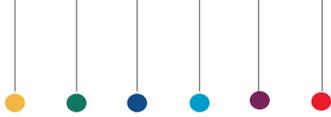


DxH 520

PERFORMANCE VERIFICATION WORKBOOK





WARNING AND PRECAUTIONS NOTICE

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT.

BECKMAN COULTER, INC. URGES ITS CUSTOMERS AND EMPLOYEES TO COMPLY WITH ALL NATIONAL HEALTH AND SAFETY STANDARDS SUCH AS THE USE OF BARRIER PROTECTION/ THIS MAY INCLUDE, BUT IS NOT LIMITED TO, PROTECTIVE EYEWEAR, GLOVES, SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY EQUIPMENT.

INTENTION FOR USE

THIS WORKBOOK IS FOR TRAINING USE ONLY. IT IS NOT INTENDED TO REPLACE YOUR INSTRUMENT'S INSTRUCTION FOR USE DOCUMENTATION. CURRENT IFU'S CAN BE FOUND ON BECKMAN COULTER'S WEB SITE AT BECKMANCOULTER.COM. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATION FOR INTENDED USE.

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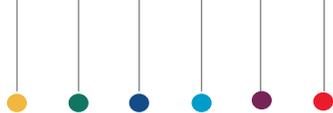
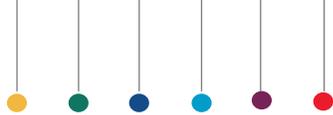
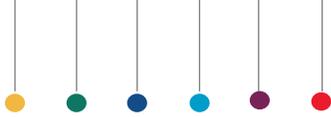


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WELCOME

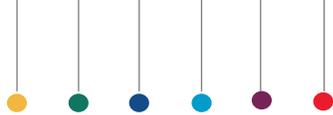
Welcome!

Beckman Coulter Inc. has created this workbook to serve you as a place to keep important implementation documents for later reference.

The installation and performance verification process will consist of the following main steps listed within the table below and who will be the key individual responsible with completing these steps:

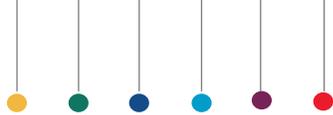
Procedures	Responsibility
Pre-Site Installation Checklist	Beckman Coulter Associates
Instrument Installation	Field Service Engineers
Basic Operation	Field Service Engineers
Precision/Repeatability	Laboratory Key Operator
Carryover	Laboratory Key Operator
Calibration	Laboratory Key Operator
DxH 500 Linearity Kit	Laboratory Key Operator
Reference Range Studies 20 donors (Male & Female)	Laboratory Key Operator
Correlation Studies Minimum 40 donors	Laboratory Key Operator
Truth Table Analysis Minimum 100 donors	Laboratory Key Operator
IQAP Enrollment	Laboratory Key Operator

Each of these steps will be covered as a chapter in this guide, additional training opportunities may be available at a later date, therefore check online at www.beckmancoulter.com for latest offerings and advance topics.



The following icons will be used throughout this guide:

	<p>This symbol indicates you are ready to complete this section of your implementation workbook. Before beginning any section assure yourself you have the required materials and the necessary time required to complete the section.</p>
	<p>This symbol indicates useful tip.</p>
	<p>This symbol indicates special items to remember.</p>
	<p>This symbol indicates a For Your Information to remember.</p>



HEMATOLOGY CUSTOMER SUPPORT CONTACTS

SALES AND SERVICE OFFICES FOR SERVICE OR TECHNICAL INFORMATION

CUSTOMER TECHNICAL SUPPORT CENTER / SERVICE

United States.....800 526-7694

ORDER ASSISTANCE

United States.....800 526-3821

BECKMAN COULTER

Web Site.....www.BeckmanCoulter.com

DxH 500 Series Data Submission

United States.....HemImplementation@Beckman.com

Sales Office:

250 South Kraemer Boulevard
Brea, CA. 92821
800 526-3821

Instrument Model _____

Serial Number _____

SID#/Instance#: _____

IQAP Participant # _____

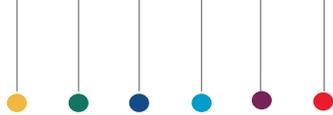
Your Account#: _____

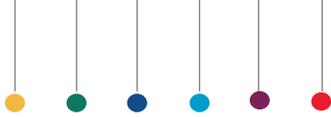
Customer Service Representative: _____
(Order/Contract Assistance)

Applications Specialist: _____

Field Service Engineer: _____

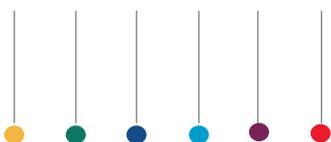
Instrument Sales Representative: _____





BEFORE YOU BEGIN

The DxH 520 Workbook is designed to assist you in making a smooth transition integrating your new Hematology System into your laboratory. Please take the time to review this book thoroughly. Within this Workbook you will find guidelines for evaluating your new analyzer. You will find procedures and worksheets to assist you with each stage of the verification process. Please note that the procedures provided outline the general steps for characterizing the performance of your new system. Your current laboratory policies or your local regulatory agency may dictate more specific procedures for your laboratory to follow. We suggest that you use this DxH 520 Workbook to store all of your installation records and subsequent characterization data for your system. We hope you will find the information contained in this manual a useful tool for making a smooth transition to your new hematology system.



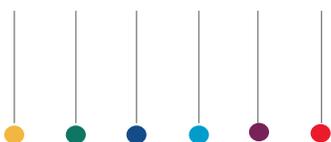
ABOUT CLIA '88

Much has been said and written about the impact of the **Clinical Laboratory Improvement Amendments of 1988** (CLIA'88) on the laboratory and method evaluation.¹ It is often confusing to determine what is needed for accreditation and certification for the different types of testing categories.

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).

The following procedures will assist you in the evaluation of a new instrument or clinical test. Not all of these procedures are required by CLIA; however, some of them may be required by the College of American Pathologists (CAP), the Joint Commission of Accreditation of Healthcare Organizations (known as JCAHO), and/or individual agencies. It is important to know local requirements as well as those of any other accrediting agencies that will impact your laboratory. The data generated from some of these procedures will help to establish the baseline characterization of your system.

Your laboratory must compile its own policies and procedures manual for method evaluation in compliance with the appropriate accrediting agencies. You are empowered to make your own decisions as to what procedures are appropriate, and which performance limits or specifications are acceptable.



PRE-SITE INSTALLATION CHECKS

We recommend that the individual responsible for the implementation of the instrument in your lab participate in the pre-installation checks with the Beckman Coulter Field Service Engineer. This may be the key operator, laboratory consultant, supervisor, or the physician. In this section you will verify the minimum instrument requirements regarding space and accessibility requirements and electrical requirements as well as operational ambient temperature, humidity and altitude requirements. To help guide the Beckman Coulter Field Service Engineer and you through the DxH 520 pre-installation checks, we provide a checklist. The checklist will assist with completing the pre-installation checks prior to the installation of the DxH 520 instrument by a certified Beckman Coulter trained Field Service Engineer. This section is intended to be a storage area for the DxH 520 Pre-Installation Checklist.

Responsibility:

- Beckman Coulter Associates

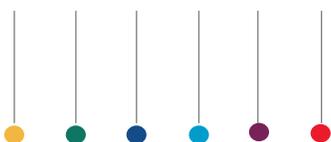
Materials Needed:

- Pre-Site Installation Checklist.

Time Required:

- Approximately ½ hour





INSTRUMENT INSTALLATION

Once your DxH 520 Hematology System arrives at your institution with the DxH 500 Series reagents, calibrators, controls, and linearity kit, you will need to carefully inspect the instrument carton and determine if all reagents are received within the proper temperature. If you see signs of mishandling, damage, or incorrect temperature, contact our customer service representative by calling 800-223-0130. Installation of the DxH 520 instrument will be performed by a certified Beckman Coulter trained Field Service Engineer. The system will be positioned on a table in a secure location away from any vibration, electromagnetic interference, or combustible materials. The instrument will require at least 4 feet of counter space and be within 6 feet of an electrical outlet.

Responsibility:

- Beckman Coulter Field Service Associate

Materials Needed:

- DxH 520 Hematology Instrument
- DxH 500 Series Controls, Calibrators and the DxH 500 Linearity Kit
- DxH 500 Series Diluent, Lyse and Cleaner reagents

Time Required:

- Approximately 3 hours

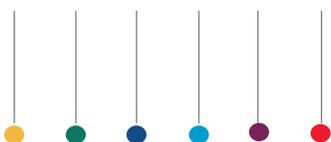
Important Note:

- The DxH 500 Series Controls, and Calibrators and DxH 500 Linearity Kit should be stored upright at 2 – 8°C when not in use. Protect tubes from overheating and freezing.



Now:

- Complete DxH 520 Instrument installation



BASIC OPERATION

To complete the required procedures for instrument implementation, you will need to know how to process patient samples through your new instrument.

Several tools are available to guide you. The reference for instrument operation and performance is found in the Instructions for Use. Future updates of this document can be found on the Beckman Coulter website at www.beckmancoulter.com.

To simplify your basic training, a Beckman Coulter trained associate will facilitate your DxH 520 basic operation training. Topics that will be covered during your instrument training are: Software and Hardware system overview, System Operations which includes Startup, Daily Checks, Instrument Setup, Shutdown and Quality Control Setup. Additional training topics will include processing quality controls, patient samples analysis, and maintenance. Extra training opportunities can be found on the Beckman Coulter Learning Lab at www.beckmancoulter.com.

Responsibility:

- Laboratory Key Operator and Beckman Coulter Field Service Associate

Materials Needed:

- **DxH 520 In-Laboratory Training Guide**
Provided in the Beckman Coulter website is the DxH 520 In-Laboratory Training guide. This training guide provides easy-to-follow one-page overview of daily procedures.
- **DxH 520 Instructions for Use**
Also provided in the Beckman Coulter website is the DxH 520 Instructions for Use. This will contain a more detailed description of the DxH 520 Instruments along with a training checklist and for Use training procedures and installation steps beyond the Quick Start Installation Guide above.
- **DxH 520 Training Checklist and Implementation Checklist**

Time Required:

- Variable



Now:

- Complete your Basic Operation Training

Important Note: To access the additional training module:

- Go to www.beckmancoulter.com
- Under Resources
 - Select Training Courses
- Register New Account or Login to your existing account
 - New Account: Fill out the form with your address and account information.
 - Existing Account: Click on Login
- Enter your Username or Email and password
- Click on the training eLearning modules.



Remember!

For data submission and non-urgent inquiries on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com

Precision/Repeatability

Repeatability is the closeness of agreement between the results of successive measurements on the same substance carried out under the same conditions of measurement. Also known as reproducibility, precision, within run precision, within-assay, within-run, intra-assay, and intra-run precision.

