510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K240252

B Applicant

Beckman Coulter, Inc

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Whole blood: 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.

Body fluid: TNC and RBC.

C Type of Test:

Quantitative test for complete blood counts (CBC) with 5-part white blood cell differential,

nucleated red blood cell counts, reticulocyte analysis and body fluid counts.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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 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
- 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

UniCel DxH 900 Coulter Cellular Analysis System

The UniCel DxH 900 Coulter Cellular Analysis System is a multi-analyzer system that may consist of a different combination of one or more of the following modules: a stand-alone DxH 900 instrument, or a stand-alone UniCel DxH Slidemaker Stainer II, or a work cell comprising of up to three UniCel DxH 900 instruments connected with or without a UniCel DxH Slidemaker Stainer II.

The UniCel DxH 900 System is a quantitative multiparameter fully automated hematology analyzer intended to perform tests on venous and capillary whole blood samples collected in K2 /K3EDTA anticoagulant and body fluids including serous fluids collected in K2 or K3EDTA, synovial fluids collected in K2/K3EDTA, or Heparin and cerebrospinal fluid (CSF) collected without anticoagulant. 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 Unicel DxH 900 Coulter Cellular Analysis System can be configured as workcell as follows:

- DxH 900: consisting of one DxH 900 instrument
- DxH Slidemaker Stainer II: consisting of one DxH Slidemaker Stainer II
- DxH 900 S: consisting of one DxH 900 configured with one DxH Slidemaker Stainer II
- DxH 900−2: consisting of two DxH 900 instruments
- DxH 900−2 S: consisting of two DxH 900 instruments configured with one DxH Slidemaker Stainer II
- DxH 900−3: consisting of three DxH 900 instruments
- DxH 900−3 S: consisting of three DxH 900 instruments configured with one DxH Slidemaker Stainer II

DxH 690T Coulter Cellular Analysis System

The DxH 690T Coulter Cellular Analysis System consists of a stand-alone tabletop DxH 690T instrument with same detection capabilities, technology, software and analytes as the DxH 900 instrument. The DxH 690T cannot be configured as a workcell.

B Principle of Operation:

The UniCel DxH 900/DxH 690T Coulter Cellular Analysis System is based on the Coulter Principle. The Coulter Principle accurately counts and sizes 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. 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 the 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. All pulses generated by the apertures are collected and sent to the Signal Conditioner Analyzer Card for analog to digital conversion. The process provides the following raw counts and digital measurements to the System Manager for processing by the algorithms where the reported parameter values, flags and histograms are generated.

The complete blood count (CBC) is the fundamental analytical test that evaluates the three main cellular components: white blood cells, red blood cells, and platelets. Sample preparation and data collection occur in the Sample Aspiration Module (SAM) and Complete Blood Count (CBC) modules on the UniCel DxH 900/DxH 690T Coulter Cellular Analysis System.

The lytic reagent for WBC is used to prepare 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 (HGB) is measured photometrically at 525 nm using the sample from the WBC analysis. A blank is introduced into the cuvette during each operating cycle. The HGB blank provides a reference to which the sample signal is compared.

The COULTER VCSn 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 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 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 data collected during each of the analytical processes is transferred to the System Manager where the digital raw values are processed by the algorithm using mathematical approaches designed for finding optimal separation between clusters of data. The identified clusters are used to calculate the frequency of cells within each population, generate parameter values, flags, histograms and data plots.

The DxH Slidemaker Stainer II allows for adaptation of the smear appearance and stain methodology. 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 for microscopic examination of the stained blood smears.

