



July 5, 2024

Beckman Coulter, Inc
Marie Steigerwalt
Staff Regulatory Affairs Specialist
11800 S.W. 147th Avenue
Miami, Florida 33196

Re: K240252

Trade/Device Name: UniCel DxH 900 Coulter Cellular Analysis System; UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System; UniCel DxH 690T Coulter Cellular Analysis System

Regulation Number: 21 CFR 864.5220

Regulation Name: Automated Differential Cell Counter

Regulatory Class: Class II

Product Code: GKZ

Dated: June 3, 2024

Received: June 4, 2024

Dear Marie Steigerwalt:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>). Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809 medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>. For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YAN CAI -S Digitally signed by YAN CAI -S
Date: 2024.07.05 13:46:27
-04'00'

for

Min Wu

Branch Chief

Division of Immunology and Hematology Devices

OHT7: Office of In Vitro Diagnostics

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K240252

Device Name

UniCel DxH 900 Coulter Cellular Analysis System ;
UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System;
UniCel DxH 690T Coulter Cellular Analysis System

Indications for Use (Describe)

The UniCel DxH 900/DxH 690T Coulter Cellular Analysis System is a quantitative, multi-parameter, automated hematology analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories.

The DxH 900/DxH 690T analyzer identifies and enumerates the following parameters:

- Whole Blood (Venous or Capillary): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF
- Pre-Diluted Whole Blood (Venous or Capillary): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV
- Body Fluids (cerebrospinal, serous or synovial): TNC and RBC

The UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System is a fully automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K240252.

807.92 (a)(1): Contact Details

Name: Beckman Coulter, Inc

Address: 11800 S.W. 147th Avenue Miami FL 33196 United States

Phone: 305-380-3800

Email: msteigerwalt@beckman.com

Contact: Marie Steigerwalt

807.92 (a)(2): Device Name

Trade Name:

UniCel DxH 900 Coulter Cellular Analysis System

UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System

UniCel DxH 690T Coulter Cellular Analysis System

Common Name: Automated differential cell counter

Classification Name: Counter, Differential Cell

Regulation Number: 21 CFR 864.5220

Product Code(s): GKZ

807.92 (a)(3): Identification of the Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K193124	UniCel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application	GKZ
K162414	UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System	GKZ

807.92 (a)(4): Device Description Summary

The UniCel DxH 900/DxH 690T System contains an automated hematology analyzer (DxH 900 or DxH 690T) designed for in vitro diagnostic use in screening patient populations by clinical laboratories. The system provides a Complete Blood Count (CBC), Leukocyte 5-Part Differential (Diff), Reticulocyte (Retic), Nucleated Red Blood Cell (NRBC) on whole blood, as well as, Total Nucleated Count (TNC), and Red Cell Count (RBC) on Body Fluids (cerebrospinal, serous and synovial).

The DxH Slidemaker Stainer II is a fully automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.

The DxH 900 System may consist of a workcell (multiple connected DxH 900 instruments with or without a DxH Slidemaker Stainer II), a stand-alone DxH 900, or a stand-alone DxH Slidemaker Stainer II. The DxH 690T System consists of a stand-alone DxH 690T instrument. The available DxH 900 workcell systems are listed in the table below.

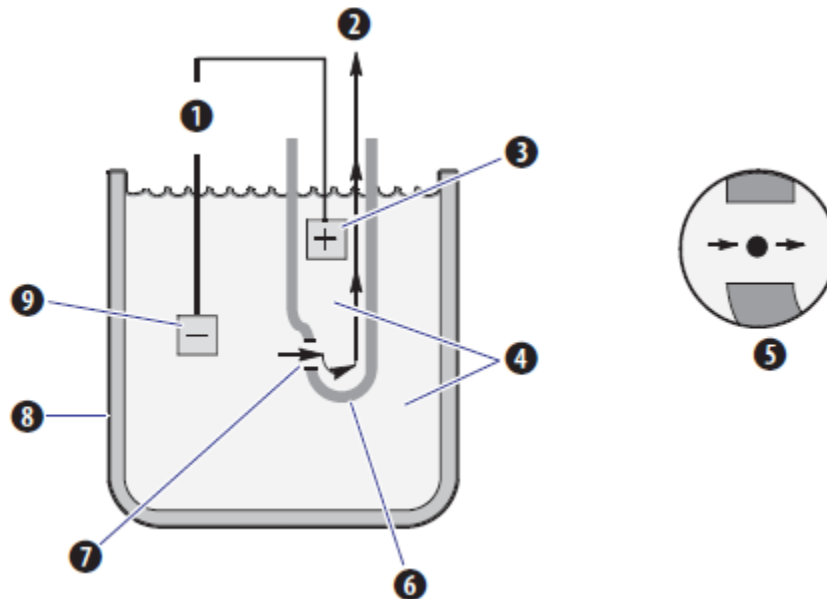
DxH 900, DxH 690T and DxH Slidemaker Stainer II Stand-alone Instruments, and DxH 900 and DxH Slidemaker Stainer II Workcell Configurations

Configuration	Topologies				System Manager	Review Stations
DxH 900	DxH 900				Standard Computer	N/A
DxH 690T	DxH 690T				Standard Computer	N/A
DxH Slidemaker Stainer II	DxH Slidemaker Stainer II				Standard Computer	N/A
DxH 900 S	DxH Slidemaker Stainer II	DxH 900			Standard Computer	Optional Stand-alone Review Station with Standard Computer
DxH 900-2	DxH 900	DxH 900			Power Computer	Power Computer
DxH 900-2 S	DxH Slidemaker Stainer II	DxH 900	DxH 900		Power Computer	One Review Station required with a Power Computer. Optional Review Station with Standard Computer
DxH 900-3	DxH 900	DxH 900	DxH 900		Power Computer	Two Review Stations required, one with Power Computer and one with Standard Computer
DxH 900-3 S	DxH Slidemaker Stainer II	DxH 900	DxH 900	DxH 900	Power Computer	Two Review Stations required, one with Power Computer and one with Standard Computer. Optional Stand-alone Workstation with Standard Computer

Principle of Operation:

The Coulter Principle is used to count and size cells by detecting and measuring changes in electrical resistance when a particle (such as a cell), in a conductive liquid, passes through a small aperture as shown in Figure 1.

Figure 1: Coulter Principle



Number	Description	Number	Description
1	Aperture Current	6	Aperture Tube
2	Vacuum	7	Aperture
3	Internal Electrode	8	Sample Beaker
4	Blood Cell Suspension	9	External Electrode
5	Detail of Aperture		

Each cell, suspended in a conductive liquid (diluent), acts as an insulator. As each cell goes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes on either side of the aperture. This causes a measurable electronic pulse. For counting, the vacuum used to pull the diluted suspension of cells through the aperture must be at a regulated volume. While the number of pulses indicates particle count, the size of the electrical pulse is proportional to the cell volume.

The lytic reagent used for the WBC prepares the blood so the system can count leukocytes and measure the amount of hemoglobin. The lytic reagent rapidly and simultaneously destroys the erythrocytes and converts a substantial proportion of the hemoglobin to a stable pigment while it leaves leukocyte nuclei intact. The absorbance of the pigment is directly proportional to the hemoglobin concentration of the sample. Hemoglobin is measured photometrically at 525 nm using the sample from the WBC analysis. Clean diluent is introduced into the cuvette during each operating cycle and is used as a blank in the calculation of the HGB.

The COULTER VCS technology is used to determine the white cell differential, nucleated red blood cell and reticulocyte parameters along with associated flags, messages, histograms and

data plots. As the particles pass through the sensing zone, a diode laser illuminates the particles. The flow cell measures volume, conductivity, multiple angles of light scatter, and axial light loss.

- For the WBC differential, sample preparation occurs at the Diff mix chamber where sample and reagents are added in the following order: Diff Lyse, blood, additional Diff Lyse followed by an air mix. Next, Diff preservative is added, followed by a second air mix, and an incubation period. The prepared sample is transferred to the module where cells are counted in an isometric sample stream. The algorithm analysis separates the WBC into five major populations.
- For NRBC, sample preparation occurs at the NRBC Diff mix chamber where sample and reagents are added in the following order: Diluent, blood, additional Diluent followed by an air mix. Next, DxH Cell Lyse is added, followed by a second air mix, and an incubation period. The prepared sample is transferred to the module where cells are counted in an isometric sample stream. The algorithm analysis separates NRBC from WBC.
- Reticulocytes are immature, non-nucleated erythrocytes retaining a small network of basophilic organelles, consisting of RNA and protoporphyrin. The enumeration of reticulocytes provides a simple, effective means to determine red cell production and regeneration. Reticulocyte immaturity is related to cell volume and light scatter. Since more immature reticulocytes are larger, contain more RNA and cause increased light scatter, the cell volume and light scatter will increase with immaturity of the cell.

The DxH Slidemaker Stainer II allows for adaptation of the smear appearance and stain methodology according to user preferences. Blood smears produced by the Slidemaker portion of the DxH Slidemaker Stainer II are moved to baskets for transfer to the Stainer portion by a robot. Microscopic examination of the stained blood smears can be used to help determine the hematologic status of a patient.

The aspiration probe aspirates the mixed sample, which is transported into the dispense probe. The probe moves to the drop placement position where blood is placed on the slide. A second slide is picked up and used to spread the drop on the first slide using the wedge technique. The prepared slide is transferred into the print shuttle where Information is thermally printed on the painted portion of the slide, and then into the basket elevator for drying. The dispense probe is cleaned in the dispense wash cup after drop placement on the slide.

For staining, the slide basket is dipped into each bath (1 to 5) for a staining time according to the active protocol. Each bath is configured to receive reagent from a predetermined supply source configured by the user. Slides are dried after staining.

807.92 (a)(5): Intended Use

The UniCel DxH 900/DxH 690T Coulter Cellular Analysis System is a quantitative, multi-parameter, automated hematology analyzer for *in vitro* diagnostic use in screening patient populations found in clinical laboratories.

The DxH 900/DxH 690T analyzer identifies and enumerates the following parameters:

- Whole Blood (Venous or Capillary): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF
- Pre-Diluted Whole Blood (Venous or Capillary): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV
- Body Fluids (cerebrospinal, serous or synovial): TNC and RBC

The UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System is a fully automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.

807.92 (a)(5): Indications for Use Comparison

The UniCel DxH 900 Coulter Cellular Analysis System, UniCel DxH 690T Coulter Cellular Analysis System, and UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System are substantially equivalent to the UniCel DxH 800 Coulter Cellular Analysis System and UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System cleared under the 510(k) numbers K193124 and K162414. There are no changes to the intended use or claims.

807.92 (a)(6): Technological Comparison

The UniCel DxH 900 Coulter Cellular Analysis System, UniCel DxH 690T Coulter Cellular Analysis System, and UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System have the same technological characteristics (principal of operation, energy source, reagents, calibrators, controls, and packaging) as the predicate devices.