A Repeatability procedure is required by your regulatory agency or your own laboratory protocol. This procedure may be used at any time to verify the precision of the instrument. This section is intended to be a storage area for the DxH 520 instrument Repeatability printout.

Responsibility:

- Laboratory Key Operator

Materials Needed:

- 1 fresh EDTA tube of blood, enough for a minimum of ten cycles
- 3 Additional tubes

Time Required: Approximately 1 hour



Important Note: Capped samples cannot be pierced more than four times. When an uncapped whole-blood is processed, separating the blood into three tubes is not necessary.

Now:

- Running Repeatability procedure



Precision/Repeatability

Remember!

Risk of loss of data. When performing a Repeatability, do not leave the screen until you have finished analyzing the required number of replicates.

Running Repeatability on DxH 520 Analyzer

STEP	ACTION
1	Separate the whole-blood sample into three tubes. NOTE: Capped samples cannot be pierced more than four times. When an uncapped whole-blood is processed, separating the blood into three tubes is not necessary.
2	Select the QC/QA icon  from the main menu.
3	On the Quality Control (Data View) screen, select the QA icon  .
4	A dialog box will appear, select the Repeatability icon  .
5	If existing data is present, a warning box will appear with the following message: <i>Repeatability table contains data. To run, repeatability data must be deleted. Print repeatability data before deleting or delete data without printing.</i> Make your selection and select the OK icon  to continue.
6	Mix the sample.
7	Fully insert the whole blood sample into the tube holder and select the Run icon  . The sample trap door will automatically close to initiate the analysis.
8	The status LED flashes red when aspiration is in progress and turns solid red throughout processing.
9	Remove the specimen tube when the sample trap door opens and the status LED is green.
10	Continue to mix the specimen tube.
11	Wait for the instrument to process the specimen and to display the results in the Repeatability screen. The instrument automatically saves the results into the database.

Precision/Repeatability

12	Complete the require number of aspirations (N=10). Replace each tube after four replicates. <u>Ensure that the sample is mixed between runs.</u> Review the Repeatability results.
13	Inspect the results for outliers and verify the CV or SD does not exceed the established Repeatability limits. See Repeatability in Chapter 1, System Overview in the DxH 520 Instructions for Use.
14	If the results fail, there could be an instrument problem; see Quality Assurance Troubleshooting in the Instructions for Use or call your Beckman Coulter Representative. Do not continue.
15	Select the Functions icon 
16	Select the Export icon  and the OK  icon to download the Repeatability runs.

Quality Assurance Troubleshooting: Repeatability

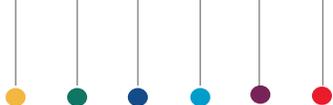
Procedure	Issue	Action
Repeatability	> % CV Limit	<ul style="list-style-type: none"> • Ensure that scheduled maintenance procedures have been performed. • Use a sample within the ranges noted in the specification. • Check for an outlier. • Repeat the test • If repeatability fails again, contact your Beckman Coulter Representative.



Note:

- For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com.





Carryover

Carryover is the amount, in percent, of sample remaining in the system and picked up by the next sample cycled. Low-to-high carryover is the amount of sample with low cell concentrations carried over to samples with high cell concentrations, such as diluent to blood. High-to-low carryover is the amount of samples with high cell concentrations carried over to samples with low cell concentrations, such as blood to diluent.

A Carryover procedure is required by your regulatory agency or your own laboratory protocol. This procedure may be used at any time to verify the performance of CBC parameters. Most Beckman Coulter hematology instruments have a high to low carryover test procedure that automates running samples and does the statistical calculations. This section is intended to be a storage area for the DxH 520 instrument Carryover printout.

Responsibility:

- Laboratory Key Operator

Materials Needed:

- 1 fresh EDTA tube of blood
- 3 Additional tubes labeled Diluent 1, Diluent 2, Diluent 3

Time Required: Approximately ½ hour



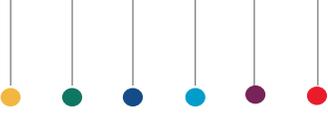
Remember!

Risk of loss of data. When performing Carryover, do not leave the screen until you have finished the entire procedure.

Now:

- Complete Carryover procedure





Carryover

Running Carryover on DxH 520 Analyzer



STEP	ACTION
NOTE:	Materials Required: One tube of whole blood Three tubes labeled Diluent 1, Diluent 2 and Diluent 3 (for use in step 2)
1	Dispense diluent by selecting the Diagnostics Icon  from the main menu.
2	Select DILUENT DISPENSE. Have a tube ready for the diluent to be dispensed and select the OK icon  to automatically dispense the diluent into each of the three labeled tubes.
3	Select the QC/QA icon  from the main menu.
4	From the Quality Control (Data view) screen, select the Quality Assurance icon  .
5	From the QA dialog box, select the Carryover icon  .
6	From the Carryover screen, select the Start icon  .
7	Select the OK icon  to delete existing information, if present.
8	Fully insert the specimen tube into the tube holder and select the Run icon  . The sample trap door will automatically close to initiate the analysis. Ensure to mix the sample gently between each cycle and repeat this process two more times.

Carryover

9	<p>Fully insert the tube labeled Diluent 1 into the tube holder and select the Run icon . Repeat process with tubes labeled Diluent 2 and 3.</p>
10	<p>Verify carryover status displays PASS. If the results fail, there could be an instrument problem; see Quality Assurance Troubleshooting in the Instructions for Use or call your Beckman Coulter Representative. Do not continue.</p>
11	<p>Select the Functions icon .</p>
	<p>Select the Export icon  and the OK  icon to download the carryover runs.</p>

Quality Assurance Troubleshooting: Carryover



Procedure	Issue	Action
Carryover	> Carryover % Limit	<ul style="list-style-type: none"> Obtain fresh diluent. Repeat the carryover test. Contact your Beckman Coulter Representative.

Note:

- For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com.



Calibration

Calibration procedure is used to set an instrument at a specific value or values using a reference method.

When the calibration procedure is performed under the following conditions, it will assure the following:

- DxH 520 instrument data output accurately reflects sample input.
- Demonstrate that the performance of the instrument is consistent with the manufacturer's claims.
- Assure when to verify vs. when to calibrate your instrument.
- To bring an established method, device or analytical system online.
- Demonstrate acceptable performance as follow-up corrective actions taken after a failed proficiency-testing event.

The DxH 500 Series Calibrator is designed for the determination of calibration factors for the DxH 500 Series Systems in conjunction with specific DxH 500 Series reagents.

Responsibility:

- Laboratory Key Operator

Materials Needed:

- DxH 500 Series Calibrator

Time Required: Approximately 1 hour

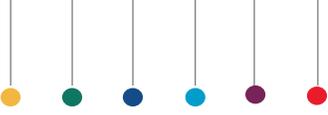


Important Note: The DxH 500 Series Calibrator should be stored upright at 2 – 8°C when not in use. Protect tubes from overheating and freezing. Unopened tubes are stable until the expiration date. Opened tubes are stable for 5 days, provided they are handled properly.

Now:

- Prepare for calibration





Calibration

Summary and Explanation

It is important that we remember that a Hematology calibrator cannot, by nature of the product, be an “absolute” constant. The product does contain a standard or exact number of cells at its creation and they are preserved to ensure a certain amount of time in which the product can be used. However, as these are viable cells, they can undergo changes due to handling that can alter the final values. The parameters most commonly affected are the RBC (cells may lyse if frozen or overheated), MCV, and Plt (may increase if there is stroma from RBC lysis). It is good practice to evaluate your current QC prior to performing the calibration procedure.

	WBC	RBC	HGB	MCV	PLT	MPV
Abnormal Low						
Normal						
Abnormal High						
Cal Ref						
Cal mean						

When to Verify Calibration

You should verify the calibration of your instrument:

- As dictated by your laboratory procedures and local or national regulations.
- When controls show evidence of unusual trends (all levels demonstrate similar parameter recovery).
- When controls exceed the manufacturer’s defined acceptable limits.
- If the average ambient room temperature changes more than 10°F or 6°C from the calibrating temperature.

Verify the calibration by analyzing a new tube of calibrator as indicated in the calibrator’s Instructions for Use.

Calibration

Verify Instrument Functions Properly

STEP	ACTION
1	Ensure the DxH 520 instrument has sufficient volume(s) of reagents to complete the calibration procedure and ensure the DxH 500 Series reagents are not expired, or contaminated.
2	Replace the Waste container for sufficient capacity.
3	Confirm instrument is properly functioning and maintained.
4	Ensure the probe and aperture are clean prior to calibration.
5	Perform Daily Checks and confirm all statuses display "PASS".

Prepare the Calibrator

Mxing and handling directions:

STEP	ACTION
1	Remove tube from refrigerator and verify that the lot number matches the lot number on the Table of Expected Results.
2	Allow the tube to warm at room temperature (15-30°C for 15 minutes before mixing.
3	<p>To mix, hold a tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.</p> <ul style="list-style-type: none"> A. Roll the tube back and forth for 20-30 seconds, occasionally invert the tube. B. Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing. C. Gently invert the tube 8-10 times immediately before sampling.

Now: Process the DxH 500 Series Calibrator



Calibration

The Table of Expected Results provided with the DxH 500 Series Calibration kit contains the expected values for the calibrator. You will use these values during the preparation of the software for running the calibrator.

Set Up the Calibration

STEP	ACTION
1	Select the QC/QA icon  from the main menu.
2	On the Quality Control (Data View) screen, select the QA icon  .
3	A dialog box will appear, select the Calibration icon  .
4	If existing data is present, a dialog box will appear with the following message: <i>Print calibration before deleting or delete data without printing.</i> Make your selection and select the OK icon  to continue.
5	Select the Setup Calibration with Barcode icon  and scan the barcode on the Table of Expected Results, or if not equipped with a barcode scanner, select the Setup Calibration Manually icon  and enter the information using the on-screen keyboard.
6	Select the OK icon  to continue. The sample trap door automatically opens.

Calibration

Run DxH 500 Series Calibrator

Remember!

Risk of loss of data. When calibrating, do not leave the screen until you have finished analyzing the required number of replicates.

STEP	ACTION
1	Prepare the DxH 500 Series Calibrator according to the Instructions for Use. It is very important to follow the mixing directions carefully.
2	Fully insert the calibrator into the tube holder and select the Run icon  . The sample trap door will automatically close to initiate the analysis.
3	The status LED flashes red when aspiration is in progress and turns solid red throughout processing.
4	Wait for the instrument to process the calibrator and to display the results in the Calibration screen. The instrument automatically saves the results into the database.
5	Remove the calibrator when the sample trap door opens and the status LED is green.
6	Ensure that the calibrator is mixed between runs.
7	When the result is displayed, select the checkbox in the EXCL. column to exclude the first (PRIME) run. Complete the required number of aspirations (N=10).
8	Review the calibration results.

