This Operation Manual is provided to guide the user in all aspects of unit set-up, operational use, and user-level maintenance of the QuickSlide™ HemaPRO Automated Hematology stainer unit.

The HemaPRO microscope slide stainer is capable of automatically performing a hematology stain sequence on a slide containing a biological specimen for *in vitro* diagnostic use. This instrument accepts standard thickness 1” X 3” X2mm glass slides that are frosted and pre-cleaned.

Two settings are programmed – one for blood smears, the second for bone marrow – and specific stain durations are customizable for each setting. A cuvette holds one slide at a time. The chamber is flooded with stain, buffer, or rinse by use of peristaltic pumps under the front cover. After staining and rinsing have been completed, the slide quality is best when promptly removed from the cuvette and dried. Do not leave the slide in the cuvette to air-dry.

Operator Responsibility – Safety Instructions

The HemaPRO ensures safe operation when installed, operated, and maintained according to common safety regulations. This section explains the potential dangers that may arise when operating the HemaPRO.

It is the operator’s responsibility to be properly qualified to operate the HemaPRO. The operator and laboratory personnel are advised to refer to this Operating Manual and the set-up letter that is packaged with the unit.

In addition, the operator is to be familiar with good laboratory practices and safety precautions.

Explanation of Symbols

| | - Power On

O - Power Off

Caution – Refer to marked paragraphs in this manual for details.

2.0 WORK AREA REQUIREMENTS

IMPORTANT!

The HemaPRO unit requires a level counter top surface of 12 inches wide by 11 inches deep with a vertical clearance of 10.5 inches. The Reagent Supply Kit should be positioned at the same level as the instrument on the counter immediately beside or behind the instrument and is connected with tubing. Do not place reagents below the instrument.

The HemaPRO has one tube that drains all of the waste fluids. The HemaPRO drain tube can be placed in a drain or into an external container to collect the waste.

The HemaPRO uses an external power supply module that is be supplied with 50-60 Hz, 110-240 V, 0.8 A. This unit requires power from a grounded outlet.

There are no special environmental requirements for operation of the HemaPRO.

The HemaPRO is assembled with tubing sets to connect the instrument to the reagents. Place the correct cannulas (opaque rigid tubes) into the corresponding reagent supply containers. Labels attached to the cannula lines indicate which reagent is to be used with each line.

In addition, the reagent module cord supplied with the reagent kit must to be plugged into the right side of the machine in order to use a new reagent kit.

3.0 RECEIVING AND UNPACKING

Unpacking and set-up assistance for the HemaPRO may be obtained by calling the Techincal Service Department of QuickSlide™ at 800-295-9588 during the hours of 8 a.m.to 5 p.m. Central time, Monday to Friday.

The HemaPRO should only be used with the provided external power supply. The external power supply is a Class I supply that must be connected to an earthed (grounded) main power outlet. Failure to connect the HemaPRO as specified will prevent the electrical safety protections features to function as designed.

4.0 MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies, Wright-Giemsa Stain Kit (Cat. No. QS-29000), Bibulous Paper, slide blotting paper (Cat. no. 28511007), Coplin Jars (Cat. no. VCJ001), Microscope lens cleaner (Cat. no. Z97), Lens Paper, non-linting (Cat. no. 52846001), Cuvette Swabs (Cat. no. AGS-SW-1000), Fisherbrand, 1” X 3”, Extra-Thick, Microslides, Pre-cleaned, Ground Edges, Frosted End (Cat. No. 1255011), Immersion Oil, Microscope (1423PH) are required but not provided.

5.0 REAGENT SUPPLY KIT

5.1 General Information

The HemaPRO accomplishes automatic hematology staining by systematically staining, buffering, and rinsing the provided biological specimen. It is critical for the success of this automated process that these unique reagents be obtained from QuickSlide™.

NOTE: For quality control purposes, Reagent Supply Kits are labeled with a Kit Number, Lot Number, and Expiration Date. These values are used to track and identify the Reagent Supply Kit used in the unit. The machine tracks the number of stain cycles that a reagent kit performs through the reagent kit module that is included with each reagent kit. Be sure to plug this into the right side of the machine with each new reagent kit.