Characteristic	Predicate DxH 800 K193124	Subject DxH 900/690T System
Intended Use	Analyzer: The UniCel DxH 800 Coulter Cellular Analysis System is a quantitative, multi-parameter, automated hematology analyzer for <i>in vitro</i> diagnostic use in screening patient populations found in clinical laboratories. The DxH 800 hematology analyzer identifies and enumerates the following parameters: • Whole Blood (Venous or Capillary): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF • Pre-Diluted Whole Blood (Venous or Capillary): WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV	Same

Characteristic	Predicate DxH 800 K193124	Subject DxH 900/690T System
	Body Fluids (cerebrospinal, serous or synovial): TNC and RBC	
Sampling Mechanism	Single aspiration probe used for all sampling. Single tube presentation – open and closed vial sampling – specimen manually mixed. Automated presentation – closed vial sampling from five-position cassette accepting a variety of defined specimen tubes. Cassette containing specimens mixed prior to starting sampling and between specimens. Maximum initial load capacity 20 cassettes - System will continuously process racks as added.	Same
Principles of Measurement	WBC, RBC, MCV, PLT: Aperture impedance (Coulter® Principle) Hemoglobin: Spectrophotometric WBC Differential, Reticulocytes, NRBC: VCSn Technology using: - Aperture impedance (DC) - Conductivity (RF) - Laser Light Scatter (Multiple angles) - Laser Light Absorbance	Same
Consumables	Analysis Reagents - COULTER DxH Diluent - COULTER DxH Diff Pack - COULTER DxH Cell Lyse - COULTER DxH Retic Pack - COULTER DxH Cleaner Quality Control & Calibrators - COULTER 6C Cell Control - COULTER 6C Plus Cell Control - COULTER Latron CP-X Control - COULTER RETIC-X Cell Control - COULTER LIN-X Control - COULTER Body Fluids Control - COULTER S-CAL Calibrator kit	Same, plus the option of the following ECO reagents: - DxH ECO Diluent (RTU) - DxH Concentrated ECO Diluent (18x) - DxH ECO Cell Lyse
Pre-Analytic Features		
System configuration	PC based workstation running Microsoft Windows 7 application specific software Handheld Barcode Scanner Printer	Same, but Windows 10
Sampling Mechanism	Single tube presentation – open and closed vial sampling. Automated presentation – closed vial sampling from 5 position cassette; Maximum initial load capacity 20 racks	Same
Mechanisms for processing	Mechanisms to achieve process of: Automated cassette transportation and specimen mixing (by rocking), sample aspiration, sample preparation, sample and reagent presentation to analytical modules, sample analysis, raw data collection, algorithmic processing and data reporting. Cassette transportation by magnetic drive	Same

Characteristic	Predicate DxH 800 K193124	Subject DxH 900/690T System
	allowing multi-directional moves and capability to return cassette to sampling position for repeat / reflex testing.	
Sample Identification	- Sample aspiration module (SAM) mounted barcode reader for automated barcode reading of cassette and sample tube identifiers. - Manual barcode scanning of sample tube identifier (handheld scanner) - Manual keyboard entry of sample identifier	Same
Sample Processing		
Aspiration Pathway	Single sampling probe and common aspiration pathway used for all sample presentation modes.	Same
Sample Aspiration Volume	Automatic, cap-piercing: 165 µL Single tube - open-vial and cap pierce: 165 µL Pre-dilute 165 µL - fixed ratio of 1 in 5 dilution of blood with diluent	Same
Throughput	For automatic mode: - CBC at 100 specimens/hr - CBC and Differential at 100 specimens/hr - CBC and Differential with NRBC at 90 specimens/hr - Retic at 45 specimens/hr	Same
Data Reporting	Workstation display graphics, hardcopy printing and transmission to Laboratory Information System (LIS)	Same
System Control and Software		
System Software	System software (embedded and workstation) designed specific to support all features of the DxH 800. The software system consists of a Data Manager component, a Universal System Manager component (including algorithms), the User Interface, all of which are resident in the system software in the workstation. In addition, an Embedded Application is resident in the analyzer. The Embedded application uploads from the workstation on system power-up. Extensive real time monitoring and reporting of system status including: Component and module activities, - System Voltages and Currents - System Pressure and Vacuum - System Temperatures - Motor activity - Mechanism Sensor status - Reagent Pump Operation - Raw data collection Single sampling probe and common aspiration pathway used for all sample presentation modes.	Same system software with enhancements to the instrument look and feel, workflow, usability, quality control and reliability.
Characteristic	Predicate DxH SMS K162414	Subject SMS II
Intended Use	The DxH Slidemaker Stainer is a fully automated slide preparation and staining device that aspirates a whole-blood sample, smears a blood film on a clean microscope slide, and delivers a variety of fixatives, stains, buffers, and rinse solutions to that blood smear.	Same

Characteristic	Predicate DxH 800 K193124	Subject DxH 900/690T System
Specimen Collection	Whole venous blood in EDTA	Same
Blood Film Preparation	Automatically prepared by DxH SMS	Same
Blood Film Requirements	Section 6.3.1 of CLSI H20-A2	Same
Consumables	Stains and Buffers: Beckman Coulter TruColor Reagents for use on the DxH Slidemaker Stainer • TruColor Wright Stain and TruColor Wright Buffer • TruColor Wright-Giemsa Stain and TruColor Wright-Giemsa Buffer Coulter TruColor Giemsa and May Grunwald Stains are not validated by Beckman Coulter for use through current default protocols on the system. Fixative: Methanol is used as a fixative for whole-blood smears in preparation for staining. Anhydrous methanol (chromatography grade, 99.8% or higher quality) is recommended. Distilled Water: Distilled water is used to rinse the stained smears before drying. CLSI Type CLRW water is recommended.	Same

807.92 (b): Non-Clinical and/or Clinical Test Summary

- a) Specimen Sampling Positions Comparability was tested on the DxH 800 (predicate) per EP09c, CLSI H26-A2, and CLSI H56 to establish equivalency for all sampling modes (Single tube open vial, Single tube closed vial, and Cassette presentations). Due to the similarities in the instrument hardware, data presented in K120771 continues to support the use of all specimen sampling positions as appropriate for the intended use of the device.

Test Panel	Reported Parameters	Specimen Type	Sampling Method
Complete Blood Count (CBC)	• WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV	whole blood	• Automated cassette closed vial • Manual single tube closed vial • Manual single tube open vial
CBC and Differential inc NRBC (CD)	• WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV • NE%, NE#, LY%, ly#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, and NRBC#	whole blood	• Automated cassette closed vial • Manual single tube closed vial • Manual single tube open vial
CBC, Differential inc NRBC and Retic (CDR)	• WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV • NE%, NE#, LY%, ly#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, and NRBC# • RET%, RET#, MRVM IRF	whole blood	• Automated cassette closed vial • Manual single tube closed vial • Manual single tube open vial
CBC and Retic (CR)	• WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV • RET%, RET#, MRVM IRF	whole blood	• Automated cassette closed vial • Manual single tube closed vial • Manual single tube open vial
Retic (R)	• RET%, RET#, MRVM IRF	whole blood	• Automated cassette closed vial • Manual single tube closed vial • Manual single tube open vial

Test Panel	Reported Parameters	Specimen Type	Sampling Method
Pre-dilute (PreDilx5)	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV	1 in 5 pre-diluted whole blood	Manual single tube open vial
Body Fluid (BF)	TNC, RBC	body fluid (cerebrospinal, serous and synovial)	Manual single tube open vial

- b) Whole blood and body fluid repeatability precision was tested on the DxH 900-3S workcell (instruments BC03127, BC03129, and BC03130) using the instrument's repeatability mode using cassette presentation for whole blood and single-tube presentation sampling for body fluids. Testing was performed according to CLSI H26-A2 and CLSI EP05-A3 to demonstrate the precision of the DxH 900 using whole blood and body fluid specimens. The whole blood and body fluid precision data provided supports the precision claims in the instructions for use. Connection of instruments into a workcell configuration does not significantly impact the precision.

Within run Repeatability of the parameters was performed using ten (10) aspirations of normal whole blood samples collected in K2EDTA. Specimens were selected for testing based on parameter value within specific ranges per parameter (measurand) to cover across the analytical measuring interval (AMI). Within run Imprecision (repeatability) was tested by performing replicate analysis of the specimens selected using the Repeatability function. Targeted specimens were used for more than one measurand. The coverage of the other measurand's measuring ranges was dependent on the spread of the samples collected to cover the measuring interval of the measurands. If normal and clinical specimens in the intended use populations were not found for estimation of precision profiles, contrived samples and control material were used.

Abnormal patient samples with low NRBC (1.00 – 2.00, >2.00 – 15.00), high NRBC (>15.00), and high Reticulocytes (>4.000 – 15.0) were not available during the test period. Instead, control material was used to assess Repeatability for these parameter values. Also, low levels for WBC 0.500 - 2.000 x10³ cells/μL, Platelet 10.0 - 15.0 x10³ cells/μL, Body fluid RBC 10,000 – 15,000 cells/mm³ and TNC 50–2,000 cells/mm³ were performed using altered whole blood samples due to no donor availability during the testing period as well.

Repeatability Results- Whole Blood CBC, DIFF, Retic

Parameter	Units	Level	N	Test Result Mean	Test Result %CV or SD	Acceptance
WBC	x10 ³ cells/μL	5.000 – 10.000	10	5.80	0.69% CV	Pass
WBC	x10 ³ cells/μL	0.500 to 2.000	10	0.59	2.02% CV	Pass
RBC	x10 ⁶ cells/μL	4.500 - 5.500	10	4.72	0.50% CV	Pass
Hgb	g/dL	14.00 - 16.00	10	15.03	0.36% CV	Pass
MCV	fL	80.00 – 90.00	10	85.39	0.22% CV	Pass
RDW %	%	12.00 – 14.00	10	13.71	1.31% CV	Pass
RDW-SD	fL	33.00 – 48.00	10	47.03	1.82% CV	Pass
Platelet	x10 ³ cells/μL	200.0 - 400.0	10	256.80	1.35% CV	Pass
Platelet	x10 ³ cells/μL	10.0 to 15.0	10	12.90	2.60% CV	Pass
MPV	fL	8.0 – 10.0	10	8.13	1.15% CV	Pass
Neut %	%	50.0 – 60.0	10	58.24	0.99 %CV	Pass
Lymph %	%	25.0– 35.0	10	26.34	2.44% CV	Pass
Mono %	%	5.0 – 10.0	10	6.22	7.66 % CV	Pass

Parameter	Units	Level	N	Test Result Mean	Test Result %CV or SD	Acceptance
Eos %	%	2.0 – 5.0	10	2.21	5.06% CV	Pass
Baso %	%	0.5 – 1.5	10	1.22	0.13 SD	Pass
NRBC	%	1.00 - 2.00	10*	1.46	0.20 SD	Pass
NRBC	%	>2.00 – 15.00	10*	9.21	4.69% CV	Pass
NRBC	%	> 15.00	10*	19.12	5.12% CV	Pass
Retic %	%	0.000 – 1.500	10	1.17	0.13 SD	Pass
Retic %	%	> 1.500 - 4.000	10	1.52	0.09 SD	Pass
Retic %	%	> 4.000 - 15.000	10*	10.07	1.44% CV	Pass
IRF	N/A	≥ 0.20	10	0.47	7.20%	Pass
MRV	fL	100.0 - 120.0	10	118.40	1.19% CV	Pass

*Control Material was used

Repeatability Results for Body Fluids

Parameter	Units	Level	N	Test Result Mean	Test Result %CV or SD	Acceptance
BF-RBC	cells/mm ³	10,000 – 15,000	10	12,643	2.42	Pass
BF-TNC	cells/mm ³	50–2,000	10	594	1.28	Pass

- c) Reproducibility testing was performed on the DxH 900-3S workcell using a single lot of all three (3) levels of 6C Plus, Retic-X, and Body Fluid cell controls. The table below shows the control material used for each material.

Control Material Used	Parameter
COULTER 6C PLUS Cell Control (3 levels)	WBC
	RBC
	HGB
	MCV
	RDW
	RDW-SD
	PLT
	MPV
	NE
	LY
	MO
	EO
	BA
	NRBC
COULTER RETIC-X Cell Control (3 levels)	RET
COULTER Body Fluids Control (3 levels)	BF TNC
	BF RBC

The controls were analyzed on one (1) DxH900-3S workcell, five (5) days, two (2) different times on the same day and three (3) shots per instrument, two (2) hours apart, per CLSI EP05-A3. The test instruments met the reproducibility specifications for all parameters.