When to Calibrate

Calibrate if:

- Calibration verification fails.
- Any component involved in dilution or primary measurement was replaced. This includes the aspiration line or probe, and the apertures.
- You are advised to do so by your Beckman Coulter Representative.

Calibration

Adjust instrument calibration and verify results:

STEP	ACTION
1	To accept the calibration, touch the Accept Calibration icon 
2	Select the Functions icon 
3	Select the Export icon  and the OK  icon to download the calibration runs.
4	Verify calibration using DxH 500 Series Calibrator as indicated in the calibrator's Instructions for Use.

Quality Assurance Troubleshooting: Calibration

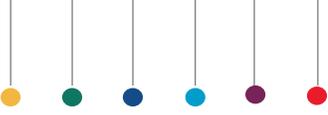


Procedure	Issue	Action
Calibration	<ul style="list-style-type: none"> • %CV • Factor % Diff • Delta Diff 	<ul style="list-style-type: none"> • Contact your Beckman Coulter Representative.

Note:

- For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com.





ABOUT DxH 500 Linearity Kit

Verification of the instrument linearity is required by your regulatory agency or your own laboratory protocol. This procedure verifies instrument specific intended use. Furthermore, CAP requirements¹³ and CLIA regulations¹⁴ both mandate that laboratories establish reportable range for each test method. Additionally, CLIA requires that laboratories verify performance specification for accuracy, precision, measuring range and reference ranges upon instrument installation and prior to patient testing².

Remember!

Please note that your laboratory may be subject to local, state, and federal regulatory laws. Different agencies may dictate more specific procedures for your laboratory to follow, therefore please contact your local regulatory agency for information on the specific requirements.

The instrument performance will need to be verified whenever new equipment is introduced to the laboratory, or when existing equipment is replaced. This documentation should be maintained with the instrument.

This section is intended to be a storage area for all instrument characterization studies printouts and for the final **DxH 500 Linearity** report.

Responsibility:

- Laboratory Key Operator

Materials Needed:

- DxH 500 Linearity Kit
- Vortex
- DxH 500 Series Calibrator
- DxH 500 Series Control
- DxH 520 Instructions for Use

Time Required:

- Approximately 3 hours

Now:

- Process DxH 500 Linearity (as follows)



PROCESS DxH 500 Linearity



Important Note: The DxH 500 Linearity should be stored upright at 2 – 8°C when not in use. Protect tubes from overheating and freezing. Unopened tubes are stable until the expiration date. Opened tubes are stable for 5 days, provided they are handled properly.



You may use your instrument's Repeatability screen. Risk of loss of data. When processing the DxH 500 Linearity when using the Repeatability screen, do not leave the screen until you have finished analyzing the required number of replicates.

Verify Instrument Functions Properly

STEP	ACTION
1	Ensure the DxH 520 instrument reagents are not expired and have sufficient volume(s) of reagents to complete the linearity procedure.
2	Check the waste container for sufficient capacity.
3	Perform Daily Checks and confirm all statuses display "PASS".
4	If you have not completed a Repeatability procedure prior to this, check instrument precision by running a normal whole blood sample at least six times. Verify the parameters are within acceptable limits.
5	Verify and document that the instrument is in good calibration and is operating properly before proceeding. If necessary adjust calibration to within laboratory tolerance limits with the DxH 500 Series Calibrator.
6	Run controls to verify the instrument performance of the DxH 520.

DxH 500 RBC Linearity

Remember!

The performance of this product is assured only if it is properly stored and used as described in the DxH 500 Linearity Instructions for Use. Incomplete mixing or improper handling of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

Mixing and handling directions: **DxH 500 RBC Linearity**

STEP	ACTION
1	Remove tubes from refrigerator and allow to warm at room temperature (15-30°C) for 15 minutes before mixing.
2	<p>To mix, hold a tube horizontally between the palms of the hands. Do not pre-mix on a mechanical mixer.</p> <p>A. Roll the tube back and forth for 20-30 seconds, occasionally invert the tube.</p> <p>B. Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.</p> <p>C. Gently invert the tube 8-10 times immediately before sampling.</p>

Process the DxH 500 RBC Linearity

STEP	ACTION
1	Select the QC/QA icon  from the main menu.
2	On the Quality Control (Data View) screen, select the QA icon  .
3	A dialog box will appear, select the Repeatability icon  .
4	<p>If existing data is present, a warning box will appear with the following message: <i>Repeatability table contains data. To run, repeatability data must be deleted. Print repeatability data before deleting or delete data without printing.</i></p> <p>Make your selection and select the OK icon  to continue.</p>

5	<p>Gently invert the tube 8-10 times immediately before sampling.</p> 
6	To prime the instrument, run first level once and discard the result.
7	Test all levels from the DxH 500 RBC Linearity set in order from low to high.
8	Run each level four times per level starting with level 1 and continuing to each consecutive level up to level 6. Remember to mix the DxH 500 RBC Linearity vials between each cycle according to the Instructions for Use.
9	Inspect the results for outliers.
10	Insert a USB flash drive into the front USB port.
11	<p>Select the Function icon .</p>
12	<p>Select the Export icon .</p>
13	<p>A warning box displays the following message: <i>You are about to Export Repeatability Data. Insert USB. Continue?</i></p> <p>Select OK icon  to accept your choice or the Exit icon  to cancel the export.</p>
14	After running the highest level, perform Daily Checks and confirm all statuses display "PASS".

DxH 500 WBC Linearity

Remember!

The performance of this product is assured only if it is properly stored and used as described in the DxH 500 Linearity Instructions for Use. Incomplete mixing or improper handling of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

Mixing and handling directions: DxH 500 WBC Linearity

STEP	ACTION
1	Remove tubes from refrigerator and allow to warm at room temperature (15-30°C) for 15 minutes before mixing.
2	<p>Mix using vortex mixer.</p> <p>A. Mix vigorously by vortexing the sample on a vortexer for 2 minutes making sure a vortex is created in the tube.</p> <p>B. Let sample sit undisturbed for 10 minutes to allow micro bubbles to dissipate before sampling.</p> <p>C. Invert the tube 8-10 times immediately before each sampling.</p>

Process the DxH 500 WBC Linearity

STEP	ACTION
1	Select the QC/QA icon  from the main menu.
2	On the Quality Control (Data View) screen, select the QA icon  .
3	A dialog box will appear, select the Repeatability icon  .
4	<p>If existing data is present, a warning box will appear with the following message: <i>Repeatability table contains data. To run, repeatability data must be deleted. Print repeatability data before deleting or delete data without printing.</i></p> <p>Make your selection and select the OK icon  to continue.</p>

5	<p>Invert the tube 8-10 times immediately before each sampling.</p> 
6	<p>To prime the instrument, run first level once and discard the result.</p>
7	<p>Test all levels from the DxH 500 WBC Linearity set in order from low to high.</p>
8	<p>Run each level four times per level starting with level 1 and continuing to each consecutive level up to level 6. Remember to mix the DxH 500 WBC Linearity vials between each cycle according to the Instructions for Use.</p>
9	<p>Inspect the results for outliers.</p>
10	<p>Insert a USB flash drive into the front USB port.</p>
11	<p>Select the Function icon .</p>
12	<p>Select the Export icon .</p>
13	<p>A warning box displays the following message: <i>You are about to Export Repeatability Data. Insert USB. Continue?</i></p> <p>Select OK icon  to accept your choice or the Exit icon  to cancel the export.</p>
14	<p>After running the highest level, perform Daily Checks and until all statuses display "PASS".</p>

DxH 500 PLT Linearity

Remember!

The performance of this product is assured only if it is properly stored and used as described in the DxH 500 Linearity Instructions for Use. Incomplete mixing or improper handling of a tube prior to use invalidates both the sample withdrawn and any remaining material in the tube.

Mixing and handling directions: DxH 500 PLT Linearity

STEP	ACTION
1	Remove tubes from refrigerator and allow to warm at room temperature (15-30°C) for 15 minutes before mixing.
2	<p>Mix using vortex mixer.</p> <p>A. Mix vigorously by vortexing the sample on a vortexer for 2 minutes making sure a vortex is created in the tube.</p> <p>B. Let sample sit undisturbed for 10 minutes to allow micro bubbles to dissipate before sampling.</p> <p>C. Invert the tube 8-10 times immediately before each sampling.</p>

Process the DxH 500 PLT Linearity

STEP	ACTION
1	Select the QC/QA icon  from the main menu.
2	On the Quality Control (Data View) screen, select the QA icon  .
3	A dialog box will appear, select the Repeatability icon  .
4	<p>If existing data is present, a warning box will appear with the following message: <i>Repeatability table contains data. To run, repeatability data must be deleted. Print repeatability data before deleting or delete data without printing.</i></p> <p>Make your selection and select the OK icon  to continue.</p>

5	<p>Invert the tube 8-10 times immediately before each sampling.</p> 
6	<p>To prime the instrument, run first level once and discard the result.</p>
7	<p>Test all levels from the DxH 500 PLT Linearity set in order from low to high.</p>
8	<p>Run each level four times per level starting with level 1 and continuing to each consecutive level up to level 6. Remember to mix the DxH 500 PLT Linearity vials between each cycle according to the Instructions for Use.</p>
9	<p>Inspect the results for outliers.</p>
10	<p>Insert a USB flash drive into the front USB port.</p>
11	<p>Select the Function icon .</p>
12	<p>Select the Export icon .</p>
13	<p>A warning box displays the following message: <i>You are about to Export Repeatability Data. Insert USB. Continue?</i></p> <p>Select OK icon  to accept your choice or the Exit icon  to cancel the export.</p>
14	<p>Remove the USB flash drive from the Front USB port.</p>
15	<p>After running the highest level, perform Daily Checks and until all statuses display "PASS".</p>
16	<p>Submit your DxH 500 Linearity results to the Beckman Coulter application support team at HemeImplementation@Beckman.com.</p> <ul style="list-style-type: none"> A. DxH 520 Daily Checks and Background Results. B. DxH 500 Linearity Assay Values and Expected Ranges. C. DxH 520 Exported Results. <p>After you submit your data, a Beckman Coulter Application Specialist will prepare tabular summaries and graphic presentations of your data.</p>

ABOUT REFERENCE RANGE

The CLIA Quality System Regulations became effective on April 24, 2003. Now the laboratory is required to check (verify) the manufacturer's performance specifications provided in the package insert – for accuracy, precision, reportable range (Measuring Range), and reference range. The DxH 520 series analyzers will contain default reference ranges for Adult male and female. DxH 520 hematology systems will also contain additional age range flagging sets. These age range flagging sets are: Neonate, Infant, Child, and Adolescent.