5.2 Ordering Information

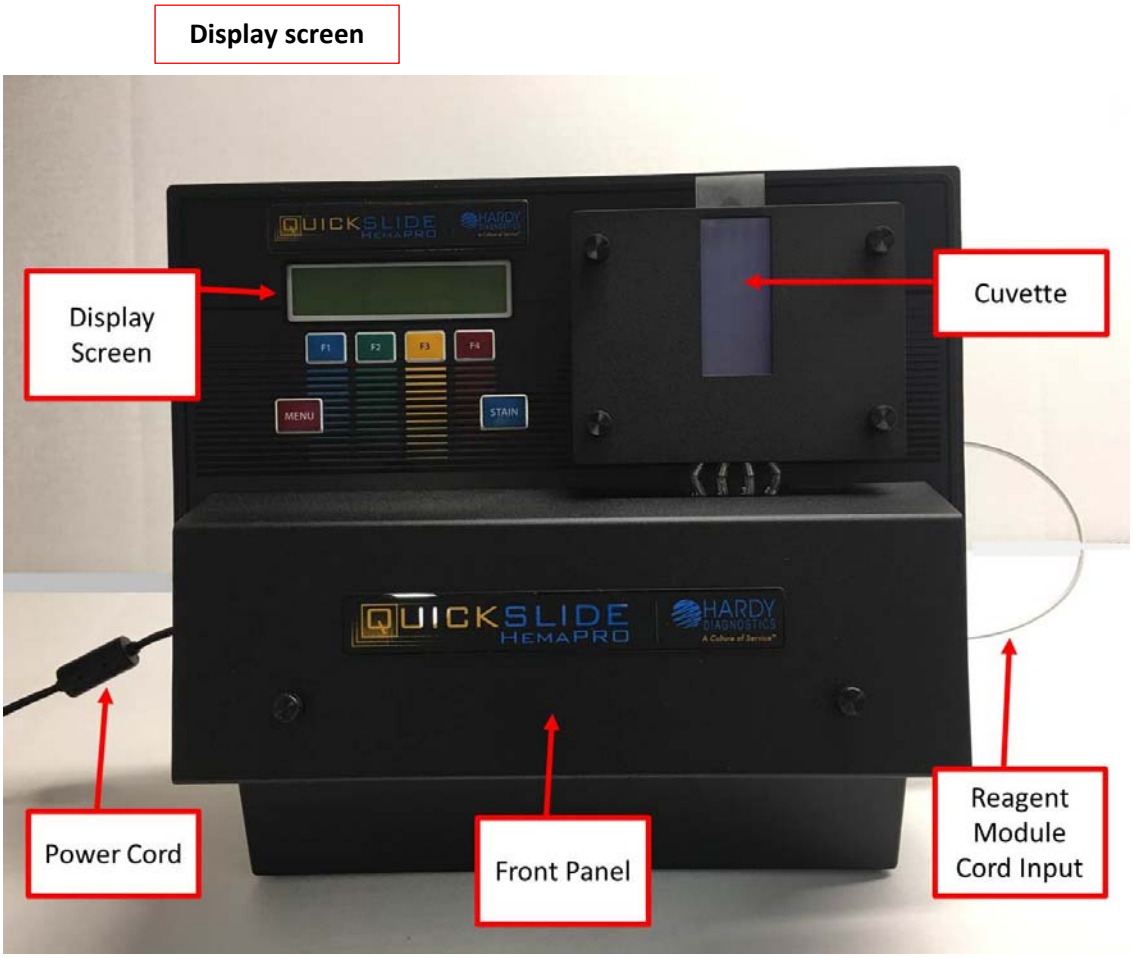
The HemaPRO reagent module regulates the consumption of the Reagent Supply Kit. When starting each stain cycle, the system displays a count of the remaining number of stain cycles available in the current kit. The remaining count should be carefully monitored so that fresh reagents may be ordered and available when needed. Call Hardy Diagnostics Customer Service at 800-266-2222 to order supplies.

5.3 Reagent Kit Installation

The HemaPRO reagents are supplied to the unit through cannulas connected to the individual reagent containers. Each tube cannula is clearly labeled, and must be inserted into the correct reagent container. The waste tube should be placed in a drain or waste container. Use care to ensure the lines are properly connected before powering on the HemaPRO unit.

6.0 OPERATIONS OVERVIEW

6.1 Instrument Diagram



The basic anatomy of the HemaPRO is identified in the diagram above and will be discussed in the procedures that follow.

Display screen – the screen that prompts which buttons to select for procedures. Buttons are color coded to more easily differentiate options.