C Instrument Description Information:

1. Instrument Name:

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

2. Specimen Identification:

- Specimen Identification is automated by Sample aspiration module (SAM) mounted barcode reader for automated barcode reading of cassette and sample tube identifiers
- Manual barcode scanning of sample tube with the use of a handheld barcode scanner
- Manual keyboard entry of sample identifier

3. Specimen Sampling and Handling:

   The UniCel DxH 900/DxH 690T Coulter Cellular Analysis System provides the user with the ability to obtain a variety of combinations of parameter results using analytical test panels. The specimen analysis can occur via following sampling methods on the analyzer:

   - Automated Cassette Closed Vial (whole blood analysis mode)
   - Manual Single Tube Closed Vial (whole blood analysis mode)
   - Manual Single Tube Open Vial (1 in 5 pre-diluted whole blood mode; body fluid analysis mode)

4. Calibration:

   COULTER® S-CAL® Calibrator (k862122) is used for determining calibration factors to ensure accurate measurements of directly measured CBC parameters. Assigned assay values are traceable to reference methods.

5. Quality Control:

   The DxH 900/DxH 690T Coulter Cellular Analysis System uses commercial controls:

   - COULTER 6C Cell Control (K081822) enables monitoring of system performance for all directly measured and calculated CBC, Diff and NRBC parameters.

   - COULTER 6C Plus Cell Control enables monitoring of system performance for all directly measured and calculated CBC, Diff and NRBC parameters.

   - COULTER Retic-X Cell Control (K930119) monitors system performance of the reticulocyte parameters.

   - COULTER LIN-X Linearity Control (K081641) verifies the reportable range, and assesses the calibration of the WBC, RBC, HGB, and PLT parameters.

- COULTER Body Fluid Control (K082162) monitors system performance of the body fluid cycle's RBC and TNC count parameters. Additionally, COULTER Body Fluid Control can be used for verification of the measuring range and linearity of the TNC and RBC in the body fluid panel.

- COULTER LATRONTM CP-X Control (K885028) determines calibration factors to ensure accurate measurements of directly measured CBC parameters. Assigned assay values are traceable to reference methods.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Unicel DxH 800 Coulter Cellular Analysis System, UniCel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application

UniCel DxH SlideMaker Stainer Coulter Cellular Analysis System

B Predicate 510(k) Number(s):

K193124, K162414

C Comparison with Predicate(s):

Device & Predicate Device(s):	K240252	K193124
Device Trade Name	UniCel DxH 900 Coulter Cellular Analysis System (DxH 900), UniCel DxH Slidemaker Stainer II (SMS II), UniCel DxH 690T Coulter Cellular Analysis System (DxH 690T),	UniCel DxH 800 Coulter Cellular Analysis System with Early Sepsis Indicator Application (ESId)
General Device Characteristic Similarities		
Intended Use/Indications For 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 hematology analyzer identifies and enumerates the following parameters:	The UniCel DxH 800 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 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 • 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.	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 ESId Application The UniCel DxH 800 Series with System Manager Software Coulter Cellular Analysis System with Early Sepsis Indicator (ESId) application is the quantitative measurement of Monocyte Distribution Width (MDW). The Early Sepsis Indicator (ESId) is intended for use with adult patients presenting to the emergency department, on whom a white blood cell differential test has been ordered. MDW is tested from a (K2EDTA) whole-blood venous sample within two hours of collection. MDW results greater than 20.0 together with other laboratory findings and clinical information, aids in identifying patients with sepsis or at increased risk of developing sepsis within the first 12 hours of hospital admission. MDW results greater than

		20.0 should be interpreted in association with other clinical information and diagnostic testing as a proportion of patients without sepsis may have an elevated MDW result at baseline. MDW results less than or equal to 20.0 cannot rule out sepsis or the development of sepsis within 12 hours of hospital admission. The Early Sepsis Indicator should not be used as the sole basis to determine the absence of sepsis. The predictive value of the Early Sepsis Indicator (ESId) for identifying sepsis in patients with hematological abnormalities has not been established.
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, MDW: VCSn Technology using:	Same