In order to establish a reference interval/ range, the Clinical and Laboratory Standards Institute (CLSI) recommends labs collect a sufficient number of qualified reference donors to produce a minimum of 120 samples. This can be a difficult task. Therefore, CLSI strongly encourages laboratories to **verify** reference values established by the manufacturer or established by another laboratory.

To **verify** a reference interval / range:

1. If a lab has previously established a reference interval (using 120 samples) for its population, it may verify that reference interval by **transference**.
 - a. You may use transference if the original study was conducted:
 - Using the same analytical system / reagent, and
 - With similar subject population as your lab.
 - b. Perform a method comparison between your new method and the method used in the original study. You may use samples that exceed the reference interval. Evaluate the relationship between the two methods. If the new method provides values that are acceptably comparable, then the reference interval/range can be transferred
2. Or, a lab may verify a reference interval/range established elsewhere or by the manufacturer by collecting a minimum of 20 samples from qualified, healthy reference donors. Your 20 donors must fairly represent your population and the population in the original study.

PERFORM VERIFICATION OF REFERENCE RANGE

Remember!

The laboratory director and/or the Medical Laboratory consultant will need to validate the normal range studies.

This section is intended to be a storage area for all instrument installation printouts, regarding Normal Range verification.

Responsibility:

- Laboratory Key Operator

Materials Needed:

- 20 Donor (Female, Male) Whole-blood samples.
- Barcode Labels [Provided]

Time Required:

- Variable

NOTE: For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com.



References

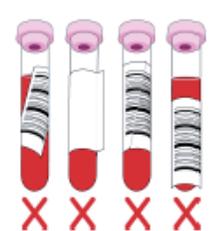
1. Clinical and Laboratory Standards Institute. Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline. CLSI document C28-A3C, 2010
2. Clinical and Laboratory Standards Institute. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline. EP09-A3, 2013.

PERFORM VERIFICATION OF REFERENCE RANGE



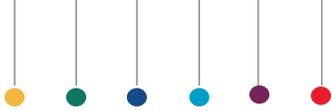
You may verify all adult normal or each sex individually. Reference range studies are typically done for Female and Male patient populations ONLY.

Reference Range Studies on the DxH 520 Analyzer

STEPS	ACTION
1	Collect whole blood in EDTA according to the tube manufacturer's instructions and procedures in CLSI GP41-A625 for venipuncture and CLSI GP42-A626 for capillary.
2	Follow the recommendations for storage and mixing shown in Sample Stability and Storage – Whole Blood in CHAPTER 1, System Overview.
3	Select (20) Female and Male specimens for the Reference Range study.
NOTE:	The correct placement of the bar-code label on the tube allows the bar-code scanner to read the information correctly.
4	<p>Affix a bar-code label to the specimen tubes. Place the bar-code label according to the image below.</p> <p>Bar-codes labels are provided within this section. [777777 Female] & [333333 Male]</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>Correct</p> </div> <div style="text-align: center;">  <p>Incorrect</p> </div> </div>
5	Specimen ID can be manually entered using the on-screen keyboard or by scanning the bar-code label of a specimen.



It is up to each laboratory to evaluate the Reference Range data and determine the acceptability and utility of the data according to the laboratory's established Policies and Procedures for method evaluation acceptance criteria.



PERFORM VERIFICATION OF REFERENCE RANGE

FEMALE BARCODE LABELS



FEMALE



FEMALE



FEMALE



FEMALE



FEMALE



FEMALE



FEMALE



FEMALE



FEMALE



FEMALE



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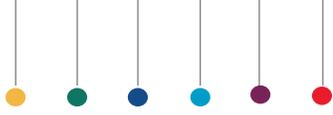
FEMALE



FEMALE



FEMALE



PERFORM VERIFICATION OF REFERENCE RANGE

MALE BARCODE LABELS



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MALE



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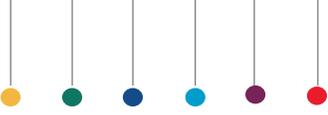
333333

MALE



333333

MALE



PERFORM VERIFICATION OF REFERENCE RANGE

Remember!

Carefully choose your samples to be included in the Reference Interval Study. Once you have samples, export the results. If a USB drive is not available, use the worksheet available in page 87.

STEPS	ACTION
1	<p>Select the Display/Run icon  from the main menu. The door automatically opens.</p> <p>NOTE: The door does not open automatically if the Worklist contains orders. Acknowledge the message displayed to open the door.</p>
2	<p>Select the Next ID icon , and from the Run Specimen-Next Specimen ID screen manually enter the barcode number or scan the bar-code label of a specimen into the Specimen ID field and continue with the selection of the Test type (CD or CBC). Verify the Specimen is WB and CP is selected. Select the OK icon . An informational dialog box displays the following message:</p> <p>Save changes to continue? Select the OK icon . An additional dialog box displays the following messages: Worklist contains entries. Confirm Next Specimen ID is correct before processing specimen. Select the OK icon  when prompted. The sample trap door will automatically open. Select the OK icon .</p>
3	<p>Prepare and mix the selected whole-blood sample according to your laboratory protocol.</p>

PERFORM VERIFICATION OF REFERENCE RANGE

4	<p>Fully insert the sample tube into the tube holder and select the Run icon . The sample trap door automatically closes to initiate the analysis.</p>
5	<p>Remove the specimen tube when the sample trap door opens and the status LED is green.</p>
6	<p>Select the Next ID icon , and from the Run Specimen-Next Specimen ID screen manually enter the barcode number or scan the bar-code label of a specimen into the Specimen ID field and continue with the selection of the Test type (CD or CBC). Verify the Specimen is WB and CP is selected. Select the OK icon .</p>
7	<p>A dialog box will display the following message.</p> <p style="text-align: center;"><i>Specimen ID previously used. Reuse Specimen ID?</i></p> <p>Select OK icon  to accept or the Exit icon  to cancel.</p>
8	<p>Continue to process whole-blood samples as instructed in steps 2 through 6 until the required number specimen is achieved.</p>
9	<p>Select the Patient Result  icon.</p>
10	<p>Select the Search  icon.</p>
11	<p>The Patient Results screen will display. Using the on-screen keyboard to enter information, in the Specimen ID field, enter the specimen barcode number.</p> <p>[777777] for female or [333333] for male.</p>

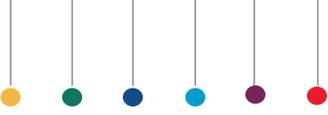
PERFORM VERIFICATION OF REFERENCE RANGE

Remember!

The original study's reference interval/range may be considered valid if no more than two of the 20 donors' values (or 10% of the results) fall outside of the original study's limits. In general, specimens should be handled in a manner similar to the patient samples.

12	Insert a USB flash drive into the front USB port.
13	Select the Function icon  .
14	<p>A warning box displays the following option:</p> <ul style="list-style-type: none"> <input type="radio"/> <i>All</i> <input type="radio"/> <i>Sequence</i> <p style="margin-left: 40px;"><i>From</i> <input type="text"/> <i>to</i> <input type="text"/></p> <p><i>Select ALL.</i></p> <p>Select Export icon  to accept your choice or the Exit icon  to cancel the export</p>
15	Remove the USB flash drive from the Front USB port.
16	Submit your DxH 500 Reference Interval results to the Beckman Coulter application support team HemeImplementation@Beckman.com .

NOTE: For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemeImplementation@Beckman.com.



ABOUT CORRELATION STUDIES

This section will discuss Correlation Studies (method comparison). Please note that your laboratory must be in compliance with all local, state and federal regulatory laws. Different agencies may dictate more specific procedures for your laboratory to follow, so contact your local regulatory agency to verify if Method Comparison is necessary for your laboratory.

Method Comparison is a regulatory requirement to show agreement between two methods. Most often, a new instrument will be compared to the lab's current method. The comparison must be completed before the new method is placed into use. Patient specimens for analysis are usually acquired from the lab's routine population. Some specimens should be specially chosen to test the complete measuring range.

Before beginning the process of method comparison, verify the performance and calibration of both the current (reference) instrument and the test instrument. Both instruments should meet the manufacturer's specifications with regard to maintenance, background checks, reproducibility/repeatability, carryover, calibration, and quality control. Refer to the DxH 520 Instructions for Use for specifications.

This section is intended to be a storage area for all DxH 520 instrument printouts regarding Method Comparison.

PERFORM CORRELATION STUDIES

CBC AND DIFF PARAMETERS COMPARISON

Specimen Collection Guidelines

The specimens collected for method comparison should reflect the typical patient population of the laboratory and be indicative of the clinically meaningful range for making medical decisions. This includes normal and abnormal inpatients, outpatients, and pediatric and specialty clinics existing in the laboratory population.

The quality of specimens is an important factor when collecting data. Poorly collected specimens contribute to poor data and lead to false conclusions. In the pages that follow, we provide you with information regarding: guidelines for properly collected specimens, general information and data analysis.

Properly collected and maintained specimens are:

- Collected in tubes containing a salt of EDTA and filled to the appropriate volume according to the tube manufacturer's specifications to ensure the proper proportion of blood to anticoagulant.
- Collected according to the tube manufacturer's instructions.
- Sufficient quantity of samples to be run on both the current instrument and the test instrument.
- Processed on both instruments within one or two hours of each other and within the same time frame as the laboratory routinely analyzes specimens.
- Thoroughly mixed before processing to establish cellular equilibration.

PERFORM CORRELATION STUDIES

Data Analysis

If a laboratory intends to compare a current automated differential to the new automated differential, then linear regression may be used. Keep the following in mind if you choose to do this:

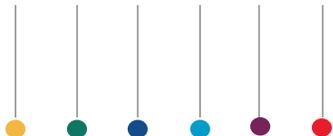


CONSIDERATIONS
Compare similar technology (e.g. 5-part diff to 5-part diff or 3-part diff to 3part diff).
Use the same samples on each instrument.
Run the samples within 2 hours on both analyzers.
Many white cell count parameters including basophils and eosinophils often have correlation coefficients in the range of 0.2 to 0.5. Slopes and intercepts for such parameters are not statistically optimal for evaluation. The only important statistic resulting from this analysis is the bias at the upper and lower limits of the normal range." (EP Evaluator Report Interpretation Guide 8.0.0.165, David G. Rhoads Associates, Inc.).