Cuvette – holds the slide during the stain procedure.

Front panel – covers the reagent supply pumps and waste drain pumps.

Reagent module cord input – where the reagent module plugs into the machine.

6.2 Specimen Slide Preparation

6.2.1 Blood Specimen [1]

6.2.1.1 For a blood, smear use a clean slide with a frosted end. Fill a capillary tube at least ¾ full with well-mixed blood. Place a drop of blood approximately 4 mm in diameter on the slide, approximately 0.5 cm from the frosted area.

6.2.1.2 Pick up a second clean slide; this will be used as the spreader slide. Do not touch the spreading edge (short, non-frosted edge) with your hands. Place the spreading end of the spreader slide at a 30-40 degree angle on the slide in front of the blood droplet. The entire short edge of the spreader slide should be in complete even contact with the lower slide. Using your other hand, pin the lower slide to the countertop to prevent it moving. In one smooth motion, draw the spreader slide back through the entire drop of blood. Once the blood spreads along the edge of the spreader slide, push the blood forward along the length of the lower slide. The blood should run out before reaching the end of the slide. This will produce the “feathered edge” and a mono-layer of blood cells on the slide. The smear should extends no more than ¾ along the length of the slide.

6.2.2 Bone Marrow Specimen [2]

6.2.2.1 Bone marrow smears should be prepared immediately following aspiration. The aspirate should be expelled into a small plastic or siliconized glass dish. Use a Pasteur pipette to pick up the spicules. Then place one drop 0.5cm from the frosted end of the slide. Place another glass microscope slide in front of the specimen at an angle of approximately 30 degrees. Pull the spreader slide back to make contact with the specimen, and then push the spreader forward in a smooth action, in contact with the slide.

6.2.3 Methanol Fixation

6.2.3.1 Fixing the specimen causes the cells to adhere to the glass slide to make possible the subsequent rinsing of the smear with water without the significant loss of cells. This can be accomplished by methanol fixation. For best results, it is required that the methanol method be used, rather than heat, since it superior in preventing lysis, distortion, or damage to the cells in clinical material. Red blood cells and white blood cells will not be harmed, whereas heat may distort or disrupt the cells.

6.2.3.2 Methanol Fixation Procedure: Air-dry the specimen. If the heat block must be used, do not set the temperature above 40°C, and do not leave the slides on the block for over an hour. It is extremely important that the specimen does not get damaged by excessive heat. Once fully dried, fix by submerging the slide in the Coplin jar filled with methanol. Please ensure that the methanol covers the whole smear. Drain off remaining methanol without rinsing by tapping the bottom edge of the slide to a paper towel and allow the slide to air dry. Do not apply heat after the methanol dries.

NOTE: Because the slide preparation technique can vary from institution to institution and technique is not always controllable (i.e., differences in smear thickness, fixation techniques, drying time, specimen adherence to different types and brands of slides, etc.). Rare instances of carryover of specimen from slide to slide can occur. The chance of this can be minimized by carefully following the instructions in this manual.

7.0 OPERATING INSTRUCTIONS

7.1 General Guidelines

7.1.1 Ensure the specimen smears are methanol fixed and dried before placing them into the cuvette. Do not place the slide in the cuvette unless the display instructs you to do so.

7.1.2 Use high quality, clean slides. We recommend Cat. No.1255011. Slides that have a different thickness may have variable staining results.

7.1.3 Replace the Tubing Kit every 6 months. Refer to section 7.4 for step by step procedure for replacing the tube kit.

7.1.4 Do not leave the stained slide in the cuvette for an extended period of time as this could result in an altered stain quality.

7.2 Instrument Preparation

7.2.1 Remove the two thumb screws to open the front panel that is covering the pump tube rollers and attach all four orange pump tubes around their pump rollers. When installing a new pump tube kit, refer to section 7.4 for detailed instructions.

7.2.2 Open the HemaPRO Reagent Kit (Cat. No. QS-29000) and remove the heat seal on the opening of each bottle.

7.2.3 Separate all four of the clear lines and check the integrity of the lines, making sure there are no significant kinks or cracks in the tubing. Wipe the ends of the four color coded cannulas with an alcohol swab and insert them into the corresponding bottles of reagents.