Analysis for Instrument Combined

Level	Parameter	Unit	N	Mean	Repeatability		Between Runs		Between Instrument		Between Days		Reproducibility	
					SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Level 1	WBC	10 ³ cells/ μ L	90	3.42	0.07	1.90	0.00	0.00	0.04	1.26	0.01	0.27	0.08	2.30
	RBC	10 ⁶ cells/ μ L	90	1.74	0.01	0.59	0.00	0.11	0.00	0.26	0.00	0.00	0.01	0.66
	HGB	g/dL	90	4.62	0.02	0.43	0.00	0.00	0.01	0.26	0.01	0.13	0.02	0.52
	MCV	fL	90	79.48	0.14	0.18	0.19	0.24	0.23	0.29	0.19	0.24	0.38	0.48
	RDW	%	90	17.09	0.15	0.89	0.14	0.82	0.08	0.44	0.00	0.03	0.22	1.28
	RDW-SD	fL	90	49.50	0.49	1.00	0.19	0.38	0.10	0.21	0.10	0.20	0.55	1.11
	PLT	10 ³ cells/ μ L	90	72.39	1.11	1.53	0.00	0.00	0.28	0.39	0.33	0.45	1.19	1.64
	MPV	fL	90	9.13	0.06	0.66	0.00	0.00	0.03	0.30	0.03	0.34	0.07	0.80
	NE	%	90	43.13	0.69	1.61	0.00	0.00	0.00	0.00	0.00	0.00	0.69	1.61
	LY	%	90	46.24	0.72	1.56	0.00	0.00	0.12	0.25	0.00	0.00	0.73	1.58
	MO	%	90	6.67	0.40	5.95	0.00	0.00	0.15	2.29	0.00	0.00	0.43	6.38
	EO	%	90	3.94	0.34	8.58	0.14	3.67	0.00	0.00	0.00	0.00	0.37	9.33
	BA	%	90	0.02	0.02	74.92	0.00	0.00	0.00	0.00	0.01	26.29	0.02	79.39
	NRBC	%	90	0.29	0.10	34.20	0.00	0.00	0.05	15.62	0.00	0.00	0.11	37.60
	RET	%	90	0.87	0.10	11.18	0.02	2.71	0.15	17.41	0.00	0.00	0.18	20.86
	BF TNC	cells/mm ³	90	120.74	6.51	5.39	3.63	3.01	3.41	2.83	3.18	2.64	8.79	7.28
	BF RBC	cells/mm ³	90	12204.83	398.75	3.27	0.00	0.00	276.21	2.26	0.00	0.00	485.07	3.97
Level 2	WBC	10 ³ cells/ μ L	90	20.52	0.17	0.83	0.11	0.53	0.24	1.16	0.06	0.28	0.32	1.55
	RBC	10 ⁶ cells/ μ L	90	3.96	0.03	0.74	0.02	0.45	0.02	0.49	0.01	0.22	0.04	1.02
	HGB	g/dL	90	11.80	0.05	0.45	0.02	0.18	0.07	0.61	0.01	0.11	0.09	0.79
	MCV	fL	90	87.38	0.19	0.22	0.05	0.05	0.25	0.29	0.15	0.17	0.35	0.40
	RDW	%	90	16.24	0.16	1.01	0.06	0.37	0.01	0.09	0.08	0.51	0.19	1.19
	RDW-SD	fL	90	52.73	0.67	1.27	0.14	0.26	0.08	0.14	0.17	0.32	0.71	1.35
	PLT	10 ³ cells/ μ L	90	424.58	7.98	1.88	0.00	0.00	0.00	0.00	0.00	0.00	7.98	1.88
	MPV	fL	90	9.44	0.06	0.58	0.00	0.00	0.05	0.54	0.02	0.18	0.08	0.82
	NE	%	90	65.12	0.68	1.05	0.00	0.00	0.00	0.00	0.12	0.19	0.69	1.07
	LY	%	90	15.71	0.50	3.21	0.07	0.46	0.13	0.80	0.09	0.60	0.53	3.39
	MO	%	90	14.16	0.52	3.65	0.26	1.84	0.00	0.00	0.00	0.00	0.58	4.09
	EO	%	90	4.96	0.41	8.33	0.00	0.00	0.00	0.00	0.00	0.00	0.41	8.33
	BA	%	90	0.06	0.03	57.53	0.00	0.00	0.00	0.00	0.00	0.00	0.03	57.53
	NRBC	%	90	9.09	0.40	4.36	0.07	0.78	0.00	0.00	0.08	0.90	0.41	4.53
	RET	%	90	2.48	0.12	4.73	0.00	0.00	0.16	6.50	0.04	1.78	0.20	8.23
	BF TNC	cells/mm ³	90	1526.92	20.38	1.33	4.95	0.32	11.01	0.72	12.20	0.80	26.64	1.74
	BF RBC	cells/mm ³	90	1681333.92	8753.35	0.52	4306.83	0.26	16235.20	0.97	963.34	0.06	18965.22	1.13
Level 3	WBC	10 ³ cells/ μ L	90	8.58	0.10	1.20	0.00	0.00	0.04	0.47	0.03	0.40	0.12	1.35
	RBC	10 ⁶ cells/ μ L	90	5.28	0.03	0.62	0.02	0.33	0.04	0.77	0.01	0.24	0.06	1.07
	HGB	g/dL	90	15.61	0.09	0.59	0.00	0.00	0.14	0.89	0.04	0.29	0.17	1.10
	MCV	fL	90	87.59	0.22	0.26	0.00	0.00	0.24	0.28	0.14	0.16	0.36	0.41
	RDW	%	90	15.47	0.17	1.09	0.00	0.00	0.00	0.00	0.00	0.00	0.17	1.09
	RDW-SD	fL	90	50.86	0.60	1.19	0.00	0.00	0.00	0.00	0.00	0.00	0.60	1.19
	PLT	10 ³ cells/ μ L	90	222.27	3.16	1.42	0.00	0.00	0.00	0.00	0.00	0.00	3.16	1.42
	MPV	fL	90	9.61	0.06	0.67	0.02	0.26	0.04	0.46	0.00	0.00	0.08	0.85
	NE	%	90	57.05	0.81	1.42	0.00	0.00	0.00	0.00	0.00	0.00	0.81	1.42
	LY	%	90	27.73	0.59	2.13	0.00	0.00	0.00	0.00	0.00	0.00	0.59	2.13
	MO	%	90	8.36	0.40	4.78	0.00	0.00	0.00	0.00	0.00	0.00	0.40	4.78
	EO	%	90	6.82	0.47	6.86	0.00	0.00	0.00	0.00	0.00	0.00	0.47	6.86
	BA	%	90	0.04	0.02	54.51	0.01	13.07	0.00	9.39	0.00	0.00	0.02	56.83
	NRBC	%	90	19.45	0.52	2.66	0.00	0.00	0.49	2.52	0.09	0.45	0.72	3.69
	RET	%	90	10.50	0.18	1.72	0.00	0.00	0.11	1.09	0.07	0.69	0.23	2.14
	BF TNC	cells/mm ³	90	65778.99	514.83	0.78	265.68	0.40	763.00	1.16	0.00	0.00	958.02	1.46
	BF RBC	cells/mm ³	90	5639354.09	50090.17	0.89	0.00	0.00	32100.78	0.57	1922.28	0.03	59524.62	1.06

Additional Body Fluid Precision Runs

Parameter	Unit	N	Mean	SD	CV%
BF RBC	cells/mm ³	11	73724	851	1.1
	cells/mm ³	10	74706	1166	1.5
	cells/mm ³	9	12624	407	3.2
BF-TNC	cells/mm ³	10	309	9	3.1
	cells/mm ³	11	1270	21	1.7
	cells/mm ³	12	696	20	3.0
	cells/mm ³	10	3070	65	2.1
	cells/mm ³	10	24879	207	0.83
	cells/mm ³	9	1281	26	2.0
	cells/mm ³	10	214	10	4.9

- d) Linearity: Whole Blood and Body Fluid Linearity was tested on the DxH 900-3S workcell per CLSI EP06-A, 2nd Ed to assess system linearity of whole blood count parameters (WBC, RBC, PLT and HGB) and Body Fluids parameters (BF-RBC and BF-TNC) across the analytical measuring interval (AMI). Fresh whole blood was obtained and concentrated to achieve a high starting value near the upper limit of the AMI for each measurand. If values near the upper limit were not achieved using whole blood, surrogate (analog) cells were used instead. Dilutions were prepared of each measurand to cover the AMI and tested in quadruplicate in random order. Each dilution series contained a minimum of seven (7) dilutions and testing was performed on three (3) instruments. For count measurands, given the wide measuring interval, additional dilutions at the low end of the range were required.

Deviation from Linearity for WBC 10³/μL on Instrument BC03127

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0.012	0.049	0.070	0.081	-0.01092	-13.44	0.100	Pass
0.024	0.098	0.128	0.131	-0.00217	-1.66	0.100	Pass
0.049	0.200	0.237	0.233	0.00389	1.67	0.100	Pass
0.098	0.400	0.460	0.434	0.02613	6.02	0.100	Pass
0.195	0.797	0.864	0.832	0.03136	3.77	0.100	Pass
0.391	1.597	1.738	1.637	0.10097	6.17	0.174	Pass
0.781	3.191	3.371	3.237	0.13337	4.12	0.200	Pass
1.563	6.385	6.466	6.447	0.01965	0.30	0.200	Pass
3.125	12.767	13.191	12.857	0.33375	2.60	0.396	Pass
6.25	25.534	26.338	25.682	0.65550	2.55	0.790	Pass
12.5	51.068	51.626	51.333	0.29268	0.57	1.549	Pass
25	102.135	103.036	102.634	0.40170	0.39	5.152	Pass
50	204.271	204.357	205.236	-0.87860	-0.43	10.218	Pass
100	408.541	408.541	410.440	-1.89885	-0.46	20.427	Pass

Deviation from Linearity for WBC 10³/μL on Instrument BC03129

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0.012	0.051	0.065	0.075	-0.00995	-13.33	0.100	Pass
0.024	0.101	0.125	0.126	-0.00057	-0.45	0.100	Pass
0.049	0.207	0.240	0.232	0.00828	3.57	0.100	Pass
0.098	0.414	0.452	0.440	0.01255	2.85	0.100	Pass
0.195	0.824	0.882	0.852	0.03068	3.60	0.100	Pass

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0.391	1.653	1.791	1.684	0.10744	6.38	0.179	Pass
0.781	3.302	3.454	3.340	0.11412	3.42	0.200	Pass
1.563	6.607	6.758	6.660	0.09798	1.47	0.203	Pass
3.125	13.211	13.531	13.293	0.23821	1.79	0.406	Pass
6.25	26.422	27.189	26.562	0.62741	2.36	0.816	Pass
12.5	52.843	53.308	53.100	0.20814	0.39	1.599	Pass
25	105.686	105.651	106.177	-0.52538	-0.49	5.283	Pass
50	211.372	212.634	212.330	0.30456	0.14	10.632	Pass
100	422.744*	422.744	424.636	-1.89156	-0.45	21.137	Pass

Deviation from Linearity for WBC $10^3/\mu\text{L}$ on Instrument BC03130

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0.012	0.049	0.071	0.083	-0.01241	-14.94	0.100	Pass
0.024	0.098	0.129	0.132	-0.00306	-2.32	0.100	Pass
0.049	0.200	0.233	0.233	-0.00007	-0.03	0.100	Pass
0.098	0.401	0.465	0.432	0.03330	7.71	0.100	Pass
0.195	0.797	0.885	0.825	0.05974	7.24	0.100	Pass
0.391	1.598	1.731	1.619	0.11153	6.89	0.173	Pass
0.781	3.192	3.383	3.200	0.18221	5.69	0.200	Pass
1.563	6.388	6.487	6.371	0.11612	1.82	0.200	Pass
3.125	12.772	13.010	12.703	0.30707	2.42	0.390	Pass
6.25	25.544	25.705	25.371	0.33456	1.32	0.771	Pass
12.5	51.088	50.632	50.707	-0.07478	-0.15	1.519	Pass
25	102.176	101.071	101.380	-0.30880	-0.30	5.054	Pass
50	204.351	198.604	202.725	-4.12083	-2.03	9.930	Pass
100	408.702	408.702	405.416	3.28643	0.81	20.435	Pass

Deviation from Linearity for RBC $10^6/\mu\text{L}$ on Instrument BC03127

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0	0.000	0.013	0.013	0.00000	0.00	0.050	Pass
10	0.858	0.856	0.867	-0.01116	-1.29	0.050	Pass
20	1.716	1.742	1.721	0.02100	1.22	0.050	Pass
30	2.574	2.567	2.574	-0.00716	-0.28	0.051	Pass
40	3.432	3.433	3.428	0.00434	0.13	0.069	Pass
50	4.290	4.344	4.282	0.06217	1.45	0.087	Pass
60	5.148	5.198	5.136	0.06234	1.21	0.104	Pass
70	6.006	5.918	5.990	-0.07216	-1.20	0.118	Pass
80	6.865	6.872	6.844	0.02801	0.41	0.137	Pass
90	7.723	7.583	7.697	-0.11449	-1.49	0.152	Pass
100	8.581	8.581	8.551	0.02935	0.34	0.172	Pass

Deviation from Linearity for RBC 10⁶/μL on Instrument BC03129

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0	0.000	0.001	0.001	-0.00000	-0.00	0.050	Pass
10	0.856	0.857	0.844	0.01336	1.58	0.050	Pass
20	1.712	1.656	1.686	-0.02994	-1.78	0.050	Pass
30	2.568	2.519	2.529	-0.00992	-0.39	0.050	Pass
40	3.424	3.416	3.372	0.04445	1.32	0.068	Pass
50	4.280	4.201	4.214	-0.01319	-0.31	0.084	Pass
60	5.136	5.062	5.057	0.00517	0.10	0.101	Pass
70	5.992	5.895	5.899	-0.00480	-0.08	0.118	Pass
80	6.848	6.670	6.742	-0.07244	-1.07	0.133	Pass
90	7.704	7.504	7.585	-0.08075	-1.06	0.150	Pass
100	8.560	8.560	8.427	0.13295	1.58	0.171	Pass