Linear regression may not be an adequate statistical tool for analysis of the differential parameters due to the variability of the manual differential. Commonly used methods for determining clinically acceptable method comparison between automated differential and manual differentials are:

- Mean Difference
- Binomial Envelope Distribution

NOTE: For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com



PERFORM CORRELATION STUDIES



FYI

The laboratory director and/or the medical laboratory consultant will need to validate the correlation studies.

Responsibility:

- Laboratory Key Operator

Materials Needed:

- Minimum of 40 Donor whole blood samples collected in K₂ or K₃ EDTA tubes.

Samples Needed:

- The number of specimens required for method comparison depends on the needs of the laboratory. CLSI EP09-A3 recommends that at least 40 samples be analyzed. Samples chosen should span the upper and lower end of the measuring range and incorporate unexpected interfering substances using the available patient population.

Time Required:

- Variable

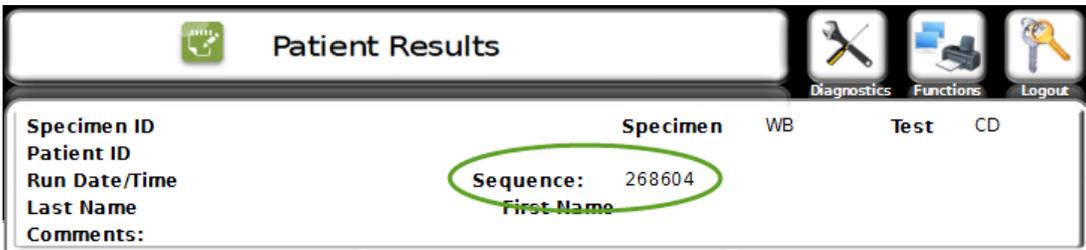
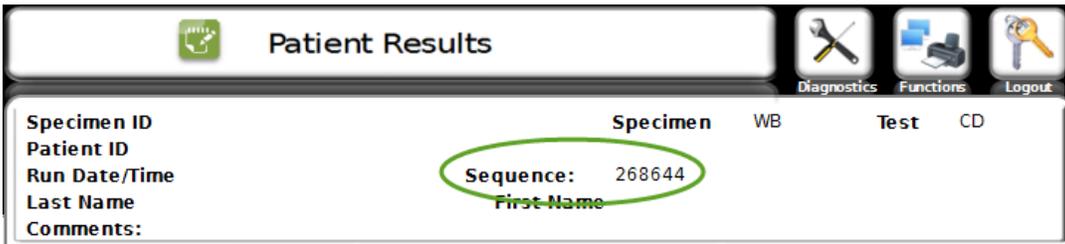
NOTE: For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com



PERFORM CORRELATION STUDIES

Steps	Action
1	Follow the recommendation for storage and mixing shown in the Instructions for Use.
2	Select the Display/Run icon  from the main menu.
3	<p>Note the following:</p> <p>If the worklist does not have any entries, the door automatically opens.</p> <p>If the worklist contains entries, the system displays a warning message.</p> <p>Verify that the Next Specimen ID on the bottom right side of the screen is correct and select the OK icon . The door automatically opens.</p>
4	<p>Identify a sample using one of the following methods:</p> <p>If the Next Specimen ID is not correct or entered, scan the specimen tube's bar code and default test is assigned OR select the Next Specimen ID icon , and from the Run Specimen-Order Entry screen manually enter the sample ID in the Specimen ID field and continue with the selection of the Test type (CD or CBC). Verify the Specimen is WB and CP is selected. Select the OK icon . An informational dialog box displays the following message:</p> <p>Save changes to continue? Select the OK icon . An additional dialog box displays the following messages: Worklist contains entries. Confirm Next Specimen ID is correct before processing specimen. Select the OK icon  when prompted. The sample trap door will automatically open.</p>
5	Prepare and mix the whole-blood sample according to your laboratory protocol.

PERFORM CORRELATION STUDIES

6	<p>Fully insert the specimen into the tube holder and select the RUN icon . The door automatically closes to initiate the analysis.</p>
7	<p>The status LED flashes red during aspiration and turns solid red throughout processing. A message in the bottom left corner of the screen indicates the Specimen ID being analyzed.</p>
8	<p>Wait for the instrument to process the sample and display the results in the Sample Analysis - Patient Results screen. The status LED turns green and the instrument automatically saves the results into the database.</p> <p>Document the first sample Sequence Numbers # associated with your Method Comparison studies.</p> <p>First Sample Sequence # _____</p> 
9	<p>Continue to process whole-blood samples until the required number (40) is achieved.</p>
10	<p>Document the last sample Sequence Numbers # associated with your Method Comparison studies.</p> <p>Last Sample Sequence # _____</p> 

PERFORM CORRELATION STUDIES

11	Select the Patient Result  icon.
12	Insert a USB flash drive into the front USB port.
13	Select the Function icon  .
14	<p>A warning box displays the following option:</p> <ul style="list-style-type: none"> <input type="radio"/> <i>All</i> <input type="radio"/> <i>Sequence</i> <p style="margin-left: 40px;"><i>From</i> <input type="text"/> <i>to</i> <input type="text"/></p> <p><i>Select Sequence and enter the sequence numbers documented in Steps 8 and 10.</i></p>
15	Select Export icon  to accept your choice or the Exit icon  to cancel the export.
16	Remove the USB flash drive from the Front USB port.
17	Submit your DxH 520 Correlation data to the Beckman Coulter application specialist support team at HemImplementation@Beckman.com .



NOTE: For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com

PERFORM CORRELATION STUDIES

The following section will provide the Laboratory Director and/or the Medical Laboratory consultant with information regarding data analysis for Method Comparison.

Data Analysis:

Upon completion of specimen collection and processing, compare results from the current instrument and the DxH 520 Hematology instruments and review for acceptable comparison. Methods of data analysis include:

1. Calculation of mean difference statistics.
2. Determination of method comparison and linear regression.
3. Graphing.

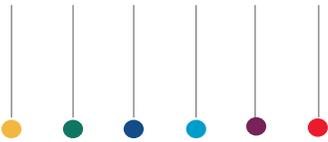
J. Westgard and M. Hunt state “Statistical tests do not provide the criteria for acceptability. Acceptability depends on whether the errors limit the clinical usefulness of the method. Statistical tests can provide specific estimates of errors upon which judgements can be made, but they are not a substitute for judgments.”²

IMPORTANT

The responsibility to determine acceptable performance of data lies with the evaluating laboratory.

Each laboratory is ultimately responsible for interpretation of comparison data and developing its own evaluation criteria for acceptability of results.

NOTE: For data submission and non-urgent inquiries on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com



TRUTH TABLE ANALYSIS



Please note that your laboratory may be subject to local, state, and federal regulatory laws. Different agencies may dictate more specific procedures for your laboratory to follow, therefore please contact your local regulatory agency for information on the specific requirements.

One of the most important tasks to accomplish during the implementation of any automated differential analyzer is to establish/verify an effective flagging protocol.

The purpose of the flagging protocol is to identify those samples which require a slide review so that significant morphology detail can be added to the automated report. The extent to which an analyzer can effectively screen

"normal" vs "abnormal" is defined as the instrument's clinical sensitivity. The

Truth Table is an effective tool for evaluation of the instrument's clinical sensitivity.

The first step in establishing an effective flagging protocol is to clearly define those findings that are considered clinically significant. A significant finding would be considered some detail that could add value to the report and ultimately affect/improve patient care.

The next step is to identify ways to flag for these findings. Some flags and codes are already built into the analyzer and are generated when the analyzer detects an unusual or unexpected distribution of particles. Additional flags can be set up by the operator to reflect the laboratory's review requirements and to support the screening process.

Specimens determined to be abnormal by the automated system should be evaluated according to the laboratory's protocols. Specimens determined to be normal by the automated system could be released without further review (autovalidation). The evaluation of the instrument's clinical sensitivity is critical because over-flagging may lead to unnecessary differential review, while under-flagging may miss abnormal samples.

The manual differential is used as a reference method to assess whether the instrument's flagging is appropriate. The lab determines the flagging limits which separate normal results from abnormal results, classifying each sample as a True Negative, True Positive, False Negative or False Positive. Reviewing and possibly adjusting the operator definable flags may further improve the efficiency of the automated differential system.

TRUTH TABLE ANALYSIS



Please note that your laboratory may be subject to local, state, and federal regulatory laws. Different agencies may dictate more specific procedures for your laboratory to follow, therefore please contact your local regulatory agency for information on the specific requirements.

Automated vs Manual Differential Data Collection

Responsibility:

- Laboratory Key Operator

Materials Needed:

When comparing the automated differential to the manual differential, ensure that the inherent variations of slide preparation are minimized by:

CONSIDERATIONS
Making quality smears
Staining with quality stain
Using optically clean microscopes
Having qualified technologist review the smear(s)

Samples Needed:

- Minimum of 100 Donor whole blood samples collected in K₂ or K₃ EDTA tubes.
- Specimens are identified by lab number on both printouts and microscopic slides for future reference.

CLSI H20-A2³ recommends that two technologists each perform a 200 cell manual differential on two different slides (total of 400 cells analyzed by each technologist). More cells counted results in a more precise and accurate reference against which to judge the accuracy of the automated method. Automated differential systems analyze thousands of cells. The Rumke Binomial Distribution Table⁴, published by C.L. Rumke in 1978, illustrates that the statistical uncertainty of reference values is a direct function of the number of cells counted. The imprecision of the manual differential is especially pronounced with low numbers (e.g., monocyte, eosinophil and basophil percent).



Time Required:

- Variable

TRUTH TABLE ANALYSIS



Beckman Coulter, Inc. does not claim to identify every abnormality in all samples. Beckman Coulter, Inc. suggests using all available flagging options to optimize the sensitivity of instrument results based on your patient population. All flagging options include reference ranges (H/L), action and critical limits, definitive flags, suspect flags, system messages, parameter codes, delta checks, decision rules and system alarms. Beckman Coulter, Inc. recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions. All Truth Tables and associated recommendations reflect the extent to which your workflow may be managed efficiently but are limited to the sample data submitted for evaluation. Accepting any of the suggested recommended changes to the current review criteria would require appropriate changes to action limits and/or lab protocol that were in place at the time of this evaluation. Finally, all observations are recommendations and subject to your review and discretion in the formation of your Laboratory's review and flagging protocols."