	• Aperture impedance (DC) • Conductivity (RF) • Laser Light Scatter (Multiple angles) • Laser Light Absorbance	
Reagents	Analysis Reagents • COULTER DxH Diluent • COULTER DxH Diff Pack • COULTER DxH Cell Lyse • COULTER DxH Retic Pack • COULTER DxH Cleaner. ECO reagents: • DxH ECO Diluent (RTU) • DxH Concentrated ECO Diluent (18x) • DxH ECO Cell Lyse	Analysis Reagents • COULTER DxH Diluent • COULTER DxH Diff Pack • COULTER DxH Cell Lyse • COULTER DxH Retic Pack • COULTER DxH Cleaner
Quality Control and 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
Mechanisms for processing	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 allowing multi-directional moves and capability to return cassette to sampling position for repeat / reflex testing.	Same
Sample Aspiration Volume	Automatic, cap-piercing: 165 µL Single tube - open-vial and cap pierce:165 µL	Same

	Pre-dilute 165 µL - fixed ratio of 1:5 dilution of blood with diluent	
Throughput	For automatic mode: • CBC at 100 specimens/hour • CBC and Differential at 100 specimens/hour • CBC and Differential with NRBC at 90 specimens/hour • Retic at 45 specimens/hour	Same
Controlling Software System	Same with enhancements to the instrument look and feel, workflow, usability, quality control and reliability.	System software (embedded and workstation) designed specific to support all features of 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.
General Device Characteristic Differences		
Software Version	DxH 900/SMS II/ESId SW 2.3.1	DxH 800/SMS/ESId 3.9.1
Graphical User Interface	Updated for a more modern look and easier navigation to available screens.	A client responsible for processing all user input and providing all responses to the user. The GUI consists of two parts: Universal System Manager User Interface, and Data Manager User Interface. These two components allow the GUI to interact with the DM and USM to fulfill the user's requests.
Workstation server	Integrated into the instrument instead of ancillary on a cart.	Workstation running system application specific software – Provides system control functions for the SPM. Receives raw data from SPM and performs analysis to generate applicable parameter results. Provides data management and storage, provides test order management, results review and reporting, quality control functionality, diagnostics, and maintenance procedures. User interaction is provided via touch screen, keyboard, and mouse. Connects with laboratory information systems (LIS) and handheld barcode reader.
Multiple Transducer Module (MTM)	Generates an impedance signal and produces laser light stimulation in the particle sensing zone of the flow cell. Outputs seven channels of data: one volume (V), one conductivity (C), and five light scatter (Sn), with an added	Generates an impedance signal and produces laser light stimulation in the particle sensing zone of the flow cell. Outputs seven channels of data: one volume (V), one conductivity (C), and five

	ferrite on the laser power cable for EMI due to the use of metal covers.	light scatter (Sn).
General Device Characteristic Similarities	DxH SMS II K240252	DxH SMS K162414
Intended use	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.	Same
Specimen collection	Whole venous blood in K2/K3 EDTA	Same
Blood Film Preparation	Automatically prepared by SMS II	Automatic preparation by DxH SMS
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. Fixatives: 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
General Device Characteristic Differences		
Software Version	DxH 900/SMS II/ESId SW 2.3.1	DxH 800/SMS/ESId 3.9.1

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition.
- CLSI EP06-2nd Edition, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach. Approved Guideline.
- CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard – Second Edition.
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition
- CLSI H56-A, Body Fluid Analysis for Cellular Composition; Approved Guideline
- CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard– Second Edition
- IEC 60601-1-2: 2014, Medical electrical equipment − Part 1-2: General requirements for basic safety and essential performance − Collateral Standard: Electromagnetic disturbances − Requirements and tests
- IEC 61010-1: Edition 3.1 2017-01, Safety requirements for electrical equipment for measurement, control, and laboratory use − Part 1: General requirements
- ISO 15223-1: 2021, Medical devices − Symbols to be used with information to be supplied by the manufacturer − Part 1: General requirements
- ISO 14971: 2019, Medical devices − Application of risk management to medical devices
- IEC 62304: 2015, Medical device software − Software life cycle processes
- Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

UniCel DxH 900 Coulter Cellular Analysis System

Repeatability −Whole Blood
Repeatability studies were performed at one testing site on the DxH 900−3S work cell composed of three DxH 900 and one SMS II under repeatability mode using cassette presentation and closed-vial sampling mode. Within run repeatability studies were performed by using ten whole blood samples covering the analytical measuring interval (AMI) collected in K2EDTA. Testing was performed randomly on one of the DxH 900 instrument of DxH 900−3S work cell. Within run imprecision (repeatability) was performed using ten aspirations (replicates) of whole blood samples and replicate analysis of the specimens was performed by using the Repeatability function. Control material was used for assaying precision of NRBC parameter.