Deviation from Linearity for RBC 10⁶/μL on Instrument BC03130

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0	0.000	0.001	0.001	-0.00000	-0.00	0.050	Pass
10	0.859	0.858	0.843	0.01505	1.78	0.050	Pass
20	1.719	1.643	1.686	-0.04258	-2.53	0.050	Pass
30	2.578	2.510	2.528	-0.01820	-0.72	0.050	Pass
40	3.437	3.419	3.370	0.04852	1.44	0.068	Pass
50	4.297	4.205	4.212	-0.00777	-0.18	0.084	Pass
60	5.156	5.070	5.055	0.01494	0.30	0.101	Pass
70	6.015	5.950	5.897	0.05299	0.90	0.119	Pass
80	6.875	6.632	6.739	-0.10730	-1.59	0.133	Pass
90	7.734	7.503	7.582	-0.07892	-1.04	0.150	Pass
100	8.593	8.593	8.424	0.16946	2.01	0.172	Pass

Deviation from Linearity for HGB g/dL on Instrument BC03127

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0	0.000	0.120	0.285	-0.16515	-57.92	0.200	Pass
10	2.607	2.823	2.860	-0.03661	-1.28	0.200	Pass
20	5.214	5.287	5.435	-0.14806	-2.72	0.200	Pass
30	7.821	7.913	8.010	-0.09618	-1.20	0.237	Pass
40	10.428	10.803	10.584	0.21903	2.07	0.324	Pass
50	13.035	13.483	13.159	0.32424	2.46	0.405	Pass
60	15.642	15.980	15.734	0.24612	1.56	0.479	Pass
70	18.249	18.560	18.309	0.25133	1.37	0.557	Pass
80	20.856	20.680	20.883	-0.20345	-0.97	0.620	Pass
90	23.463	23.030	23.458	-0.42824	-1.83	0.691	Pass
100	26.070	26.070	26.033	0.03697	0.14	0.782	Pass

Deviation from Linearity for HGB g/dL on Instrument BC03129

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0	0.000	0.057	0.122	-0.06576	-53.71	0.200	Pass
10	2.649	2.697	2.749	-0.05218	-1.90	0.200	Pass
20	5.299	5.360	5.375	-0.01527	-0.28	0.200	Pass
30	7.948	8.047	8.002	0.04497	0.56	0.241	Pass
40	10.597	10.730	10.628	0.10188	0.96	0.322	Pass
50	13.247	13.377	13.255	0.12212	0.92	0.401	Pass
60	15.896	15.937	15.881	0.05570	0.35	0.478	Pass
70	18.545	18.453	18.507	-0.05406	-0.29	0.554	Pass
80	21.195	21.030	21.134	-0.10382	-0.49	0.631	Pass
90	23.844	23.620	23.760	-0.14024	-0.59	0.709	Pass
100	26.493	26.493	26.387	0.10667	0.40	0.795	Pass

Deviation from Linearity for HGB g/dL on Instrument BC03130

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0	0.000	0.140	0.242	-0.10242	-42.25	0.200	Pass
10	2.666	2.897	2.872	0.02461	0.86	0.200	Pass
20	5.331	5.407	5.502	-0.09503	-1.73	0.200	Pass
30	7.997	8.090	8.131	-0.04133	-0.51	0.243	Pass
40	10.663	11.013	10.761	0.25236	2.35	0.330	Pass
50	13.328	13.437	13.391	0.04606	0.34	0.403	Pass
60	15.994	16.060	16.020	0.03976	0.25	0.482	Pass
70	18.660	18.833	18.650	0.18345	0.98	0.565	Pass
80	21.325	21.103	21.280	-0.17618	-0.83	0.633	Pass
90	23.991	23.660	23.909	-0.24915	-1.04	0.710	Pass
100	26.657	26.657	26.539	0.11788	0.44	0.800	Pass

Deviation from Linearity for PLT 10³/μL on Instrument BC03127

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0.098	2.991	3.700	4.633	-0.93316	-20.14	5.000	Pass
0.195	5.951	6.767	7.635	-0.86840	-11.37	5.000	Pass
0.391	11.933	14.100	13.701	0.39922	2.91	5.000	Pass
0.781	23.836	26.633	25.770	0.86303	3.35	5.000	Pass
1.563	47.703	52.733	49.971	2.76209	5.53	5.000	Pass
3.125	95.375	102.533	98.311	4.22209	4.29	5.127	Pass
6.25	190.750	202.833	195.022	7.81116	4.01	10.142	Pass
12.5	381.500	402.867	388.444	14.42262	3.71	20.143	Pass
25	763.000	795.467	775.288	20.17887	2.60	39.773	Pass
50	1526.000	1559.700	1548.975	10.72472	0.69	77.985	Pass
100	3052.000	3052.000	3096.350	-44.35026	-1.43	152.600	Pass

Deviation from Linearity for PLT $10^3/\mu\text{L}$ on Instrument BC03129

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0.098	2.942	3.433	4.366	-0.93287	-21.37	5.000	Pass
0.195	5.855	6.533	7.332	-0.79861	-10.89	5.000	Pass
0.391	11.739	13.167	13.325	-0.15790	-1.19	5.000	Pass
0.781	23.448	26.567	25.249	1.31800	5.22	5.000	Pass
1.563	46.926	52.200	49.158	3.04198	6.19	5.000	Pass
3.125	93.823	100.433	96.916	3.51776	3.63	5.022	Pass
6.25	187.646	201.733	192.461	9.27207	4.82	10.087	Pass
12.5	375.292	403.633	383.553	20.08069	5.24	20.182	Pass
25	750.583	779.800	765.735	14.06461	1.84	38.990	Pass
50	1501.167	1555.267	1530.101	25.16578	1.64	77.763	Pass
100	3002.333	3002.333	3058.832	-56.49855	-1.85	150.117	Pass

Deviation from Linearity for PLT $10^3/\mu\text{L}$ on Instrument BC03130

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0.098	3.029	3.367	4.120	-0.75307	-18.28	5.000	Pass
0.195	6.026	6.800	7.145	-0.34457	-4.82	5.000	Pass
0.391	12.084	12.900	13.257	-0.35660	-2.69	5.000	Pass
0.781	24.137	26.100	25.418	0.68170	2.68	5.000	Pass
1.563	48.304	52.367	49.804	2.56259	5.15	5.000	Pass
3.125	96.577	103.333	98.513	4.82009	4.89	5.167	Pass
6.25	193.154	202.933	195.963	6.97056	3.56	10.147	Pass
12.5	386.308	404.667	390.862	13.80483	3.53	20.233	Pass
25	772.617	784.367	780.660	3.70671	0.47	39.218	Pass
50	1545.233	1569.033	1560.256	8.77714	0.56	78.452	Pass
100	3090.467	3090.467	3119.449	-28.98200	-0.93	154.523	Pass

Deviation from Linearity for TNC cells/ mm^3 on Instrument BC03127

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0.02	18.551	35.000	30.871	4.12949	13.38	5.000	Pass
0.04	37.102	45.333	49.445	-4.11131	-8.31	5.000	Pass
0.06	55.652	63.667	68.019	-4.35212	-6.40	6.367	Pass
0.08	74.203	89.667	86.593	3.07374	3.55	8.967	Pass
0.1	92.754	97.000	105.167	-8.16707	-7.77	9.700	Pass
10	9275.400	9295.000	9299.367	-4.36665	-0.05	929.500	Pass
20	18550.800	19726.000	18586.437	1139.56307	6.13	1972.600	Pass
30	27826.200	27860.667	27873.507	-12.84054	-0.05	2786.067	Pass
40	37101.600	36818.333	37160.577	-342.24416	-0.92	3681.833	Pass
50	46377.000	46537.667	46447.648	90.01890	0.19	4653.767	Pass
60	55652.400	55888.333	55734.718	153.61528	0.28	5588.833	Pass
70	64927.800	64934.000	65021.788	-87.78833	-0.14	6493.400	Pass
80	74203.200	74464.667	74308.859	155.80806	0.21	7446.467	Pass
90	83478.600	82905.000	83595.929	-690.92889	-0.83	8290.500	Pass
100	92754.000	92754.000	92882.999	-128.99917	-0.14	9275.400	Pass

Deviation from Linearity for TNC cells/mm³ on Instrument BC03129

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0.02	18.972	27.333	29.292	-1.95844	-6.69	5.000	Pass
0.04	37.944	47.667	48.503	-0.83605	-1.72	5.000	Pass
0.06	56.916	67.000	67.714	-0.71366	-1.05	6.700	Pass
0.08	75.887	90.333	86.925	3.40873	3.92	9.033	Pass
0.1	94.859	102.000	106.136	-4.13555	-3.90	10.200	Pass
10	9485.933	9593.000	9615.552	-22.55231	-0.23	959.300	Pass
20	18971.867	20269.333	19221.024	1048.30955	5.45	2026.933	Pass
30	28457.800	28782.333	28826.495	-44.16193	-0.15	2878.233	Pass
40	37943.733	38453.667	38431.967	21.69993	0.06	3845.367	Pass
50	47429.667	47965.667	48037.438	-71.77155	-0.15	4796.567	Pass
60	56915.600	57668.667	57642.910	25.75698	0.04	5766.867	Pass
70	66401.533	66629.333	67248.381	-619.04783	-0.92	6662.933	Pass
80	75887.467	77711.333	76853.853	857.48069	1.12	7771.133	Pass
90	85373.400	86751.333	86459.324	292.00921	0.34	8675.133	Pass
100	94859.333	94859.333	96064.796	-1205.4623	-1.25	9485.933	Pass

Deviation from Linearity for TNC cells/mm³ on Instrument BC03130

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0.02	18.885	31.333	31.494	-0.16058	-0.51	5.000	Pass
0.04	37.769	50.000	50.452	-0.45154	-0.89	5.000	Pass
0.06	56.654	68.000	69.409	-1.40917	-2.03	6.800	Pass
0.08	75.539	90.667	88.367	2.29988	2.60	9.067	Pass
0.1	94.424	98.667	107.324	-8.65775	-8.07	9.867	Pass
10	9442.367	9505.667	9491.349	14.31801	0.15	950.567	Pass
20	18884.733	20211.000	18970.161	1240.83898	6.54	2021.100	Pass
30	28327.100	28414.667	28448.973	-34.30672	-0.12	2841.467	Pass
40	37769.467	37804.667	37927.786	-123.11908	-0.32	3780.467	Pass
50	47211.833	46924.000	47406.598	-482.59811	-1.02	4692.400	Pass
60	56654.200	57072.333	56885.410	186.92286	0.33	5707.233	Pass
70	66096.567	65844.667	66364.223	-519.55617	-0.78	6584.467	Pass
80	75538.933	75947.333	75843.035	104.29813	0.14	7594.733	Pass
90	84981.300	85579.333	85321.848	257.48577	0.30	8557.933	Pass
100	94423.667	94423.667	94800.660	-376.99326	-0.40	9442.367	Pass

Deviation from Linearity for BF RBC on Instrument BC03127

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit (±)	Conclusion
0.015	954.328	1205.333	1144.669	60.66387	5.30	500.000	Pass
0.02	1272.438	1705.333	1463.115	242.21809	16.55	500.000	Pass
0.04	2544.875	2654.333	2736.898	-82.56504	-3.02	500.000	Pass
0.06	3817.313	4231.333	4010.682	220.65183	5.50	500.000	Pass
0.08	5089.751	5632.667	5284.465	348.20204	6.59	500.000	Pass
0.1	6362.188	6485.333	6558.248	-72.91442	-1.11	500.000	Pass
20	1272437.67	1277341.33	1273972.46	3368.87281	0.26	63867.067	Pass

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
30	1908656.50	1891584.67	1910864.02	-19279.358	-1.01	94579.233	Pass
40	2544875.33	2490719.33	2547755.59	-57036.256	-2.24	124535.967	Pass
50	3181094.17	3199415.67	3184647.15	14768.5135	0.46	159970.783	Pass
60	3817313.00	3813229.67	3821538.72	-8309.0507	-0.22	190661.483	Pass
70	4453531.83	4495862.00	4458430.28	37431.7184	0.84	224793.100	Pass
80	5089750.67	5112301.67	5095321.85	16979.8209	0.33	255615.083	Pass
90	5725969.50	5736287.67	5732213.41	4074.25670	0.07	286814.383	Pass
100	6362188.33	6362188.33	6369104.97	-6916.6408	-0.11	318109.417	Pass