7.2.3.1 Place the "**Stain**" line that has a **blue tag** into the Wright-Giemsa Stain bottle.

7.2.3.2 Place the "**Rinse**" line that has a **white tag** into the Wright-Giemsa Rinse bottle.

7.2.3.3 Place the "**Buffer**" line that has a **green tag** into the Wright-Giemsa Buffer bottle.

7.2.3.4 Place the "**Waste**" line that has a **red tag** into an established waste disposal container. Waste disposal regulations vary according to jurisdiction. Please dispose of waste according to your facility and local regulations.

7.2.4 Remove the reagent pack module (the short cord that looks like a phone cord) from the reagent pack box. Connect the reagent pack module to the receptacle on the right-hand side of the instrument.

NOTE: If the Reagent Pack module is not plugged in when the unit is turned on, the message "SELF-TEST FAILURE: Pack not connected" will appear. Turn unit off, connect Reagent Pack and turn unit on to continue.

The HemaPRO will only accept stain packs with an included module sold by Hardy Diagnostics QuickSlide™ to ensure optimal results. The instrument is calibrated only for these reagents. The use of other stain packs or solutions will produce unreliable results and void the warranty.

7.3 Stain Procedure

7.3.1 Plug the power cord into the left-hand side of the instrument, directly above the on/off switch. Make sure the power is turned off and then plug the wall transformer into the wall.

7.3.2 Power the instrument on. The instrument will perform a Self-Test during which all supply lines will be properly primed. Once the Self-Test is finished, the cuvette will drain and the instrument will display an option to prime **<F1>**, or to continue **<F4>**.

7.3.3 Select the blue **<F1>** button two separate times. This will Prime the unit **twice** before staining slides (Press <F1>, allow a prime to run. Once the first run is complete, press <F1> again to proceed through the second round of priming).

7.3.4 Once priming of the instrument is complete, press the red **<F4>** button to continue. This will bring you to a menu where the desired stain type can be selected. Press **<F1>** for a **blood smear**. Press **<F4>** for a **bone marrow smear**.

7.3.5 Before placing the slide in the cuvette, press the red **<F4>** button to prepare the cuvette for staining.

NOTE: Do not place the slide into the cuvette until the display screen reads: "**NOW load slides THEN press STAIN to Time!**"

7.3.6 When prompted, load the fixed slide into the cuvette with the specimen facing out towards the front (facing you). Once the slide is loaded' press the blue **<STAIN>** button.

NOTE: for best results, use Hardy Diagnostics recommended blank slides (Cat. no. 1255011).

7.3.7 Once the staining process is complete (about one minute for blood smears), promptly remove the slide from the cuvette and press the red **<F4>** button to continue.

NOTE: DO NOT leave slide in the cuvette after staining. The stain quality is best when the slide is promptly removed from the cuvette and dried.

7.3.8 Wipe the back side of the slide and let it completely dry before viewing the slide under the microscope.

7.4 Tube Kit Replacement

The orange pump tubes and the clear/opaque lines with color coded cannulas must be replaced every six months.

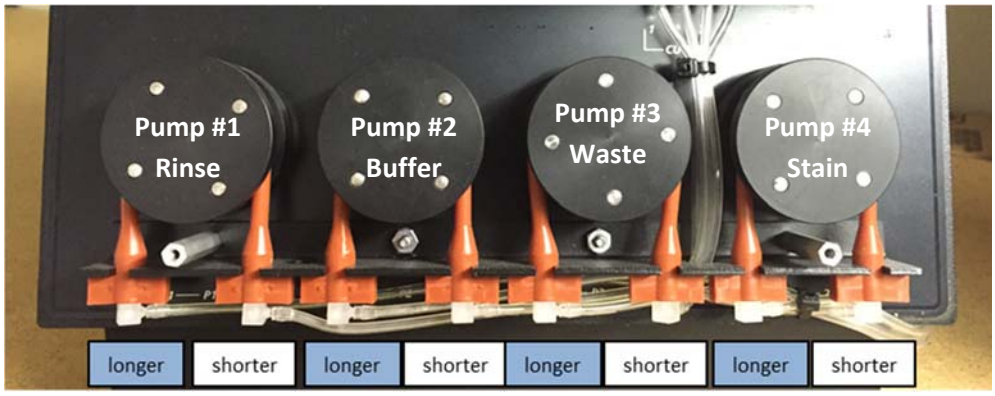
7.4.1 Empty the waste container.