The mean, standard deviation (SD), coefficient of variation (CV), and 95% CI were calculated for each parameter. The SD or %CV point estimates were evaluated against the evaluation criteria. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Parameter	Test Range	N	Test Result Mean	Test Result %CV/SD
WBC ($x10^3/\mu L$)	0.500 – 2.000	10	0.59	2.02% CV
	5.000 – 10.000	10	5.80	0.69% CV
RBC ($x10^6/\mu L$)	4.500 – 5.500	10	4.72	0.50% CV
HGB (g/dL)	14.00 – 16.00	10	15.03	0.36% CV
MCV (fL)	80.00 – 90.00	10	85.39	0.22% CV
RDW %	12.00 – 14.00	10	13.71	1.31% CV
RDW-SD (fL)	33.00 – 48.00	10	47.03	1.82% CV
Platelet ($x10^3/\mu L$)	10.0 – 15.0	10	12.90	2.60% CV
	200.0 – 400.0	10	256.80	1.35% CV
MPV (fL)	8.0 – 10.0	10	8.13	1.15% CV
NE (%)	50.0 – 60.0	10	58.24	0.99 %CV
LY (%)	25.0 – 35.0	10	26.34	2.44% CV
MO (%)	5.0 – 10.0	10	6.22	7.66 % CV
EO (%)	2.0 – 5.0	10	2.21	5.06% CV
BA (%)	0.5 – 1.5	10	1.22	0.13 SD
NRBC (%)	1.00 – 2.00	10	1.46	0.20 SD
	>2.00 – 15.00	10	9.21	4.69% CV
	> 15.00	10	19.12	5.12% CV
RET %	0.000 – 1.500	10	1.17	0.13 SD
	> 1.500 – 4.000	10	1.52	0.09 SD
	> 4.000 – 15.000	10	10.07	1.44% CV
IRF	≥ 0.20	10	0.47	7.20%
MRV (fL)	100.0 – 120.0	10	118.40	1.19% CV

Repeatability Body Fluid

Repeatability studies were performed at one testing site on the DxH 900−3S work cell composed of three DxH 900 and one SMS II under repeatability mode using manual single-tube and open-vial sampling mode. Study was conducted using leftover body fluid samples (4 peritoneal, 2 pleural and 1 synovial) tested within four hours of draw collected from a total of seven subjects. A total of three samples in the BF-RBC range and seven samples in the BF-TNC range were included. The CV%, SD and 95% CI were calculated for each analyte for each sample with at least nine aspirations (replicates). All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Parameter	**Test Range**	**N**	**Test Result Mean**	**Test Result %CV**
BF-RBC ($cells/mm^3$)	10,000 – 15000	10	12643	2.42
BF-TNC ($cells/mm^3$)	50 – 2000	10	594	1.28

Reproducibility – Whole Blood

Reproducibility studies were performed at one testing site on one DxH 900−3S work cell composed of three DxH 900 and one SMS II to evaluate the within-run, between-run, between-day, between-instrument, and total reproducibility of the DxH 900. Testing was performed using three levels of each whole blood control material (COULTER 6C Plus Cell Control and COULTER Retic-X Cell Control). Each level was run in triplicates twice per day per instrument with two hours apart for five days using a single lot of controls and reagents across the three DxH 900−3S work cell. The mean, SD and CV% were reported for each parameter and all parameters met the acceptance criteria. Results are summarized below.