Deviation from Linearity for BF RBC on Instrument BC03129

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0.015	957.169	1145.000	1122.947	22.05325	1.96	500.000	Pass
0.02	1276.225	1530.333	1442.930	87.40381	6.06	500.000	Pass
0.04	2552.450	2803.333	2722.861	80.47273	2.96	500.000	Pass
0.06	3828.675	3959.667	4002.792	-43.12502	-1.08	500.000	Pass
0.08	5104.900	5676.667	5282.723	393.94390	7.46	500.000	Pass
0.1	6381.125	6627.000	6562.654	64.34616	0.98	500.000	Pass
20	1276225.00	1274035.67	1280094.08	-6058.4121	-0.47	63701.783	Pass
30	1914337.50	1892034.00	1920059.62	-28025.619	-1.46	94601.700	Pass
40	2552450.00	2528795.33	2560025.16	-31229.826	-1.22	126439.767	Pass
50	3190562.50	3237730.67	3199990.70	37739.9675	1.18	161886.533	Pass
60	3828675.00	3843700.67	3839956.24	3744.42739	0.10	192185.033	Pass
70	4466787.50	4521090.67	4479921.78	41168.8873	0.92	226054.533	Pass
80	5104900.00	5113788.00	5119887.32	-6099.3196	-0.12	255689.400	Pass
90	5743012.50	5759083.67	5759852.86	-769.19302	-0.01	287954.183	Pass
100	6381125.00	6381125.00	6399818.40	-18693.400	-0.29	319056.250	Pass

Deviation from Linearity for BF RBC on Instrument BC03130

Dilution	Expected Value	Mean of Measured Value	Predicted Value from linear	Deviation	% Deviation	Acceptance Limit ($\pm$)	Conclusion
0.015	953.086	1047.000	1113.100	-66.09964	-5.94	500.000	Pass
0.02	1270.781	1712.667	1433.869	278.79789	19.44	500.000	Pass
0.04	2541.563	2663.333	2716.945	-53.61197	-1.97	500.000	Pass
0.06	3812.344	4286.333	4000.022	286.31151	7.16	500.000	Pass
0.08	5083.125	5300.000	5283.098	16.90165	0.32	500.000	Pass
0.1	6353.906	6897.667	6566.175	331.49179	5.05	500.000	Pass
20	1270781.27	1266443.67	1283227.32	-16783.653	-1.31	63322.183	Pass
30	1906171.90	1899907.67	1924765.58	-24857.916	-1.29	94995.383	Pass
40	2541562.53	2527694.00	2566303.85	-38609.847	-1.50	126384.700	Pass
50	3176953.17	3219698.67	3207842.11	11856.5565	0.37	160984.933	Pass
60	3812343.80	3871521.00	3849380.37	22140.6263	0.58	193576.050	Pass
70	4447734.43	4590433.00	4490918.64	99514.3627	2.22	229521.650	Pass
80	5083125.07	5142751.33	5132456.90	10294.4324	0.20	257137.567	Pass
90	5718515.70	5764944.33	5773995.16	-9050.8312	-0.16	288247.217	Pass
100	6353906.33	6353906.33	6415533.43	-61627.095	-0.96	317695.317	Pass

The data presented in this submission supports the linear range for whole blood and body fluids as described in the Instructions for Use. The data supports that connection of instruments into a workcell configuration does not significantly impact the linearity.

Parameter	Units	Linearity Range Results
WBC	10 ³ cells/μL	0.064 – 408.5
RBC	10 ⁶ cells/μL	0.001 - 8.560
PLT	10 ³ cells/μL	3.2 – 3002
HGB	g/dL	0.04 - 26.070
BF-RBC	cells/mm ³	1113.10 – 6,353,906
BF-TNC	cells/mm ³	31.50 – 92,745

- e) Carryover: Whole Blood and Body Fluid High to Low Carryover was conducted on the DxH 900-3S workcell per CLSI H26-A2. Three (3) test instruments were used for each of the WBC, RBC, Hgb, and PLT parameters. One (1) replicate from each of the three (3) High Target Value tubes followed by one (1) replicate from each of the three (3) Low Target Value tubes were analyzed. Each of the Low Target Value tubes was only aspirated once. This step was repeated three (3) times for each parameter. The WBC, RBC, Hgb, and PLT parameters for Carryover were calculated using the formula % carryover = [(LTV 1- LTV 3)/(HTV 3-LTV 3)] X100, where HTV=high target value, LTV=low target value. The data presented in the submission supports there is no detectable carryover for whole blood or body fluids as described in the Instructions for Use. The data supports that connection of instruments into a workcell configuration does not impact carryover.
- f) Performance Detection Capability Limits: Limit of Blank (LoB), Lower Limit of Detection (LLoD) and Lower Limit of Quantitation (LLoQ) was conducted on the DxH 900-3S workcell per CLSI EP17-A2 to evaluate the LoB, LLoD and LLoQ for WBC, PLT, BF-RBC, and BF-TNC.

LoB was performed using DxH diluent as blank in the CBC, CDR, CD and CR test panel in cassette presentation, five (5) replicates of each panel were analyzed for a total of twenty (20) replicates in the AM and PM for three (3) days for a total of 120 whole blood cassette presentation cycles. Twenty (20) replicates of DxH diluent (blank) were analyzed in the single tube presentation as BF cycle in the AM and PM for three (3) days for a total of 120 single tube BF cycles. In both scenarios, two (2) lots of DxH diluent and DxH Cell Lyse reagents were used.

To test for LLoD and LLoQ, a dilution of a fresh whole blood sample was prepared to obtain a stock solution with a value in one of the following target ranges (WBC 60-70 x 10³/μL, PLT 7-9 x 10³/μL, TNC 45-50 cells/mm³, and BF-RBC 2450- 2470 cells/mm³). Four (4) samples per parameter were obtained for a total of sixteen (16) samples per instrument. Three (3) sets of eleven (11) dilutions of the stock solution were prepared in 10% increments from 0% to 100%. One (1) set of dilutions was analyzed on each of the test instruments. Five (5) replicates of each dilution level were analyzed on each test instrument in the CBC test panel for WBC and PLT and five (5) replicates of each were analyzed on each instrument in the BFC test panel for TNC and BF-RBC.

Bias was established by analyzing five (5) normal whole blood samples each day in duplicate on the test instruments and DxH 800 comparator using the CBC test panel.

The limit of quantitation data provided supports the intended use of the device and the lower limit of the analytical measuring interval per the instructions for use. The data supports that connection of instruments into a workcell configuration does not significantly impact the analytical measuring range. For WBC, PLT, BF-TNC, and BF-RBC, LLoQ are aligned with the background limit and the lower limit of the measuring range. These are parameters where there is a clinical interest (medical decision level) on very low or near zero values.

LLoQ Results

Parameter	Units	Acceptance limit (LoQ)	LoQ result
WBC	x10 ³ cells/μL	≤0.050	0.019
PLT	x10 ³ cells/μL	≤3.000	0.757
BF TNC	cells/mm ³	≤20.000	14.004
BF RBC	cells/mm ³	≤1000.000	979.869

- g) Reference Ranges: Studies to assess the Adult Reference Interval (Whole Blood) were conducted on the DxH 900 per CLSI EP28-A3c to verify the reference intervals for male and female adults on the DxH 900/DxH 690T Analyzer are the same as the DxH 800 Analyzer (predicate). The data verifies the DxH 800 references ranges presented in the IFU are transferable to the DxH 900/DxH 690T. The data supports that connected workcells have the same reference ranges as a stand-alone instrument.

Reference Ranges for Adults Combined Male and Female

Parameter	Unit	Mean	95% Confidence Lower Limit	95% Confidence Upper Limit
WBC	x 10 ³ cells/μL	6.3	3.6	11.2
RBC	x 10 ⁶ cells/μL	4.52	3.73	5.50
Hemoglobin	g/dL	13.4	11.4	15.9
HCT	%	39.0	33.3	45.7
MCV	fL	86.4	73.7	95.5
MCH	pg	29.6	24.3	33.2
MCHC	g/dL	34.2	32.5	35.8
RDW	%	13.8	12.3	17.0
RDW-SD	fL	41.4	37.1	47.8
Platelet	x 10 ³ cells/μL	257	159	386
MPV	fL	9.2	7.5	11.2
Neutrophil	%	58.5	43.3	76.6
Lymphocyte	%	29.6	16.0	43.5
Monocyte	%	8.3	4.5	12.5
Eosinophil	%	2.8	0.6	7.9
Basophil	%	0.7	0.2	1.4
Neutrophil	x 10 ³ cells/μL	3.7	1.8	7.8
Lymphocyte	x 10 ³ cells/μL	1.8	1.0	3.0
Monocyte	x 10 ³ cells/μL	0.5	0.3	1.0
Eosinophil	x 10 ³ cells/μL	0.2	0.0	0.5
Basophil	x 10 ³ cells/μL	0.0	0.0	0.1
Reticulocyte	%	1.10	0.50	2.17
Reticulocyte	x 10 ⁶ cells/μL	0.0498	0.0221	0.0963
MRV	fL	108.8	97.4	120.2
IRF	NA	0.40	0.29	0.53
NRBC	%	0.1	0.0	0.4
NRBC	x 10 ³ cells/μL	0.01	0.00	0.02

Reference Ranges for Adult Females

Parameter	Unit	Mean	95% Confidence Lower	95% Confidence Upper
WBC	x 10 ³ cells/ μ L	6.7	3.8	11.8
RBC	x 10 ⁶ cells/ μ L	4.26	3.63	4.92
Hemoglobin	g/dL	12.6	10.9	14.3
HCT	%	36.9	31.2	41.9
MCV	fL	86.8	75.5	95.3
MCH	pg	29.6	24.7	32.8
MCHC	g/dL	34.1	32.3	35.6
RDW	%	14.0	12.3	17.7
RDW-SD	fL	42.0	37.6	50.3
Platelet	x 10 ³ cells/ μ L	278	179	408
MPV	fL	9.2	7.9	10.8
Neutrophil	%	59.7	42.7	76.8
Lymphocyte	%	29.4	16.0	45.9
Monocyte	%	7.6	4.3	10.9
Eosinophil	%	2.4	0.5	7.0
Basophil	%	0.7	0.2	1.3
Neutrophil	x 10 ³ cells/ μ L	4.1	1.9	8.2
Lymphocyte	x 10 ³ cells/ μ L	1.9	1.1	3.1
Monocyte	x 10 ³ cells/ μ L	0.5	0.2	0.9
Eosinophil	x 10 ³ cells/ μ L	0.2	0.0	0.5
Basophil	x 10 ³ cells/ μ L	0.0	0.0	0.1
Reticulocyte	%	1.11	0.51	2.17
Reticulocyte	x 10 ⁶ cells/ μ L	0.04	0.0230	0.0935
MRV	fL	108.	96.4	118.0
IRF	NA	0.40	0.26	0.52
NRBC	%	0.1	0.0	0.3
NRBC	x 10 ³ cells/ μ L	0.01	0.00	0.02

Reference Ranges for Adult Males

Parameter	Unit	Mean	95% Confidence Lower	95% Confidence Upper
WBC	x 10 ³ cells/ μ L	5.9	3.6	10.2
RBC	x 10 ⁶ cells/ μ L	4.81	4.06	5.63
Hemoglobin	g/dL	14.2	12.5	16.3
HCT	%	41.3	36.7	47.1
MCV	fL	86.1	73.0	96.2
MCH	pg	29.6	23.8	33.4
MCHC	g/dL	34.4	32.5	36.3
RDW	%	13.6	12.1	16.2
RDW-SD	fL	40.8	36.5	45.9
Platelet	x 10 ³ cells/ μ L	234	152	348
MPV	fL	9.2	7.4	11.4
Neutrophil	%	57.3	43.5	73.5
Lymphocyte	%	29.8	15.2	43.3
Monocyte	%	9.0	5.5	13.7
Eosinophil	%	3.2	0.8	8.1
Basophil	%	0.7	0.2	1.5
Neutrophil	x 10 ³ cells/ μ L	3.4	1.7	7.6
Lymphocyte	x 10 ³ cells/ μ L	1.7	1.0	3.2
Monocyte	x 10 ³ cells/ μ L	0.5	0.3	1.1
Eosinophil	x 10 ³ cells/ μ L	0.2	0.0	0.5
Basophil	x 10 ³ cells/ μ L	0.0	0.0	0.1
Reticulocyte	%	1.09	0.42	2.23
Reticulocyte	x 10 ⁶ cells/ μ L	0.0523	0.0188	0.1086
MRV	fL	109.5	97.5	122.7

IRF	NA	0.41	0.30	0.54
NRBC	%	0.2	0.0	0.6
NRBC	x 10 ³ cells/μL	0.01	0.00	0.02

- h) Whole Blood Method Comparison was tested according to EP09c & CLSI H26-A2 to support substantial equivalency by comparison of the CBC, NRBC, DIFF and RETIC values obtained on the DxH 800 Analyzer (predicate) to the values obtained on the DxH 900 Analyzer. This included adult and pediatric samples. The data provided for whole blood method comparison is comprehensive, covering the analytical measurement interval (AMI). Data was collected from multiple sites on both stand-alone and connected workcell instrument configurations using both legacy and ECO reagents. Data were analyzed pooled and by site to support the substantial equivalence of the DxH 900 to the DxH 800 for CBC, NRBC, DIFF and RETIC parameters. This data supports the intended use of the DxH 900 in stand-alone and connected workcell configurations and supports the use of ECO reagents.