7.4.2 Remove the three reagent cannulas labeled "**Stain,**" "**Buffer,**" and "**Rinse**" from the stain bottles and place them all into the empty waste container.

7.4.3 Run two prime cycles while these cannulas are in an empty waste container in order to purge all of the fluid from the old cannulas.

7.4.4 Power the instrument off.

7.4.5 Unscrew the two thumbscrews holding the front panel pump cover in place. This will expose the four pump tube rollers, the orange pump tubes, and the reagent lines.



7.4.6 First, remove the orange pump tubes off of the rollers.

7.4.7 Pull the bottom "T" of the orange pump tube so that it is free of the black rack that holds the pump tubes in place.

7.4.8 Using a hemostat or forceps (tweezers), pull the clear lines straight down from where they connect to the base of the cuvette chamber to completely remove the tube kit from the machine.

Removal of the cannulas can be difficult. Pull the tubes off of the cuvette using a hemostat or forceps. DO NOT use a lubricant to remove or replace cannula tubing. This will cause a poor seal to occur and could cause leakage from the tubes during the staining process.

7.4.9 Replace the tube sets one at a time, starting from left to right. The longest lines are to be positioned on the left side of the orange pump tubes, and the shorter lines on the right side of the pump tubes. Pull the shorter tube of each line through the hole and connect to the correct metal connector at the base of the cuvette. Refer to the image above for clarification.

7.4.10 After installation, power the instrument on as explained in Section 7.3.1-7.3.4.

8.0 SYSTEM SOFTWARE OPERATION

8.1 Stain Time Customization

8.1.1 Press the red "**Menu**" key. This allows for customization of stain and buffer times for both blood and bone marrow stains separately.

NOTE: The recommended factory setting for **blood specimen** is a 30 second stain and a 30 second buffer. The recommended factory setting for **bone marrow specimen** is a 180 second stain and a 180 second buffer.

NOTE: If the stain and buffer times are adjusted to anything other than the factory settings, the technician will have to reset those stain and buffer times with the installation of each new reagent kit.

8.1.2 Stain and buffer times are changed in five second intervals. Press the green **<F2>** key to increase staining time and press the blue **<F1>** to decrease staining times. Press **<F4>** to save the custom stain and buffer times.

8.2 Sound Settings

8.2.1 Press the red "Menu" key until it brings you to the sound setting options menu. Press the blue **<F1>** button to turn the alerts off and red **<F4>** button to turn the machine alerts on.

NOTE: It is not recommended that the sound be turned off, as these alerts are meant to inform the technician when the machine needs attention.

8.3 Setting Fill Levels

The fill levels for this machine are factory set for a standard 1" X 3" X 2mm glass slide. We recommend Cat. No.1255011.The fill levels can be customized to fit the operator's preferences.

8.3.1 Prime the unit twice, press the blue **<F1>** button**,** before resetting fill levels.

8.3.2 Once the unit is primed, power the instrument off.

8.3.3 Place a blank 1" X 3" X 2mm slide into the cuvette. A slide must be loaded before fill levels can be adjusted.

8.3.4 Power the instrument back on and wait for the Main Menu to appear.

8.3.5 Once this appears, power the instrument off once again.

8.3.6 While the machine is off, hold down the red **<F4>** button. While still holding the **<F4>** button, power the instrument back on.

8.3.7 Once the instrument is powered back on, select the red **<F4>** button again.
8.3.8 If the cuvette has any residual fluid remaining, press and hold the blue **<F1>** button until it has emptied completely. When cuvette is completely empty, press the red **<F4>** button, this will set the "empty" level for the cuvette.

8.3.9 With the slide still in cuvette, press and hold the green **<F2>** button until the cuvette fills up to the desired level with stain. Release the **<F2>** button when the desired stain fill level has been met.

8.3.10 Press the blue **<F1>** button to drain the cuvette until it is empty. Press the red **<F4>** button when the cuvette is completely empty.

8.3.11 Use the red **<F4>** key to set both fill levels for the rinse and buffer. These levels are set simultaneously. Once these levels are set, drain the cuvette.

8.3.12 To save the new fill levels, press the **MENU** button. The unit will automatically save the fill levels and cycle back to the Main Menu.

Fill levels set without a 1" X 3" X 2mm slide inserted in the cuvette during programing will result in incorrect fill levels. This will lead to overflow of the reagents onto the operating area. This can lead to possible damage of the unit's surroundings.