Parameter	Level	N	Mean	Within Run		Between Run		Between Instrument		Between Days		Total	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
WBC ($x10^3/\mu L$)	1	90	3.42	0.07	1.90	0.00	0.00	0.04	1.26	0.01	0.27	0.08	2.30
	2	90	20.52	0.17	0.83	0.11	0.53	0.24	1.16	0.06	0.28	0.32	1.55
	3	90	8.58	0.10	1.20	0.00	0.00	0.04	0.47	0.03	0.40	0.12	1.35
RBC ($x10^6/\mu L$)	1	90	1.74	0.01	0.59	0.00	0.11	0.00	0.26	0.00	0.00	0.01	0.66
	2	90	3.96	0.03	0.74	0.02	0.45	0.02	0.49	0.01	0.22	0.04	1.02
	3	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)	1	90	4.62	0.02	0.43	0.00	0.00	0.01	0.26	0.01	0.13	0.02	0.52
	2	90	11.80	0.05	0.45	0.02	0.18	0.07	0.61	0.01	0.11	0.09	0.79
	3	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)	1	90	79.48	0.14	0.18	0.19	0.24	0.23	0.29	0.19	0.24	0.38	0.48
	2	90	87.38	0.19	0.22	0.05	0.05	0.25	0.29	0.15	0.17	0.35	0.40
	3	90	87.59	0.22	0.26	0.00	0.00	0.24	0.28	0.14	0.16	0.36	0.41
RDW (%)	1	90	17.09	0.15	0.89	0.14	0.82	0.08	0.44	0.00	0.03	0.22	1.28
	2	90	16.24	0.16	1.01	0.06	0.37	0.01	0.09	0.08	0.51	0.19	1.19
	3	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)	1	90	49.50	0.49	1.00	0.19	0.38	0.10	0.21	0.10	0.20	0.55	1.11
	2	90	52.73	0.67	1.27	0.14	0.26	0.08	0.14	0.17	0.32	0.71	1.35
	3	90	50.86	0.60	1.19	0.00	0.00	0.00	0.00	0.00	0.00	0.60	1.19
PLT ($x10^3/\mu L$)	1	90	72.39	1.11	1.53	0.00	0.00	0.28	0.39	0.33	0.45	1.19	1.64
	2	90	424.58	7.98	1.88	0.00	0.00	0.00	0.00	0.00	0.00	7.98	1.88
	3	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)	1	90	9.13	0.06	0.66	0.00	0.00	0.03	0.30	0.03	0.34	0.07	0.80
	2	90	9.44	0.06	0.58	0.00	0.00	0.05	0.54	0.02	0.18	0.08	0.82
	3	90	9.61	0.06	0.67	0.02	0.26	0.04	0.46	0.00	0.00	0.08	0.85
NE (%)	1	90	43.13	0.69	1.61	0.00	0.00	0.00	0.00	0.00	0.00	0.69	1.61
	2	90	65.12	0.68	1.05	0.00	0.00	0.00	0.00	0.12	0.19	0.69	1.07
	3	90	57.05	0.81	1.42	0.00	0.00	0.00	0.00	0.00	0.00	0.81	1.42
LY (%)	1	90	46.24	0.72	1.56	0.00	0.00	0.12	0.25	0.00	0.00	0.73	1.58
	2	90	15.71	0.50	3.21	0.07	0.46	0.13	0.80	0.09	0.60	0.53	3.39
	3	90	27.73	0.59	2.13	0.00	0.00	0.00	0.00	0.00	0.00	0.59	2.13
MO (%)	1	90	6.67	0.40	5.95	0.00	0.00	0.15	2.29	0.00	0.00	0.43	6.38
	2	90	14.16	0.52	3.65	0.26	1.84	0.00	0.00	0.00	0.00	0.58	4.09
	3	90	8.36	0.40	4.78	0.00	0.00	0.00	0.00	0.00	0.00	0.40	4.78
EO (%)	1	90	3.94	0.34	8.58	0.14	3.67	0.00	0.00	0.00	0.00	0.37	9.33
	2	90	4.96	0.41	8.33	0.00	0.00	0.00	0.00	0.00	0.00	0.41	8.33
	3	90	6.82	0.47	6.86	0.00	0.00	0.00	0.00	0.00	0.00	0.47	6.86
BA (%)	1	90	0.02	0.02	74.92	0.00	0.00	0.00	0.00	0.01	26.29	0.02	79.39
	2	90	0.06	0.03	57.53	0.00	0.00	0.00	0.00	0.00	0.00	0.03	57.53
	3	90	0.04	0.02	54.51	0.01	13.07	0.00	9.39	0.00	0.00	0.02	56.83
NRBC (%)	1	90	0.29	0.10	34.20	0.00	0.00	0.05	15.62	0.00	0.00	0.11	37.60
	2	90	9.09	0.40	4.36	0.07	0.78	0.00	0.00	0.08	0.90	0.41	4.53
	3	90	19.45	0.52	2.66	0.00	0.00	0.49	2.52	0.09	0.45	0.72	3.69
RET (%)	1	90	0.87	0.10	11.18	0.02	2.71	0.15	17.41	0.00	0.00	0.18	20.86
	2	90	2.48	0.12	4.73	0.00	0.00	0.16	6.50	0.04	1.78	0.20	8.23