Preparing for Truth Table Analysis

TRUTH TABLE ASSISTANCE

Assistance is available with a Beckman Coulter Application Specialist to discuss the following Truth Table areas:

- Key Operator Manual differential and truth table studies
- Individual Laboratory Requirement
- Sample Selection consideration
- Data Submission
- Expectations
- Final Report



NOTE: For data submission and non-urgent inquires on the DxH 520 implementation workbook or instrument operation, contact Customer Technical Support by emailing HemImplementation@Beckman.com

TRUTH TABLE ANALYSIS DIFF PARAMETERS COMPARISION

Truth Table Differential

DATA COLLECTION

The ideal truth table would include **a minimum of 100 samples with 50% having an abnormal slide review**. Specimens should be collected into K₂ or K₃ EDTA. For optimum performance, all specimens should be analyzed within time limits recommended by the manufacturer(s). Analyze the same specimen within 2 hours on all instruments for accurate comparison. Refer to CLSI Standard for Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; H20-A2 or current revision.

In addition, a complete manual differential should be performed. A complete manual differential includes WBC differential, RBC and Plt morphology and WBC and Plt estimate. Results of other test procedures, e.g. manual Plt count, should be also noted.

Poor statistics could be obtained because of the imprecision of the manual differential. This will be especially pronounced in cell populations with lower numbers.

The statistical error of the manual differential can be reduced by performing several 200-cell differentials. Differential counts by several technologists are preferred. The CLSI protocol (H20) recommends two (2) technologists each doing a 200-cell differential for each sample. If you choose to have multiple technologists perform manual differentials, average them and submit the average differential counts.

Ensure a random sampling of the population. Specimens analyzed should represent your a general hospital population. Results should span as much of the clinical range of the instrument as possible. Check your instrument specifications.

Random sampling should include:

- Specimens with normal values.
- Abnormal specimens representing various types of leukocyte (WBC) disorders including but not limited to:

Leukemias	Lymphocytosis	Lymphopenia
Granulopenia	Granulocytosis	Eosinophilia
Basophilia		

- Abnormal specimens representing various types of erythrocyte (RBC) disorders including but not limited to:

Hemoglobinopathy	Polycythemia
Microcytic anemia	Macrocytic anemia

TRUTH TABLE ANALYSIS DIFF PARAMETERS COMPARISON

Truth Table Differential

CONSIDERATIONS

- Abnormal specimens representing various types of platelets (PLT) disorders including but not limited to:

Thrombocytosis	Thrombocytopenia
Morphological platelet disorders	

If total vote outs (dashes), incomplete computation (dots) or results with system-generated messages are observed for any specimen, repeat the analysis of that specimen on the evaluation instrument. Submit both the original and repeated values.

Results for all specimens analyzed on all instruments should be obtained and labeled appropriately. For each specimen, collect the following data:

ASSEMBLE

The Evaluation "Test" instrument result(s). If possible, printed results
The Reference "Current" instrument result(s). If possible, printed results
Any confirmatory results
Export specimen results to a flash drive. If possible, printed results

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TRUTH TABLE ANALYSIS

Truth Table Differential

Define Review Limits and Review Protocol

To establish review limits and a review protocol for your laboratory's patient population and specific needs:

Steps	Action
1	Define and record a Test instrument review protocol on the Differential Review Limit and Protocol worksheet.
2	Record the instrument-generated flags that require further action.
3	Define the high and low limits your laboratory uses to take slide review action on an automated differential result.
4	Be specific, define less than and greater than with "or equal to" if applicable; e.g. if > 10% is your limit for Eosinophil, then 10% is normal or negative and 11 % is abnormal or positive. Depending upon your protocol results falling outside these abnormal limits require either a smear scan or a full manual differential.
5	Complete the Differential review limit and protocol worksheet.
6	Upon your protocol, results failing outside these abnormal limits require either a smear scan or a full manual differential.

DIFFERENTIAL REVIEW LIMIT AND PROTOCOL WORKSHEET

1. Define Test Instrument Review Protocol (Abnormal Limits)

a. All Instrument generated flags will be used. List exceptions below.

b. Operator Defined Flags

	Instrument Review Limits	
	Low	High
WBC		
RBC		
HGB		
HCT		
MCV		
MCH		
MCHC		
RDW		
RDW-SD		
PLT		
MPV		
LY%		
MO%		
NE%		
EO%		
BA%		
LY #		
MO #		
NE #		
EO #		
BA #		

2. Define Reference Manual Differential Abnormal Limits

LIMITATION STATEMENT:

All numerical results reported for Basophil count and percent values must be reflexed for manual microscopy or followed up for additional testing based on the laboratory's SOP.

Segmented Neutrophils		Metamyelocytes	
Band Neutrophils		Myelocytes	
Lymphocytes		Promyelocytes	
Variant Lymphocytes		Blasts	
Monocytes		NRBCs	
Eosinophils		RBC Morphology	
Basophils		PLT Morphology	
Other (Specify)		WBC Morphology	

TRUTH TABLE ANALYSIS

How to Establish a Truth Table

The automated differential’s **sensitivity**, **specificity** and **efficiency** in distinguishing normal and abnormal specimens are determined using Truth Table analysis. The manual differential is used as a reference to assess whether the instrument has correctly classified the specimen as normal (released without further view-auto-validation) or abnormal (requiring review).

To Perform a Truth Table Analysis:

Step	Action
1	For each specimen analyzed on the DxH 520 Instrument: <ol style="list-style-type: none"> a. Classify the instrument results as Normal (“negative”) if no flags or messages are present. b. Classify the instrument results as Abnormal (“positive”) if flags or messages are present.
2	Perform a manual differential on all samples evaluated in Step 1. <ol style="list-style-type: none"> a. Classify as Abnormal (“positive”) any morphological or distributional abnormality observed. b. Classify as Normal (“negative”) any manual differential count in which all cell types are normal and within your established limits.
3	Categorize each specimen as one of the following four categories and record the results on the differential Truth Table Worksheet: <ul style="list-style-type: none"> ▶ True Negative (TN): Normal (negative) by both test (new instrument) and reference (manual diff) methods. ▶ True Positive (TP): Abnormal (positive) by both test (new instrument) and reference (manual diff) methods. ▶ False Negative (FN): Normal (negative) by test method (new instrument) and abnormal (positive) by reference (manual diff) method. ▶ False Positive (FP): Abnormal (positive) by test method (new instrument) and normal (negative) by reference method (manual diff).

Step	Action
4	Calculate and record on the Differential Truth Table Worksheet the following:

- a. **True Negative:** the percentage of specimens considered normal (negative) by both the test method (new instrument) and the reference method (manual diff).

$$\% \text{ TN} = (\# \text{ True Negatives} / \text{total number of specimens}) \times 100$$
- b. **True Positive:** the percentage of specimens considered abnormal (positive) by both the test method (new instrument) and the reference method (manual diff).

$$\% \text{ TP} = (\# \text{ True Positives} / \text{total number of specimens}) \times 100$$
- c. **False Negative:** the percentage of specimens considered normal by the test method (new instrument) and abnormal by the reference method (manual diff).
Galen/Gambino

$$\% \text{ FN} = (\# \text{ False Negatives} / \text{total number of specimens}) \times 100$$
CLSI

$$\% \text{ FN} = (\# \text{ True Negative} / (\text{True Negative} + \text{False Positives})) \times 100$$
- d. **False Positive:** the percentage of specimens considered abnormal by the test method (new instrument) and normal by the reference method (manual diff).
Galen/Gambino

$$\% \text{ FP} = (\# \text{ False Positives} / \text{total number of specimens}) \times 100$$
CLSI

$$\% \text{ FP} = (\text{False Positive} / (\text{False Positive} + \text{TN})) \times 100$$
- e. **Specificity:** the percentage of manual differential normals that were also normal on the instrument.

$$\text{Specificity} = \# \text{ True Negatives} \div \# (\text{True Negative} + \text{False Positives}) \times 100$$
- f. **Sensitivity:** the percentage of manual differential abnormal that were also abnormal on the instrument.

$$\text{Sensitivity} = \# \text{ True Positives} \div \# (\text{True Positives} + \text{False Negatives}) \times 100$$
- g. **Predictive Value of a Negative Test (PVN):** the percentage of specimens that were normal on both the instrument and the manual differential.

$$\text{PVN} = \# \text{ True Negatives} \div \# (\text{True Negatives} + \text{False Negatives}) \times 100$$

- h. **Predictive Value of a Positive Test (PVP):** the percentage of specimens that were abnormal on both the instrument and the manual differential.

$$\text{PVP} = \# \text{ True Positives} \div \# (\text{True Positives} + \text{False Positives}) \times 100$$

- i. **Agreement:** the percentage of specimens correctly categorized by the automated differential.

$$[\# (\text{True Positives} + \text{True Negatives}) \div \text{total number of specimens}] \times 100$$

IMPORTANT



The Truth Table format can be used for a variety of purpose. It is important to understand that the statistics reflect the patient mix that is used during the study. The focus of an Implementation Truth Table is to optimize Sensitivity. Focus on the False Negative Samples. Evaluate if there is a particular flag that could be added or modified so that these same samples would be flagged. Determine what is an acceptable balance between False Negative (missed significant findings) and False Positive sample (increased review rate). The responsibility to determine acceptable performance of above data lies with the evaluating laboratory.

IMPORTANT

DIFFERENTIAL TRUTH TABLE WORKSHEET

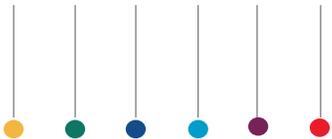
1. Classify differentials into one of four categories and total each column.