9.0 SERVICE AND SUPPLIES

If a problem is encountered that is beyond the scope of this manual or additional assistance is required, contact our QuickSlide™ Technical Support Team at (800) 295-9588.

If additional supplies are needed, reagents and tubing kits can be ordered through Hardy Diagnostics Customer Service. Call (800) 266-2222, or got to www.HardyDiagnostics.com. Alternatively, you can contact your preferred distributor.

Catalog Number	Description
QS-29000	HemaPRO Stain Kit
QS-002	HemaPRO Replacement Tubing Kit
1255011	Fisherbrand, 1" X 3", Extra-Thick, Microslides, Pre-cleaned, Ground Edges, Frosted End

10.0 Safety Data Sheets

Safety Data Sheets (SDS) for any associated reagents kits can be found at www.HardyDiagnostics.com.

11.0 References

1. *Samples for Hematology*. 2014. Cornell University College of Veterinary Medicine, Ithaca, NY.

2. Lee, S.H., et al. 2008. ICSH Guidelines for the standardization of bone marrow specimens and reports. *International Journal of Laboratory Hematology*.

12.0 HemaPRO Warranty

What is Covered. Hardy Diagnostics (Seller) represents and warrants to Buyer that all products shipped by Seller to Buyer, as of the date of such shipment, shall conform in all material respect to the specifications last published at www.HardyDiagnostics.com before the time of shipment of the products. SELLER MAKES NO OTHER WARRANTIES TO BUYER, EXPRESS OR IMPLIED, AND HEREBY EXPRESSLY DISCLAIMS ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

What Is Not Covered. This warranty does not cover any claims, actions, losses, damages, demands, liabilities, costs or expenses, including attorney's fees or expenses, whether a suit or other proceeding is initiated or not, which may arise from, but not limited to, the following events: (i) misrepresentations made by Buyer, (ii) any neglect by Buyer or end-users, (iii) Buyer's or end-users' use of products not in compliance with published specifications thereto or not for their intended purposes, (iv) Buyer's or end-users' modifications or alterations of products, (v) damage from Buyer or end-user misuse, or operation outside of the environmental specifications for the products, or (vi) any other act, or failure to act, not in accordance with the terms and conditions of this warranty by Buyer. SELLER HEREBY EXCLUDES AND IN NO EVENT SHALL BE LIABLE TO BUYER FOR SPECIAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS.

For the reliable operation of the QuickSlide instruments, use of the QuickSlide brand of reagents, and for the GramPRO instruments, use the PROBond slides with superior specimen adhesion, is required. The use of other brands will void this warranty.

How Long Coverage Lasts. This warranty lasts for a period of twelve months from the time of shipment, except for products that have an expiration date, in which case the warranty lasts until the expiration date. Before an instrument warranty expires or is close to expiration, customers may purchase up to four (4) successive extended warranty renewals each covering a period of twelve (12) months from the date of purchase of the extended warranty.

What Hardy Diagnostics Will Do. This warranty provides that Seller will either replace the product upon its return or, alternatively, credit Buyer's purchase price for the product upon its return, at Seller's option, and that this remedy is intended to be the sole and exclusive remedy of Buyer.

The liability of Seller under this warranty, whether in contract, tort, or otherwise, shall not, except as expressly provided herein, exceed Buyer's purchase price on which such liability is based.

How to Get Service. In order to be eligible for service under this warranty, the problem must be reported to Seller in writing within five business days after it becomes apparent while the warranty lasts, provided an opportunity is afforded for examination of the purchase by Seller.

Governing Law. This warranty shall be governed by the Uniform Commercial Code as adopted in the State of Wyoming.

13.0 Training Checklist

Trainee Name: _____

HemaPRO Training Checklist

Refer to the user manual for each item on this checklist. Check the box for each item trained.

Trainee's Initials

_____ Specimen Slide Preparation: Section 6.2

_____ Loading Slides: Section 7.3.5, Section 7.3.6

_____ Instrument Preparation: Section 7.2

_____ Explanation of Stain Processing: Section 7.3

_____ Explanation of Display: Section 7.3.2, Section 7.3.3, Section 7.3.4

_____ General Maintenance: Section 7.1

_____ Registering Reagent Kits: Section 7.2.4

_____ Tubing Kit Change: Section 7.4

Trainee Signature: _____ Date: _____

Trainer Signature: _____ Date: _____