Parameter	Level	N	Mean	Within Run		Between Run		Between Instrument		Between Days		Total	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
	3	90	10.50	0.18	1.72	0.00	0.00	0.11	1.09	0.07	0.69	0.23	2.14

Reproducibility−Body Fluids

Reproducibility studies were performed at one testing site on one DxH 900−3S work cell composed of three DxH 900 and one SMS II to evaluate the within-run, between-run, between-day, between-instrument, and total reproducibility of the DxH 900. Testing was performed using three levels of each body fluid control material (COULTER Body Fluid Cell Controls). Each level was run in triplicates twice per day per instrument with two hours apart for five days using a single lot of controls and reagents across the three DxH 900−3S work cell. The mean, SD and CV% were reported for each parameter and all parameters met the acceptance criteria. Results are summarized below.

Parameter	Level	N	Mean	Within run		Between Run		Between Instrument		Between Day		Total	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
BF-TNC (cells/mm^3)	1	90	120.74	6.51	5.39	3.63	3.01	3.41	2.83	3.18	2.64	8.79	7.28
	2	90	1526.92	20.38	1.33	4.95	0.32	11.01	0.72	12.20	0.80	26.64	1.74
	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)	1	90	12204.83	398.75	3.27	0.00	0.00	276.21	2.26	0.00	0.00	485.07	3.97
	2	90	1681333.92	8753.35	0.52	4306.83	0.26	16235.20	0.97	963.34	0.06	18965.22	1.13
	3	90	5639354.09	50090.17	0.89	0.00	0.00	32100.78	0.57	1922.28	0.03	59524.62	1.06

UniCel DxH 690T Coulter Cellular Analysis System (DxH 690T)

Repeatability-Whole blood

Repeatability study was performed at one testing site on one DxH 690T system. This study was conducted by using normal and clinical whole blood samples collected in K2EDTA, contrived samples and control material covering the analytical measuring interval (AMI) ranges for various parameters. Repeatability for the CBC, Differential, NRBC and Reticulocyte parameters was performed in the automatic CBC/Diff/Retic (CDR) test panel. The mean, standard deviation (SD), coefficient of variation (CV), and 95% CI were calculated for each parameter. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements. The results are summarized below.

Parameter	Test Range	N	Test Result Mean	Test Result %CV/SD
WBC (x10^3/µL)	5.000 – 10.000	10	7.83	1.12% CV
RBC (x10^6/µL)	4.500 – 5.500	10	4.85	0.64% CV
HGB (g/dL)	14.00 – 16.00	10	15.30	0.41% CV
MCV (fL)	80.00 – 90.00	10	86.18	0.38% CV
RDW %	12.00 – 14.00	10	13.68	0.87% CV
RDW-SD (fL)	33.00 – 48.00	10	46.77	1.68% CV
Platelet	200.0 – 400.0	10	230.80	1.17% CV
MPV (fL)	8.00 – 10.00	10	8.69	0.83 %CV
NE (%)	50.00 – 60.00	10	54.70	1.46% CV
LY (%)	25.00 – 35.00	10	27.39	2.61% CV
MO (%)	5.00 – 10.00	10	5.85	5.10% CV
EO (%)	2.00 – 5.00	10	2.13	8.4% CV
BA (%)	0.50 – 1.50	10	0.83	0.24 SD