	REFERENCE (Manual Differential)			
		Normal (Negative)	Abnormal (Positive)	Total
TEST (new instrument)	Normal (Negative)	(TN)	(FP)	
	Abnormal (Positive)	(FN)	(TP)	
	Total			

2. Calculate the following parameters.

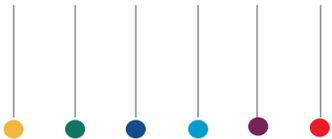
PARAMETER	CALCULATION	RESULT (%)
% TN	Number of TN/Total	
% TP	Number of TP/Total	
% FN	Number of FN/Total	
% FP	Number of FP/Total	
Specificity	$[\# \text{ TN} / \# (\text{TN} + \text{FP})] \times 100$	
Sensitivity	$[\# \text{ TP} / \# (\text{TP} + \text{FN})] \times 100$	
Predictive Value of a Negative Test	$[\# \text{ TN} / \# (\text{TN} + \text{FN})] \times 100$	
Predictive Value of Positive Test	$[\# \text{ TP} / \# (\text{TP} + \text{FP})] \times 100$	
Agreement	$[(\# \text{ TP} + \# \text{ TN}) / \text{Total}] \times 100$	

2. Reviewed by _____ Date _____



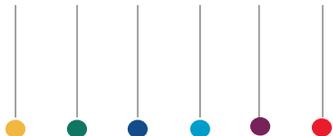
TRUTH TABLE ANALYSIS WORKSHEET

Sample ID			
Tech ID	Tech ID	Tech ID	Tech ID
Segs	Segs	Segs	Segs
Bands	Bands	Bands	Bands
Meta	Meta	Meta	Meta
Myelo	Myelo	Myelo	Myelo
Pro	Pro	Pro	Pro
Blast	Blast	Blast	Blast
Lymph	Lymph	Lymph	Lymph
Atyp Ly	Atyp Ly	Atyp Ly	Atyp Ly
Mono	Mono	Mono	Mono
Eos	Eos	Eos	Eos
Baso	Baso	Baso	Baso
NRBC	NRBC	NRBC	NRBC
Other	Other	Other	Other
Total	Total	Total	Total
Significant RBC morph	Significant RBC morph	Significant RBC morph	Significant RBC morph
Significant PLT observations	Significant PLT observations	Significant PLT observations	Significant PLT observations



TRUTH TABLE ANALYSIS WORKSHEET

Sample ID			
Tech ID	Tech ID	Tech ID	Tech ID
Segs	Segs	Segs	Segs
Bands	Bands	Bands	Bands
Meta	Meta	Meta	Meta
Myelo	Myelo	Myelo	Myelo
Pro	Pro	Pro	Pro
Blast	Blast	Blast	Blast
Lymph	Lymph	Lymph	Lymph
Atyp Ly	Atyp Ly	Atyp Ly	Atyp Ly
Mono	Mono	Mono	Mono
Eos	Eos	Eos	Eos
Baso	Baso	Baso	Baso
NRBC	NRBC	NRBC	NRBC
Other	Other	Other	Other
Total	Total	Total	Total
Significant RBC morph	Significant RBC morph	Significant RBC morph	Significant RBC morph
Significant PLT observations	Significant PLT observations	Significant PLT observations	Significant PLT observations



DxH 520 DATA SUBMISSION CHECKLIST

This checklist must be filled and attached to email along with 7 files listed below. Submit your checklist to the Beckman Coulter application specialist support team at HemImplementation@Beckman.com.

Customer information:

Name of Hospital/Institution:	
Primary Contact Name:	
Telephone Number:	
Email address	
DxH 520 Serial Number/Instance number (s):	
Reference Instrument Information (Serial Number, Manufacturer, model)	

Files to be attached

Procedure		Date Completed	Technician	Date Submitted
RBC/HGB Linearity export file (all levels). CSV	<input type="checkbox"/>			
PLT Linearity export file (all levels).CSV	<input type="checkbox"/>			
WBC Linearity export file (all levels).CVS	<input type="checkbox"/>			
DxH 520 (test) correlation data exports file. CVS	<input type="checkbox"/>			
Reference instrument correlation data export file .CSV	<input type="checkbox"/>			
Data Entry Worksheet for DxH 520 validation (if cannot be exported from Analyzer)	<input type="checkbox"/>			
Package insert for R & D Linearity to include ranges & Lot #	<input type="checkbox"/>			

- *Please ensure sample IDs in reference and test methods match.*
- *Please perform Linearity studies in REPEATABILITY mode.*
- *Follow instructions in DXH520 implementation workbook how to export data to USB drive.*
- *Please ensure any PHI is removed per laboratory protocol from submitted patient records*

Date _____



IQAP ENROLLMENT

The Beckman Coulter Hematology Interlaboratory Quality Assurance Program (IQAP) is a peer comparison program offered to users of Beckman Coulter instrumentation worldwide. IQAP complements and enhances your laboratory's in-house quality control. Customers with instrumentation configured with Beckman Coulter reagents, and using Beckman Coulter calibrators and controls are eligible for this free program. IQAP is an added-value service provided at no additional cost to Beckman Coulter customers and allows laboratories to compare results to those of other laboratories running the same lot number of controls. In addition, the online eIQAP portal you can easily submit, view and compare QC reports with hematology peer groups worldwide.

Participation is voluntary!

Responsibility:

- Laboratory Key Operator

Materials Needed:

- Computer with Internet Access

Time Required:

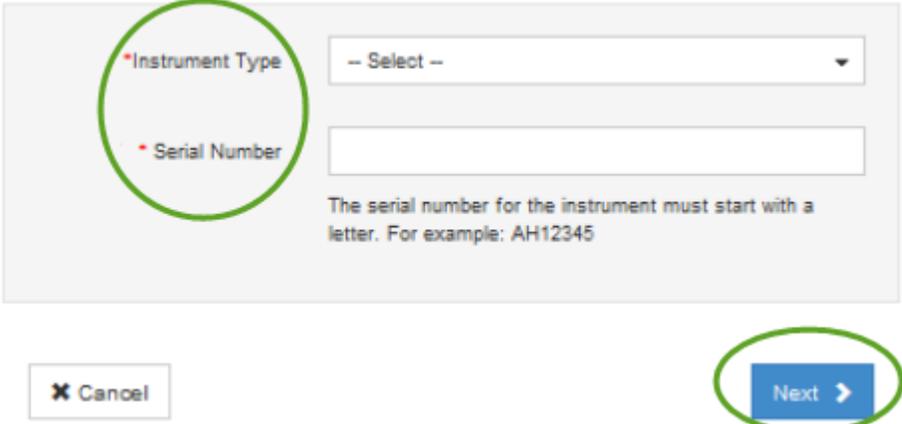
- Variable



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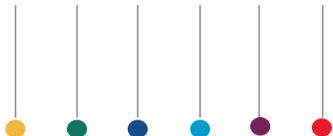
IQAP ENROLLMENT

STEPS	ACTION
1	<p>Access the Beckman Coulter eIQAP web site at:</p> <div style="border: 1px solid #ccc; border-radius: 10px; padding: 5px; display: inline-block; margin: 10px 0;"> https://qapweb.beckmancoulter.com </div>
2	<p>Select Need an Account? Click here to Register.</p> <div style="border: 1px solid #ccc; padding: 10px; margin: 10px auto; width: 80%; text-align: center;"> <p>Please Sign In using your Beckman Coulter account</p> <p>User ID</p> <input style="width: 80%; margin-bottom: 5px;" type="text" value="User ID"/> <p>Password</p> <input style="width: 80%; margin-bottom: 5px;" type="password" value="Password"/> <p>Forgot username or password?</p> <p>Sign in</p> <p>Need an account? Click here to register..</p> </div>
3	<p>Complete the information on the Account Registration screen.</p> <div style="border: 1px solid #ccc; padding: 10px; margin: 10px auto; width: 90%;"> <p style="font-size: small; margin: 0;">Beckman Coulter QAP Account Registration</p> <p style="font-size: x-small; margin: 0;">Welcome to Beckman Coulter Quality Assurance Program registration. After completing your registration you will be able to access the program(s).</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p><small>* Username</small> <input style="width: 90%;" type="text"/></p> <p><small>Only alpha numeric characters between 8 and 20 characters are allowed.</small></p> <p><small>* Password</small> <input style="width: 90%;" type="password"/></p> <p><small>* Confirm Password</small> <input style="width: 90%;" type="password"/></p> </div> <div style="width: 45%;"> <p><small>* First Name</small> <input style="width: 90%;" type="text"/></p> <p><small>* Last Name</small> <input style="width: 90%;" type="text"/></p> <p><small>* Telephone</small> <input style="width: 90%;" type="text"/></p> <p><small>* Phone Extension</small> <input style="width: 90%;" type="text"/></p> <p><small>* Fax</small> <input style="width: 90%;" type="text"/></p> <p><small>* Email</small> <input style="width: 90%;" type="text"/></p> <p><small>* Repeat Email</small> <input style="width: 90%;" type="text"/></p> </div> <div style="width: 45%;"> <p><small>* Name Question</small> <input style="width: 90%;" type="text" value="Name of the city you were born."/></p> <p><small>* Birth Address</small> <input style="width: 90%;" type="text"/></p> </div> <div style="width: 45%;"> <p><small>* Institution</small> <input style="width: 90%;" type="text"/></p> <p><small>* Department</small> <input style="width: 90%;" type="text"/></p> <p><small>* Address 1</small> <input style="width: 90%;" type="text"/></p> <p><small>* Address 2</small> <input style="width: 90%;" type="text"/></p> <p><small>* City/Town</small> <input style="width: 90%;" type="text"/></p> <p><small>* State/Province</small> <input style="width: 90%;" type="text"/></p> <p><small>* Zip/Postal Code</small> <input style="width: 90%;" type="text"/></p> <p><small>* Country</small> <input style="width: 90%;" type="text" value="Anguilla"/></p> </div> </div> <div style="font-size: x-small; margin-top: 10px;"> <p>Terms and Conditions</p> <p>1. Your Acceptance of Agreement. This Service Agreement ("Agreement") is between you and Beckman Coulter, Inc. ("Beckman Coulter") and constitutes a legal agreement that governs the relationship of information and your use of Beckman Coulter's quality assurance program service and support (herein and herein collectively referred to as the "Service"). You must agree to the terms of this agreement before you can use the Service. If you do not agree to these terms please do not use the Service. THIS AGREEMENT IS ENFORCEABLE AGAINST YOU AND, IF APPLICABLE, TO ANY LEGAL ENTITY ON WHOSE BEHALF THE SERVICE IS USED; FOR EXAMPLE, YOUR EMPLOYER.</p> <p>Authority to Use Services. You represent and warrant that you have all necessary right, power and authority to enter into this Agreement and to perform the acts required of you hereunder. To use and/or register for the Service you must be an individual who is in a working contract with Beckman Coulter, and is covered by a contract derived from requesting the Service under the laws of the United States or other applicable jurisdiction, including the authority to enroll you needs or that allows you use the Service. By agreeing to this Agreement you represent that you understand and agree to the foregoing.</p> <p>Changes to this Agreement. Beckman Coulter may change, add or remove any part of this Agreement, or any part of the Service at any time. Should you refuse to accept any updated terms presented to you by Beckman Coulter you must discontinue using the Service.</p> <p>2. Description and Use of Services.</p> </div> </div>

4	Select the Terms and Conditions, and select  to complete the registration process.
5	Wait for the system response thanking you for registering. You will receive an email thanking you for registering.
NOTE	The eIQAP enrollment phase can only be performed after having completed the Registration process and received the Congratulations message. Beckman Coulter recommends completing the Enrollment phase immediately after registering for eIQAP.
6	If you logged out of the system, log back in. If you are still logged in, select Continue with Hematology/Cytometry enrollment .
7	<p>Select the Instrument Type from the dropdown list, complete the required field for Serial Number and select Next.</p> 
8	Verify and complete the information required on the screen and select Next .
9	Wait for the system response to indicate that the enrollment in eIQAP was successful. If done, select Sign Out or select Back to Dashboard to add additional instruments.



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APPENDIX - GLOSSARY

Accuracy of a test is the closeness of the test result to the true value.