General Statistics for All Sites Combined

Parameter	Unit	N	Reference			Test			Difference	95% Confidence Limits	
			Mean	Min	Max	Mean	Min	Max		Lower	Upper
HCT	%	734	32.65	8.46	61.94	32.35	8.40	60.67	-0.297	-0.333	-0.260
MCH	pg	733	29.62	13.72	73.63	29.72	14.14	73.76	0.099	0.067	0.131
MCHC	g/dL	733	33.23	25.31	57.50	33.47	26.09	57.50	0.236	0.199	0.273
NE	10 ³ cells/μL	673	6.69	0.01	92.84	6.77	0.01	94.69	0.082	0.030	0.134
LY	10 ³ cells/μL	673	4.33	0.04	257.99	4.32	0.05	257.91	-0.020	-0.049	0.010
MO	10 ³ cells/μL	670	0.98	0.00	56.47	0.99	0.00	58.59	0.004	-0.010	0.017
EO	10 ³ cells/μL	647	0.19	0.00	4.71	0.18	0.00	1.92	-0.005	-0.017	0.006
BA	10 ³ cells/μL	666	0.06	0.00	0.85	0.06	0.00	1.21	0.003	-0.001	0.007
RETc	10 ⁶ cells/μL	726	0.07	0.00	0.82	0.08	0.00	0.89	0.003	0.002	0.003
NRBCc	10 ³ cells/μL	616	0.11	0.00	30.23	0.11	0.00	34.92	0.008	-0.008	0.023
RBC	10 ⁶ cells/μL	734	3.73	0.94	8.20	3.71	0.93	8.06	-0.020	-0.023	-0.016
HGB	g/dL	734	10.83	2.96	19.76	10.81	2.97	19.64	-0.022	-0.029	-0.016
MCV	fL	734	88.97	54.20	128.05	88.63	54.19	128.29	-0.342	-0.386	-0.297
RDW	%	733	16.50	11.97	39.78	16.49	12.08	39.15	-0.004	-0.035	0.027
RDWSD	fL	733	51.30	34.13	99.75	51.01	33.69	98.44	-0.288	-0.377	-0.199
PLT	10 ³ cells/μL	687	263.10	3.57	1477.44	263.03	3.86	1449.60	-0.075	-0.743	0.592
MPV	fL	687	8.68	6.14	12.83	8.75	6.22	13.30	0.076	0.058	0.094
NE	%	681	63.59	0.31	97.65	63.61	1.02	97.62	0.014	-0.068	0.096
LY	%	681	24.06	0.97	98.44	24.08	0.62	98.09	0.014	-0.067	0.095
MO	%	678	9.66	0.34	97.44	9.65	0.32	97.62	-0.014	-0.075	0.048
EO	%	655	2.18	0.01	18.63	2.16	0.01	18.26	-0.017	-0.038	0.004
BA	%	674	0.63	0.01	5.58	0.64	0.03	6.34	0.007	-0.017	0.031
RETp	%	727	2.18	0.02	22.15	2.26	0.04	23.79	0.075	0.053	0.096
IRF	N/A	723	0.44	0.02	0.86	0.45	0.03	0.83	0.002	-0.002	0.005
MRV	fL	727	116.60	75.50	168.01	115.49	83.20	169.45	-1.115	-1.373	-0.858
WBC	10 ³ cells/μL	723	11.84	0.08	273.54	11.90	0.08	282.90	0.055	0.011	0.098
NRBC	%	619	0.62	0.01	115.54	0.61	0.01	130.63	-0.005	-0.056	0.047

Regression Statistics and Correlation for All Sites Combined

Parameter	Unit	Slope	95% Confidence Limits		Intercept	95% Confidence Limits		Correlation	95% Confidence Limits	
			Lower	Upper		Lower	Upper		Lower	Upper
HCT	%	0.987	0.983	0.992	0.117	-0.010	0.243	0.99860	0.99838	0.99879
MCH	pg	1.019	0.999	1.039	-0.464	-1.051	0.124	0.99420	0.99330	0.99498
MCHC	g/dL	1.024	0.982	1.066	-0.571	-1.970	0.828	0.95210	0.94483	0.95843
NE	10 ³ cells/ μ L	1.010	1.004	1.017	0.000	-0.000	0.000	0.99490	0.99407	0.99562
LY	10 ³ cells/ μ L	1.003	0.995	1.011	-0.003	-0.009	0.003	0.99980	0.99977	0.99983
MO	10 ³ cells/ μ L	0.994	0.985	1.003	0.003	0.001	0.004	0.99850	0.99825	0.99871
EO	10 ³ cells/ μ L	1.008	0.986	1.029	0.00002	-0.00033	0.00038	0.84660	0.82324	0.86710
BA	10 ³ cells/ μ L	1.010	0.940	1.080	0.0002	-0.0014	0.0019	0.68370	0.64102	0.72216
RETe	10 ⁶ cells/ μ L	1.028	1.016	1.040	0.0004	0.0002	0.0006	0.98720	0.98521	0.98893
NRBCc	10 ³ cells/ μ L	0.834	0.746	0.922	0.00002	-0.00040	0.00044	0.99930	0.99918	0.99940
RBC	10 ⁶ cells/ μ L	0.994	0.990	0.997	0.005	-0.006	0.016	0.99920	0.99908	0.99931
HGB	g/dL	0.995	0.992	0.997	0.035	0.009	0.060	0.99950	0.99942	0.99957
MCV	fL	0.998	0.990	1.006	-0.163	-0.872	0.546	0.99780	0.99746	0.99810
RDW	%	0.999	0.967	1.032	0.004	-0.501	0.510	0.99260	0.99145	0.99360
RDWSD	fL	0.980	0.966	0.993	0.761	0.127	1.394	0.99400	0.99307	0.99481
PLT	10 ³ cells/ μ L	1.000	0.996	1.004	0.025	-0.457	0.507	0.99890	0.99872	0.99905
MPV	fL	1.012	0.991	1.033	-0.025	-0.200	0.151	0.97770	0.97414	0.98077
NE	%	1.001	0.997	1.005	-0.050	-0.321	0.221	0.99860	0.99837	0.99880
LY	%	1.001	0.996	1.005	-0.002	-0.117	0.112	0.99840	0.99814	0.99862
MO	%	1.005	0.992	1.018	-0.058	-0.174	0.057	0.99580	0.99512	0.99639
EO	%	0.985	0.969	1.000	0.016	-0.013	0.046	0.99310	0.99196	0.99408
BA	%	0.888	0.709	1.066	0.078	-0.022	0.177	0.81790	0.79125	0.84145
RETP	%	1.014	0.984	1.045	0.044	-0.011	0.098	0.99210	0.99087	0.99317
IRF	N/A	0.985	0.955	1.015	0.008	-0.006	0.023	0.93350	0.92344	0.94228
MRV	fL	1.001	0.980	1.021	-1.205	-3.571	1.161	0.97160	0.96722	0.97540
WBC	10 ³ cells/ μ L	1.006	1.003	1.009	0.003	-0.009	0.015	0.99960	0.99954	0.99965
NRBC	%	1.115	0.876	1.354	-0.075	-0.174	0.023	0.99830	0.99801	0.99855

- i) Body Fluid Method Comparison was tested according to EP09c, CLSI H26-A2 and CLSI H56 to establish equivalency of the Body Fluid obtained on the DxH 800 Analyzer (Predicate) to the values obtained on the DxH 900 Analyzer (subject). The data for body fluid method comparison is comprehensive data covering the AMI, from multiple sites including stand-alone and connected workcell instrument configurations using both legacy and ECO reagents. Data were analyzed pooled and by site to support the substantial equivalence of the DxH 900 to the DxH 800 for BF-TNC and BF-RBC parameters. This data supports the intended use of the DxH 900 in stand-alone and connected workcell configuration and supports the use of ECO reagents.

General Statistics of BF for All Sites Combined

Parameter	Unit	N	Reference			Test				95% Confidence Limits	
			Mean	Min	Max	Mean	Min	Max		Difference	Lower
BF RBC	cells/mm^3	130	1155683.06	1017.44	6001500.00	1158284.86	1085.99	6034566.00	2601.802	-1857.223	7060.827
BF TNC	cells/mm^3	195	2837.31	20.69	56226.96	2888.18	25.01	56066.86	50.878	29.921	71.834

Regression Statistics and Correlation of BF for All Sites Combined

Parameter	Unit	Slope	95% Confidence Limits		Intercept	95% Confidence Limits		Correlation	95% Confidence Limits	
			Lower	Upper		Lower	Upper		Lower	Upper
BF RBC	cells/mm ³	0.998	0.991	1.005	-18.721	-95.808	58.367	0.99991	0.99988	0.99994
BF TNC	cells/mm ³	1.014	1.000	1.027	1.101	-1.626	3.827	0.99989	0.99985	0.99992

- j) Flagging analysis was conducted to evaluate the flagging capabilities of the DxH 900 using the flagging results obtained from the samples used in the method comparison study, from three (3) clinical sites, based on CLSI H20-A2 guidelines. A total of 735 residual normal (no flags, marked as negative) and abnormal (contained flags, marked as positive) whole blood samples were tested and compared to the predicate.

The results were classified according to the following categories:

- TN (True negative): DxH 900 result and predicate result are both negative (normal sample).
- TP (True positive): DxH 900 result and predicate result are both positive (abnormal sample).
- FN (False Negative): DxH 900 gives a negative result (normal sample) whereas predicate gives a positive result (abnormal sample).
- FP (False Positive): DxH 900 gives a positive result (abnormal sample) whereas predicate gives a negative result (normal sample).

The NPA, PPA and OPA were calculated for each pathology and abnormality, using the following calculations:

Negative Percent Agreement (NPA): $TN / (TN+FP)$

Positive Percent Agreement (PPA): $TP / (TP+FN)$

Overall Percent Agreement (OPA): $(TP+TN) / (TP+FN+FP+TN)$

A summary of the results is presented in the table below. All of the distributional cases described in CLSI H20 are important medical decision levels and showed good clinical negative and positive percent agreement between the DxH 900 and DxH 800. The morphological agreement was based on DxH 800 (predicate) flagging for immature granulocytes, variant lymphocytes and left shift. Morphological results showed good clinical negative and positive percent agreement between the DxH 900 and DxH 800.

Flagging Study NPA, PPA, OPA

Category of Abnormalities	N	TP	FP	FN	TN	NPA (95% Confidence Limits)	PPA (95% Confidence Limits)	OPA (95% Confidence Limits)
Morphological Abnormalities for WB	735	193	23	25	494	.9555 (0.9341 to 0.9702)	0.8853 (0.8362 to 0.9211)	0.9347 (0.9145 to 0.9504)
Distributional Study of WB	735	419	35	22	259	.8810 (0.8389 to 0.9131)	0.9501 (0.9256 to 0.9668)	0.9224 (0.9008 to 0.9397)

- k) DxH 690T - The only differences between the UniCel DxH 900 Coulter Cellular Analysis System and UniCel DxH 690T Coulter Cellular Analysis System are the designed inability to connect as part of a workcell and the lack of the base cabinet with the quad diluent feature (ability to load 4 diluent boxes). All other hardware and software are identical on the DxH 900 and DxH 690T instruments. In order to show that analytical and clinical study data collected on a DxH 900 would also be representative of the DxH 690T, performance verification testing was completed. Testing was performed on one (1) DxH 690T along with one (1) DxH 900 and for accuracy, one (1) DxH 800. Test cases included Daily Checks, Daily Shutdown, Calibration and Initial Control Recover, Daily Control Recovery, Repeatability, Linearity using LIN-X Linearity Control, Comparability- whole blood

accuracy, and Carryover. All test cases met the predetermined acceptance criteria. Results of each test case are summarized here:

- Daily Checks - The Daily Checks cycle was performed on days when testing was performed before analysis of control material or blood specimens. Daily Checks results were within the instrument limits and background limits shown each day before the analysis of control material or blood specimens.