Parameter	Test Range	N	Test Result Mean	Test Result %CV/SD
NRBC (%)	>2.00 – 15.00	10	8.93	4.38% CV
	> 15.00	10	18.86	3.02% CV
RET %	0.00 – 1.50	10	1.22	0.13 SD
IRF	≥ 0.20	10	0.35	7.29% CV
MRV (fL)	100.0-120.0	10	109.77	1.20% CV

Pre-diluted whole blood imprecision studies
Refer to the 510(k) submission K120771.

2. Linearity
The study was performed according to CLSI EP06 2nd Edition guideline.

Whole Blood
Linearity of whole blood parameters including RBC, WBC, HGB and PLT were determined on the one DxH 900−3S work cell composed of three DxH 900 and one SMS II. Fresh whole blood was obtained and concentrated to achieve a high starting value near the upper limit of the analytical measuring interval (AMI) for each of the parameters. Dilutions were prepared of each parameter to cover the entire AMI including the lower range of AMI. A minimum of nine levels were prepared for each measurand and testing was performed in four replicates on all three DxH 900 instruments in DxH 900−3S with one reagent lot.

Results are presented in the table below. All results met the predefined acceptance criteria and were determined to be acceptable.

Parameter (unit)	Linear Range
WBC ($10^3/\mu L$)	0.064 – 408.55
RBC ($10^6/\mu L$)	0.001 – 8.56
HGB (g/dL)	0.04 – 26.07
PLT ($10^3/\mu L$)	3.2 – 3002.00

Body Fluid
Linearity studies for BF TNC parameter was performed using commercially available control material on the one DxH 900−3S work cell composed of three DxH 900 and one SMS II. Testing was performed on each of the three DxH 900 instruments in the DxH 900−3S. A minimum of nine sample levels were prepared and different levels were tested in four replicates and analyzed in random order.

Linearity studies for BF RBC was performed using a normal donor whole blood. Testing was performed on each of the three DxH 900 instruments in the DxH 900-3S. A minimum of nine sample levels were prepared and different levels were tested in four replicates and analyzed in random order. Results are presented in the table below. All results met the predefined acceptance criteria and were determined to be acceptable.

Parameter (unit)	Linear Range
BF RBC (cells/mm^3)	1113.10 – 6353906.00
BF TNC (cells/mm^3)	31.50 – 92745.00

3. Analytical Specificity/Interference:

Refer to 510(k) submission K081930.

4. Assay Reportable Range:

The upper limit of the assay reportable range for each of the parameters was determined by the linearity studies and lower limit were determined by the LoQ and linearity studies. The reportable range result for each parameter for UniCel DxH 900/DxH 690T Coulter Cellular Analysis System is provided in the table below:

Parameter	Reportable Range
WBC	(0.05 – 400.00) x $10^3/\mu L$
RBC	(0.005 – 8.50) x$10^6/\mu L$
HGB	0.10 g/dL – 25.50 g/dL
PLT	(3 – 3000) x $10^3/\mu L$
BFTNC	(20 − 89000) x cells/mm^3
BFRBC	(1000 − 6200000) x cells/mm^3

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Whole Blood Sample Stability
Refer to 510(k) submission K140911.

Body Fluid Sample Stability
Refer to published literature: *"*Leukocyte Survival in Cerebrospinal Fluid." J Clin Microbiol. 1986 May;23(5):965-6 and CLSI H56-A "Body Fluid Analysis for Cellular Composition; Approved Guideline.

6. Detection Limit:

Whole Blood
Limits of Blank (LoB), Limit of Detection (LoD) and the Limit of Quantification (LoQ) were performed for UniCel DxH 900/DxH 690T Coulter Cellular Analysis System for WBC and PLT according to CLSI EP17-A2. Testing was performed at one site using one DxH 900−3S composed of three DxH 900 and one SMS II. The studies were conducted on each of the three DxH 900 instrument.