Carryover The amount in percent of sample remaining in the system and picked up by the next sample cycled. Low-to-high carryover is the amount of sample with low cell concentrations carried over to sample with high cell concentration, such as diluent to blood. High-to-low carryover is the amount of samples with high cell concentrations carried over to samples with low cell concentrations such as blood to diluent.

Coefficient of Variation (CV%) is the standard deviation expressed in terms of the percentage of the mean.

Linear regression is a statistical technique to find the line that best predicts Y from X.

Mean is the center of distribution. It is used to describe or summarize a collection of data by defining an average.

Mean Difference is the unknown minus the known.

Measuring range (linearity) is a set of values of measurands for which the error of a measuring instrument is intended to lie within specified limits.

Outlier is a result outside of the established range.

Precision is the closeness of results of repeated analysis performed on the same material. Precision is often expressed quantitatively as standard deviations, or coefficients of variation. (also known as repeatability or reproducibility)

Patient Population is the group of individual values about which a generalization is derived.

Reference interval is the interval between and including the lower reference limit to the upper reference limit of the reference population (e.g., 95% of persons presumed to be healthy or normal).

Repeatability/Reproducibility is the closeness of results of repeated analysis performed on the same material. Precision is often expressed quantitatively as standard deviations, or coefficients of variation. (also known as precision or reproducibility)

Standard Deviation (SD) is a measure of the dispersion or variation in the results about the mean.

True Negative is the percentage of specimens considered normal (negative) by both the test method (new instrument) and the reference method (manual diff).

True Positive is the percentage of specimens considered abnormal (positive) by both the test method (new instrument) and the reference method (manual diff).

Truth Table is a technique for evaluation of method sensitivity, specificity and efficiency.

REFERENCES

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2. Westgard J and Hunt M. Use and Interpretation of Common Statistical Tests in Method-comparison Studies. *Clinical Chemistry*, 1973; 19(1): 49-57.
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4. Duncan KL and Gottfried EL. Utility Of The Three-Part Differential Count. *American Journal of Clinical Pathology*, 1987; 88:308-313.
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6. Ardron MJ, Westgard JC and Dutcher TF. Band Neutrophil Counts Are Necessary For The Diagnosis Of Infection In Patients With Normal Total Leukocyte Counts. *American Journal of Clinical Pathology*, 1994; 11:646-649.
7. Gossens W, VanHove L and Verwilghen RL. Monocyte Counting: Discrepancies In Results Obtained With Different Automated Instruments. *Journal of Clinical Pathology*, 1991; 44:224-227.
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9. CLSI C28-A2, How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline-Second Edition, June 2000.
10. CLSI C24-A2 Statistical Quality Control for Quantitative Measurement : Principles and Definitions; Approved Guideline-Second Edition, 1999.
11. Westgard, JO. "But is it really out?" Doing the wrong QC wrong. Essay 115. September 2007.
12. College of American Pathologists, 2004, Commission on laboratory Accreditation Inspection Checklist HEM.30250
13. Clinical laboratory Improvement Amendments as set forth in 42 CFR 493.1253 Standard.

WEBSITES FOR LABORATORY REFERENCE

Beckman Coulter Inc.

www.beckmancoulter.com

www.beckmancoulter.com/qap

Clinical Laboratory Standards Institute (CLSI)

www.clsi.org

Collage of American Pathologist (CAP)

www.cap.org

Joint Commission (JCAHO)

www.jointcommission.org

Centers for Medicare and Medicaid Services (CMS)

www.cms.hhs.gov

Clinical Laboratory Improvements Amendments

www.cms.hhs.gov/clia

Proficiency Testing Providers

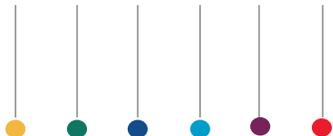
www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp

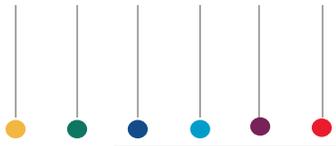
Media Lab, Inc. (Online Compliance and Continuing Education for Clinical Laboratories)

www.medialabinc.net

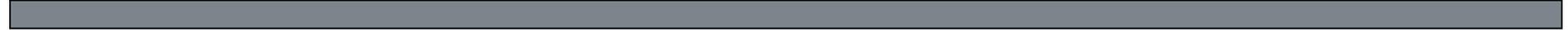
Westgard QC (Tools, Technologies and Training for Healthcare Laboratories)

www.westgard.com





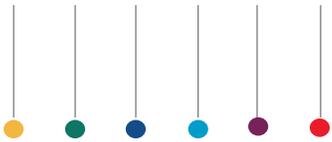
PERFORM REFERENCE INTERVAL/RANGE WORKSHEET



	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV	LY%	MO%	NE%	EO%	BA%
Patient 1																
Patient 2																
Patient 3																
Patient 4																
Patient 5																
Patient 6																
Patient 7																
Patient 8																
Patient 9																
Patient 10																
Patient 11																
Patient 12																
Patient 13																
Patient 14																
Patient 15																
Patient 16																
Patient 17																
Patient 18																
Patient 19																
Patient 20																

Proposed Reference Intervals

Patient Low																
Patient High																

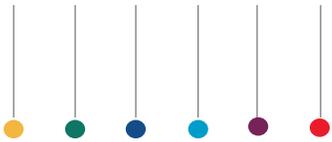


PERFORM CORRELATION STUDIES WORKSHEET



Current (reference) Instrument

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV	LY%	MO%	NE%	EO%	BA%
Patient 1																
Patient 2																
Patient 3																
Patient 4																
Patient 5																
Patient 6																
Patient 7																
Patient 8																
Patient 9																
Patient 10																
Patient 11																
Patient 12																
Patient 13																
Patient 14																
Patient 15																
Patient 16																
Patient 17																
Patient 18																
Patient 19																
Patient 20																

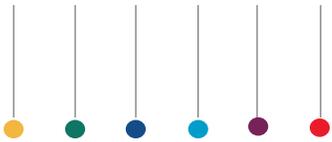


PERFORM CORRELATION STUDIES WORKSHEET



Current (reference) Instrument

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV	LY%	MO%	NE%	EO%	BA%
Patient 21																
Patient 22																
Patient 23																
Patient 24																
Patient 25																
Patient 26																
Patient 27																
Patient 28																
Patient 29																
Patient 30																
Patient 31																
Patient 32																
Patient 33																
Patient 34																
Patient 35																
Patient 36																
Patient 37																
Patient 38																
Patient 39																
Patient 40																



PERFORM CORRELATION STUDIES WORKSHEET



DxH 520 (Test) Instrument

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV	LY%	MO%	NE%	EO%	BA%
Patient 1																
Patient 2																
Patient 3																
Patient 4																
Patient 5																
Patient 6																
Patient 7																
Patient 8																
Patient 9																
Patient 10																
Patient 11																
Patient 12																
Patient 13																
Patient 14																
Patient 15																
Patient 16																
Patient 17																
Patient 18																
Patient 19																
Patient 20																

PERFORM CORRELATION STUDIES WORKSHEET

DxH 520 (Test) Instrument

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	RDW-SD	PLT	MPV	LY%	MO%	NE%	EO%	BA%
Patient 21																
Patient 22																
Patient 23																
Patient 24																
Patient 25																
Patient 26																
Patient 27																
Patient 28																
Patient 29																
Patient 30																
Patient 31																
Patient 32																
Patient 33																
Patient 34																
Patient 35																
Patient 36																
Patient 37																
Patient 38																
Patient 39																
Patient 40																

TRUTH TABLE ANALYSIS WORKSHEET



Sample ID			
Tech ID	Tech ID	Tech ID	Tech ID
Segs	Segs	Segs	Segs
Bands	Bands	Bands	Bands
Meta	Meta	Meta	Meta
Myelo	Myelo	Myelo	Myelo
Pro	Pro	Pro	Pro
Blast	Blast	Blast	Blast
Lymph	Lymph	Lymph	Lymph
Atyp Ly	Atyp Ly	Atyp Ly	Atyp Ly
Mono	Mono	Mono	Mono
Eos	Eos	Eos	Eos
Baso	Baso	Baso	Baso
NRBC	NRBC	NRBC	NRBC
Other	Other	Other	Other
Total	Total	Total	Total
Significant RBC morph	Significant RBC morph	Significant RBC morph	Significant RBC morph
Significant PLT observations	Significant PLT observations	Significant PLT observations	Significant PLT observations

DIFFERENTIAL REVIEW LIMIT AND PROTOCOL WORKSHEET

1. Define Test Instrument Review Protocol (Abnormal Limits)

- a. All Instrument generated flags will be used. List exceptions below.

b. Operator Defined Flags

	Instrument Review Limits	
	Low	High
WBC		
RBC		
HGB		
HCT		
MCV		
MCH		
MCHC		
RDW		
RDW-SD		
PLT		
MPV		
LY%		
MO%		
NE%		
EO%		
BA%		
LY #		
MO #		
NE #		
EO #		
BA #		

2. Define Reference Manual Differential Abnormal Limits

LIMITATION STATEMENT:

All numerical results reported for Basophil count and percent values must be reflexed for manual microscopy or followed up for additional testing based on the laboratory's SOP.

Segmented Neutrophils		Metamyelocytes	
Band Neutrophils		Myelocytes	
Lymphocytes		Promyelocytes	
Variant Lymphocytes		Blasts	
Monocytes		NRBCs	
Eosinophils		RBC Morphology	
Basophils		PLT Morphology	
Other (Specify)		WBC Morphology	

DIFFERENTIAL TRUTH TABLE WORKSHEET

3. Classify differentials into one of four categories and total each column.

	REFERENCE (Manual Differential)			
		Normal (Negative)	Abnormal (Positive)	Total
TEST (new instrument)	Normal (Negative)	(TN)	(FP)	
	Abnormal (Positive)	(FN)	(TP)	
	Total			

2. Calculate the following parameters.

PARAMETER	CALCULATION	RESULT (%)
% TN	Number of TN/Total	
% TP	Number of TP/Total	
% FN	Number of FN/Total	
% FP	Number of FP/Total	
Specificity	$[\# \text{ TN} / \# (\text{TN} + \text{FP})] \times 100$	
Sensitivity	$[\# \text{ TP} / \# (\text{TP} + \text{FN})] \times 100$	
Predictive Value of a Negative Test	$[\# \text{ TN} / \# (\text{TN} + \text{FN})] \times 100$	
Predictive Value of Positive Test	$[\# \text{ TP} / \# (\text{TP} + \text{FP})] \times 100$	
Agreement	$[(\# \text{ TP} + \# \text{ TN}) / \text{Total}] \times 100$	

3. Reviewed by _____ Date _____