Background Limits

Parameter	Limit
WBC	$\leq 0.05 \times 10^3 /\mu\text{L}$
RBC	$\leq 0.005 \times 10^6 /\mu\text{L}$
HGB	$\leq 0.1 \text{ g/dL}$
PLT	$\leq 3 \times 10^3 /\mu\text{L}$
NRBC Region	$\leq 10 \text{ Events}$
NRBC Total	$\leq 60 \text{ Events}$
DIFF	$\leq 100 \text{ Events}$
RET	$\leq 600 \text{ Events}$

- Daily Shutdown - A shutdown cycle was performed each day prior to Daily Checks according to the IFU. The shutdown cycle was performed successfully each day following completion of the testing or in the morning prior to the Daily Checks cycle. The Shutdown cycle put cleaner into the system and removed cleaner and left the instrument ready for the Daily Checks cycle.
- Calibration and Initial Control Recovery - Initial calibration was performed on the test instruments using the COULTER S-Cal Calibrator. Calibration was verified by analyzing each level of COULTER 6C Plus Cell Control. Calibration was initially performed using S-Cal lot 113161240, expiration 5/4/19. The HGB and MCV were adjusted on Instrument SN BC09305, and the RBC parameter was adjusted on Instrument SN BA51011. For verification, all three levels of 6C Plus Cell Control recovered within the expected ranges set for each level on all test instruments.
- Daily Control Recovery - A minimum of one replicate of COULTER Latron CP-X was analyzed each day after the Daily Checks cycle. A minimum of one replicate of each level of COULTER 6C Plus Cell Control, and COULTER Retic-X Cell Control was analyzed each day during the evaluation period. The controls were analyzed each day that testing was performed on an instrument. In the event of a flag, partial aspiration or non-numeric result on a control run, the control was repeated. In each case, a control result was recovered within the assigned ranges and without flags. For all test instruments, results for all controls were within the expected assay ranges prior to data collection each day data collection was performed.
- Repeatability - Within Run Repeatability for the CBC, Differential, NRBC and Reticulocyte parameters was performed using ten aspirations (n=10) in the automatic CDR test panel. The customer "Repeatability" application in the software was used to capture the results. Repeatability testing was performed using a combination of normal whole blood samples, abnormal samples, manipulated samples, and COULTER 6C Plus Cell Control Level 2 and Level 3

to obtain the ranges for each parameter required. Testing was performed across three (3) days. The test instruments met the repeatability specifications for all parameters. The COULTER 6C Plus Cell Control Level 2 was used to obtain NRBC >2-5 and COULTER 6C Plus Cell Control Level 3 was used to obtain NRBC >15. Results are listed in the tables below.

Repeatability DxH 900 Automatic CDR Mode

Parameter	Level	Specification	N	Test Result Mean	Test Result %CV or SD	Acceptance
WBC	5.00 – 10.00	$\leq 3.0\% \text{ CV}$	10	5.006	1.12%	Pass
RBC	4.50 to 5.50	$\leq 1.5\% \text{ CV}$	10	4.67	0.51%	Pass
Hgb	14.00 - 16.00	$\leq 1.5\% \text{ CV}$	10	14.98	0.37%	Pass
MCV	80.00 – 90.00	$\leq 1.0\% \text{ CV}$	10	87.28	0.41%	Pass
RDW %	12.00 – 14.00	$\leq 2.5\% \text{ CV}$	10	13.47	0.98%	Pass
RDW-SD	33.00 – 48.00	$\leq 2.5\% \text{ CV}$	10	46.55	1.01%	Pass
Platelet	200.00 - 400.00	$\leq 3.5\% \text{ CV}$	10	252.5	1.37%	Pass
MPV	8.00 – 10.00	$\leq 2.5\% \text{ CV}$	10	8.66	1.15%	Pass
Neut %	50.00 – 60.00	$\leq 3.5\% \text{ CV}$	10	56.24	1.17%	Pass
Lymph %	25.00 – 35.00	$\leq 5.0\% \text{ CV}$	10	25.48	2.04%	Pass
Mono %	5.00 – 10.00	$\leq 10.0\% \text{ CV}$	10	7.61	5.71%	Pass
Eos %	2.00 – 5.00	$\leq 13.5\% \text{ CV}$ or $\leq 0.5 \text{ SD}$	10	2.58	6.64 %	Pass
Baso %	0.50 – 1.50	$\leq 0.5 \text{ SD}$	10	0.95	0.23 SD	Pass
NRBC	2.00 – 15.00	$\leq 20\% \text{ CV}$	10	9.17	4.89%	Pass
NRBC	>15.00	$\leq 15\% \text{ CV}$	10	19.49	1.49%	Pass
Retic %	0.00 – 1.50	$\leq 0.25 \text{ SD}$	10	1.187	0.09 SD	Pass
IRF	≥ 0.2	$\leq 20\% \text{ CV}$	10	0.42	7.15%	Pass
MRV	100.00 - 120.00	$\leq 5.0\% \text{ CV}$	10	111.93	0.94%	Pass

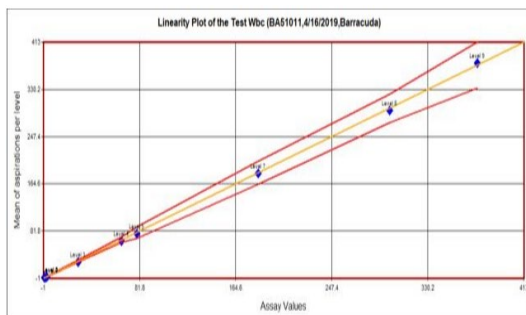
Repeatability DxH 690T Automatic CDR Mode

Parameter	Level	Specification	N	Test Result Mean	Test Result %CV or SD	Acceptance
WBC	5.00 – 10.00	$\leq 3.0\% \text{ CV}$	10	7.83	1.12%	Pass
RBC	4.50 - 5.50	$\leq 1.5\% \text{ CV}$	10	4.85	0.64%	Pass
Hgb	14.00 - 16.00	$\leq 1.5\% \text{ CV}$	10	15.30	0.41%	Pass
MCV	80.00 – 90.00	$\leq 1.0\% \text{ CV}$	10	86.18	0.38%	Pass
RDW %	12.00 – 14.00	$\leq 2.5\% \text{ CV}$	10	13.68	0.87	Pass
RDW-SD	33.00 – 48.00	$\leq 2.5\% \text{ CV}$	10	46.77	1.68%	Pass
Platelet	200.00 - 400.00	$\leq 3.5\% \text{ CV}$	10	230.8	1.17%	Pass

Parameter	Level	Specification	N	Test Result Mean	Test Result %CV or SD	Acceptance
MPV	8.00 – 10.00	$\leq 2.5\% \text{ CV}$	10	8.69	0.83%	Pass
Neut %	50.00 – 60.00	$\leq 3.5\% \text{ CV}$	10	54.70	1.46%	Pass
Lymph %	25.00 – 35.00	$\leq 5.0\% \text{ CV}$	10	27.39	2.61%	Pass
Mono %	5.00 – 10.00	$\leq 10.0\% \text{ CV}$	10	5.85	5.10%	Pass
Eos %	2.00 – 5.00	$\leq 13.5\% \text{ CV}$ or $\leq 0.5 \text{ SD}$	10	2.13	8.14%	Pass
Baso %	0.50 – 1.50	$\leq 0.5 \text{ SD}$	10	0.83	0.24 SD	Pass
NRBC	2.00 – 15.00	$\leq 20\% \text{ CV}$	10	8.93	4.38%	Pass
NRBC	> 15.00	$\leq 15\% \text{ CV}$	10	18.86	3.02%	Pass
Retic %	0.00 – 1.50	$\leq 0.25 \text{ SD}$	10	1.22	0.13 SD	Pass
IRF	≥ 0.20	$\leq 20\% \text{ CV}$	10	0.35	7.29%	Pass
MRV	100.0-120.0	$\leq 5.0\% \text{ CV}$	10	109.77	1.20%	Pass

- Linearity using COULTER LIN-X Linearity Controls - Linearity was performed in the CBC test panel for WBC, RBC, Hgb and PLT using LIN-X Linearity Control. Linearity with the COULTER LIN-X Linearity Control was performed on the DxH 900 and DxH 690T test instruments. LIN-X Linearity Control passed for all data points on both test instruments.

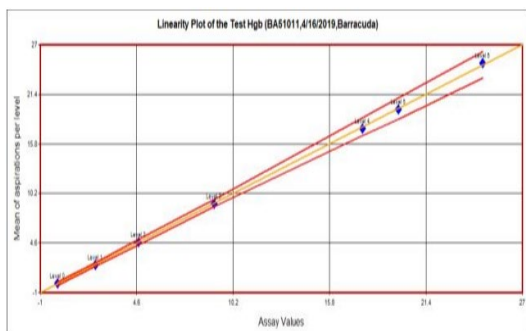
DxH 900 WBC Linearity



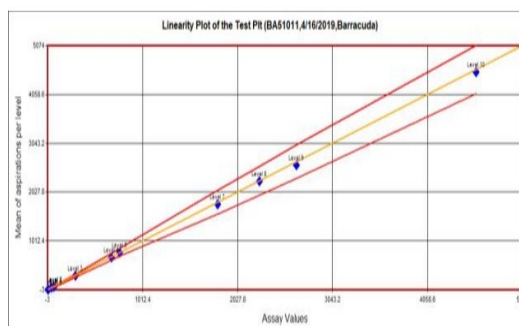
DxH 900 RBC Linearity



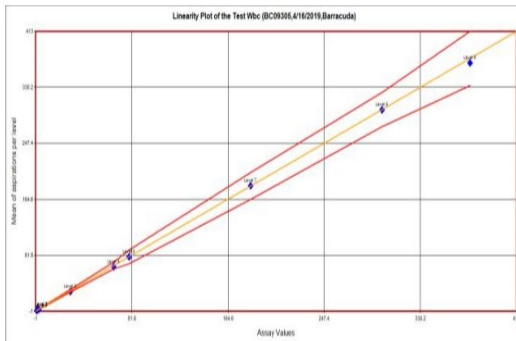
DxH 900 Hgb Linearity



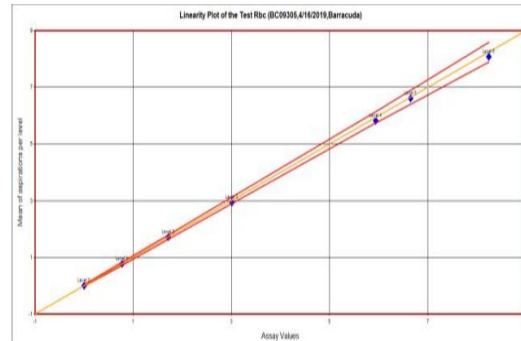
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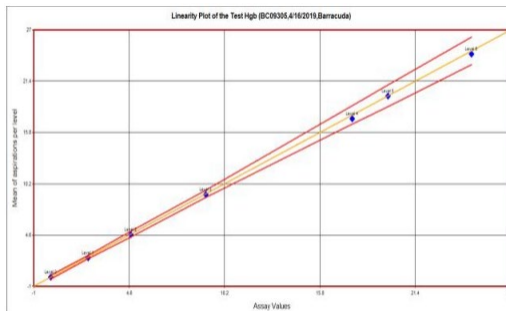
DxH 690T WBC Linearity



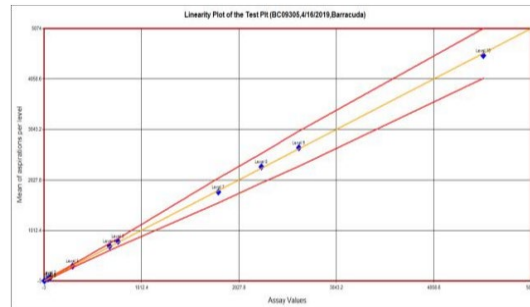
DxH 690T RBC Linearity



DxH 690T Hgb Linearity



DxH 690T PLT Linearity



- Accuracy - A total of 382 whole blood specimens (60 normal, 322 abnormal) were collected. Accuracy testing was performed in the automatic mode using the CDR test panel by analyzing each blood sample once through the DxH 900 and DxH 690T instruments and the DxH 800 (predicate). COULTER S-Cal Calibrator was analyzed on the test and comparator instruments each day of accuracy testing if zero calibration was required. Results for CBC, Differential, NRBC, RET, IRF, and MRV parameters were compared using the specifications of the DxH 800. Weighted Deming analysis was performed for WBC, RBC, and PLT, and Deming analysis was performed for the WBC Differential, RETIC, IRF, and MRV parameters, and the remaining CBC parameters. The average bias and upper and lower limits of bias for the complete data set, 25th, 50th, 75th percentiles, and medical decision points were compared to the DxH 800 accuracy specifications for each parameter. Although the COULTER S-Cal Calibrator was analyzed every day of testing, no adjustments were required. Regression analysis was performed for NRBC to obtain the coefficient of variation to compare to the DxH 800 specification. Parameters results with “R” flags, had non-numeric, or partial aspiration were excluded from the analysis.

The CBC, WBC Differential, MRV, RET, IRF, and NRBC results for accuracy met the DxH 800 accuracy specifications for the DxH 900 and DxH 690T instruments. Mean difference and average lower and upper bias statistics for the CBC, WBC differential, MRV and IRF parameter comparisons follow. The acceptance limit was calculated from the DxH 800 accuracy specification. Results for the 25th, 50th and 75th percentiles and medical decision levels are not shown, but all recovered within the accuracy specification.

Mean Difference/Bias Statistics DxH 900 vs DxH 800 (predicate)

Parameter	N	Clinical Range	Mean Comp.	Mean Test	Mean Diff	Lower Bias	Upper Bias	Acc.* Limit
WBC	376	0.06 – 148.83	9.88	9.82	-0.07	-0.10	-0.04	± 0.20
RBC	376	1.68 – 8.49	3.84	3.84	0.01	0.00	0.01	± 0.07
Hgb	374	4.95 -24.84	11.12	11.10	-0.02	-0.03	-0.01	± 0.3
MCV	374	66.15 -115.06	88.05	87.66	-0.39	-0.43	-0.34	± 1.7
RDW	374	11.93 – 27.60	16.52	16.46	-0.06	-0.09	-0.03	± 0.80
RDW-SD	374	35.88 – 92.31	50.94	51.08	0.14	0.02	0.25	± 5.00
PLT	338	7.80 -788.70	230.05	224.93	-5.12	-5.97	-4.27	± 16.10
MPV	338	6.58-12.21	8.73	8.90	0.17	0.15	0.19	± 0.60
Neutrophil	346	0.66-96.2	64.26	63.98	-0.28	-0.39	-0.18	± 6.40
Lymphocyte	346	1.03-98	23.01	23.42	0.41	0.31	0.51	± 2.30
Monocyte	346	0.00-92.73	9.81	9.67	-0.15	-0.23	-0.07	± 1.00
Eosinophil	346	0.00 – 20.30	2.31	2.30	0.00	-0.03	0.02	± 0.50
Basophil	346	0.00 - 3.61	0.61	0.63	0.02	-0.01	0.06	± 0.50
RET	374	0.03-15.20	1.81	1.82	0.01	-0.01	0.03	± 0.50
MRV	374	76.42-170.24	117.49	117.28	-0.22	-0.61	0.18	± 15.00
IRF	374	0.00-0.77	0.45	0.44	0.00	-0.01	0.00	± 0.20

* = Acceptance limit calculated from Deming Regression analysis

Mean Difference/Bias Statistics DxH 690T vs DxH 800 (predicate)

Parameter	N	Clinical Range	Mean Comp.	Mean Test	Mean Diff	Lower Bias	Upper Bias	Acc.* Limit
WBC	368	0.06 – 148.83	9.86	9.82	-0.04	-0.08	0.01	± 0.20
RBC	369	1.68 – 8.49	3.85	3.84	-0.01	-0.02	-0.01	± 0.07
Hgb	367	4.95 -24.84	11.16	11.13	-0.03	-0.05	-0.02	± 0.30
MCV	367	66.15 -115.06	87.99	87.71	-0.28	-0.32	-0.23	± 1.70
RDW	367	11.93 – 27.60	16.51	16.49	-0.02	-0.04	0.01	± 0.80
RDW-SD	367	35.88 – 92.31	50.88	51.15	0.26	0.15	0.37	± 5.00
PLT	334	7.80 -788.70	230.45	231.48	1.03	0.25	1.81	± 16.10
MPV	335	6.58-12.21	8.73	8.68	-0.06	-0.09	-0.03	± 0.60
Neutrophil	340	0.66-96.2	64.69	64.42	-0.27	-0.38	-0.16	± 6.40
Lymphocyte	340	1.03-98	22.56	22.94	0.38	0.28	0.47	± 2.20
Monocyte	340	0.00-92.73	9.79	9.68	-0.11	-0.20	-0.02	± 1.00
Eosinophil	340	0.00 – 20.30	2.34	2.34	-0.01	-0.04	0.02	± 0.50
Basophil	340	0.00 - 3.61	0.61	0.63	0.02	-0.03	0.07	± 0.50
RET	371	0.03-15.20	1.78	1.90	0.12	0.09	0.15	± 0.50
MRV	371	76.42-170.24	117.27	117.09	-0.17	-0.59	0.25	± 15.0
IRF	371	0.00-0.77	0.44	0.44	-0.01	-0.01	0.00	± 0.20

* = Acceptance limit calculated from Deming Regression analysis

Regression Statistics and Correlation for DxH 900 (Test) vs DxH 800 (Predicate)

Parameter	Unit	Slope	95% Confidence Limits		Intercept	95% Confidence Limits		Correlation	95% Confidence Limits	
			Lower	Upper		Lower	Upper		Lower	Upper
WBC	x 10 ³ cells/μL	0.994	0.991	0.996	-0.002	-0.004	0.000	0.99969	0.99962	0.99974
RBC	x 10 ⁶ cells/μL	1.013	1.010	1.017	-0.042	-0.054	-0.030	0.99955	0.99945	0.99963
Hemoglobin	g/dL	0.989	0.986	0.993	0.101	0.061	0.141	0.99957	0.99947	0.99965
MCV	fL	0.995	0.988	1.003	0.020	-0.623	0.663	0.99798	0.99752	0.99835
RDW	%	0.999	0.987	1.012	-0.042	-0.235	0.152	0.9954	0.99437	0.99625
RDW-SD	fL	1.005	0.988	1.022	-0.120	-0.947	0.707	0.99395	0.99259	0.99506
Platelet	x 10 ³ cells/μL	0.979	0.974	0.983	-0.456	-0.994	0.082	0.99896	0.99872	0.99916
MPV	fL	1.019	0.995	1.043	0.009	-0.190	0.209	0.98282	0.97875	0.98611
Neutrophil	%	1.001	0.995	1.007	-0.347	-0.753	0.059	0.99878	0.99849	0.99901
Lymphocyte	%	1.007	0.998	1.015	0.258	0.085	0.431	0.99855	0.9982	0.99882
Monocyte	%	0.989	0.965	1.012	-0.036	-0.238	0.166	0.99703	0.99633	0.9976
Eosinophil	%	0.997	0.982	1.012	0.003	-0.028	0.034	0.99617	0.99527	0.9969
Basophil	%	0.964	0.604	1.323	0.045	-0.148	0.238	0.6141	0.54388	0.67578
Reticulocyte	%	0.987	0.949	1.026	0.033	-0.027	0.093	0.9916	0.98971	0.99314
MRV	fL	0.989	0.960	1.019	1.051	-2.508	4.610	0.96892	0.96204	0.97457
IRF	%	0.960	0.911	1.008	0.016	-0.009	0.040	0.92773	0.91213	0.94064

Regression Statistics and Correlation for DxH 690T (Test) vs DxH 800 (Predicate)

Parameter	Unit	Slope	95% Confidence Limits		Intercept	95% Confidence Limits		Correlation	95% Confidence Limits	
			Lower	Upper		Lower	Upper		Lower	Upper
WBC	x 10 ³ cells/μL	0.994	0.992	0.997	0.000	-0.002	0.002	0.99945	0.99932	0.99955
RBC	x 10 ⁶ cells/μL	1.008	1.004	1.012	-0.039	-0.053	-0.025	0.99955	0.99944	0.99963
Hemoglobin	g/dL	0.985	0.982	0.989	0.130	0.092	0.168	0.99955	0.99945	0.99964
MCV	fL	1.001	0.994	1.008	-0.342	-0.950	0.267	0.99784	0.99735	0.99824
RDW	%	1.003	0.991	1.016	-0.072	-0.269	0.124	0.99593	0.99500	0.99668
RDW-SD	fL	1.017	1.001	1.034	-0.627	-1.411	0.158	0.99460	0.99338	0.99560
Platelet	x 10 ³ cells/μL	1.012	1.001	1.024	-0.854	-2.236	0.527	0.99901	0.99878	0.99920
MPV	fL	0.995	0.970	1.020	-0.015	-0.227	0.196	0.96869	0.96132	0.97468
Neutrophil	%	1.002	0.996	1.009	-0.428	-0.832	-0.023	0.99862	0.99829	0.99889
Lymphocyte	%	1.012	1.004	1.020	0.117	-0.065	0.298	0.99854	0.99819	0.99882
Monocyte	%	0.972	0.959	0.986	0.158	0.025	0.290	0.99647	0.99564	0.99715
Eosinophil	%	0.992	0.972	1.012	0.011	-0.029	0.050	0.99526	0.99413	0.99617
Basophil	%	1.481	0.383	2.579	-0.275	-0.275	-0.275	0.47300	0.38606	0.55161
Reticulocyte	%	1.031	0.987	1.074	0.062	-0.004	0.129	0.98788	0.98515	0.99011
MRV	fL	0.996	0.961	1.030	0.349	-3.792	4.491	0.96512	0.95738	0.97148
IRF	%	1.018	0.971	1.065	-0.014	-0.038	0.009	0.92436	0.90801	0.93791

- Carryover - Within mode carryover was performed in the automatic CDR mode using the customer “Carryover” application in the software. Normal whole blood, clinical samples, and blood altered by concentration, or the addition of analogs were used to achieve the following levels for testing:

- WBC > 90.0
- WBC > 300
- RBC > 6.20
- Hgb > 22.0
- PLT > 900

Carryover was performed on the DxH 690T and DxH 900. Carryover results for both test instruments recovered within the DxH 800 carryover limits.

Carryover WBC > 90

CnDR Mode	WBC	RBC	Hgb	PLT	Diff	NRBC	Retic
DxH 690T	0.11%	0.03%	0.26%	0.07%	22, 20, 35	12, 5, 7	25, 20, 22
DxH 900	0.09%	0.05%	0.23%	0.17%	11,15,37	7,1,3	10,6,3
Spec	≤0.5%	≤0.5%	≤1.0%	≤1.0%	≤200 Events	≤75 Events	≤600 Events

Carryover WBC > 300

CnDR Mode	WBC	RBC	Hgb	PLT	Diff	NRBC	Retic
DxH 690T	0.18%	0.04%	0.18%	0.02%	42, 36, 16	24, 12,10	27, 20, 25
DxH 900	0.13%	0.05%	0.13%	0.06%	31, 29, 28	15, 4, 1	19, 6, 7
Spec	≤0.5%	≤0.5%	≤1.0%	≤1.0%	≤200 Events	≤100 Events	≤600 Events

Carryover RBC > 6.20

CnDR Mode	WBC	RBC	Hgb	PLT	Diff	NRBC	Retic
DxH 690T	0.25%	0.03%	0.30%	0.12%	25, 15, 24	12, 16, 9	23, 15, 16
DxH 900	0.22%	0.04%	0.16%	-0.03%	30, 14, 39	11,2, 1	27, 8, 11
Spec	≤0.5%	≤0.5%	≤1.0%	≤1.0%	≤200 Events	≤75 Events	≤600 Events

Carryover Hgb > 22.0

CnDR Mode	WBC	RBC	Hgb	PLT	Diff	NRBC	Retic
DxH 690T	0.20%	0.03%	0.17%	0.03%	31, 16, 15	9, 3, 6	44, 9, 4
DxH 900	0.19%	0.03%	0.17%	-0.23%	14, 37, 28	1, 5, 3	37, 8, 3
Spec	≤0.5%	≤0.5%	≤1.0%	≤1.0%	≤200 Events	≤75 Events	≤600 Events

Carryover Platelet > 900

CnDR Mode	WBC	RBC	Hgb	PLT	Diff	NRBC	Retic
DxH 690T	0.15%	0.03%	0.13%	0.10%	22, 15, 14	11, 5, 8	12, 15, 11
DxH 900	0.13%	0.05%	0.22%	0.09%	31, 26, 23	2, 2, 3	16, 13, 13
Spec	≤0.5%	≤0.5%	≤1.0%	≤1.0%	≤200 Events	≤75 Events	≤600 Events

807.92 (b)(3): Conclusions from Analytical and Performance Data

All data provided for the nonclinical and clinical testing demonstrates that the UniCel DxH 900/DxH 690T Coulter Cellular Analysis System (DxH 900, DxH 690T) and the UniCel DxH Slidemaker Stainer II Coulter Cellular Analysis System (SMS II) are as safe, as effective, and perform as well as or better than the UniCel DxH 800 Coulter Cellular Analysis System (DxH 800) and the UniCel DxH Slidemaker Stainer Coulter Cellular Analysis System (SMS).