The LoB study was conducted by using DxH diluent as blank. The blanks were run in five replicates for each parameter for a total of 20 replicates in two runs per day using two lots of DxH diluent in cassette presentation cycle over three days. The results obtained from all samples were used to calculate the LoB for each parameter.

The LoD and LoQ studies were performed by using precision profile approach as per CLSI EP17-A2. Testing was conducted by using fresh whole blood samples collected in K2EDTA. Three sets of 11 dilutions of the undiluted whole blood stock were prepared in 10% increments from 0% to 100%. One set of dilutions was analyzed on each of the DxH 900 instrument. Five replicates of each dilution level were analyzed on each test instrument.

All results met the predefined acceptance criteria and were determined to be acceptable. The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values for whole blood parameters are summarized below:

Parameter	LoB	LoD	LoQ
WBC (10^3 /µL)	0.007	0.012	0.019
PLT (10^3 /µL)	0.400	0.682	0.774

Body Fluid
Limits of Blank (LoB), Limit of Detection (LoD) and the Limit of Quantification (LoQ) for BF TNC and BF RBC study was conducted according to CLSI EP17-A2. Testing was performed at one site using one DxH 900−3S composed of three DxH 900 and one SMS II. The studies were conducted on each of the three DxH 900 instrument.

In LoB studies, testing was conducted over three days using DxH diluent as blank. The blanks were run in 20 replicates for each parameter for a total of 120 replicates in two runs per day using two lots of DxH diluent in single tube BF cycle. The results obtained from all samples were used to calculate the LoB for each parameter.

In LoD and LoQ studies, testing was performed using precision profile approach as per CLSI EP17-A2. Normal venous whole blood specimens collected in tubes containing K2EDTA anticoagulant were used in this study. Three sets of 11 dilutions of the undiluted whole blood stock were prepared in 10% increments from 0% to 100%. One set of dilutions was analyzed on each of the DxH 900 instrument. Five replicates of each dilution level were analyzed on each test instrument in the BF cycle for both BF TNC and BF RBC.

All results met the predefined acceptance criteria and were determined to be acceptable. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values for whole blood parameters are summarized below:

Parameter	LoB	LoD	LoQ
BF TNC (cells/mm^3)	5.000	8.871	14.004
BF RBC (cells/mm^3)	494.500	836.545	979.869

7. Assay Cut-Off:

Not applicable

8. Carry-Over:

Whole Blood
Carry-over was evaluated by assaying K2EDTA whole blood samples with high WBC, RBC, HGB and PLT values followed immediately by samples with low values in accordance with the CLSI H26-A2 guideline. High Target Value sample were run in three replicates followed

by three replicates of a Low Target Value sample using the cassette presentation mode. Three sets of carry-over sequences were run for each parameter on each instrument of one DxH 900−3S system at one testing site. The percentage of carry-over is calculated and all carry-over results for DxH900-3S system met specifications.

Body Fluid
Carry-over for body fluid parameters (BF RBC and BF WBC) was evaluated by assaying whole blood samples with high RBC and RBC parameter. DxH Diluent was used as Low target value samples. Carryover that could influence a body fluid result was assessed by running whole blood specimens using the CDR cassette mode with high parameter values followed by diluent analyzed in the body fluid single-tube close vial mode. Three sets of carry-over sequences were run for each parameter on each instrument of one DxH 900−3S system at one testing site in accordance with the CLSI H26-A2 guideline. For Body Fluid parameters, carry-over is calculated as the cell counts in each of the diluent sample and all results met the acceptance criteria.

B Comparison Studies:

1. Method Comparison with Predicate Device:

UniCel DxH 900 Coulter Cellular Analysis System

Whole Blood Studies
Method comparison study were performed to assess the performance of the UniCel DxH 900 Coulter Cellular Analysis System to the predicate UniCel DxH 800 Coulter Cellular Analysis System. The study was conducted at three sites with two sites using DxH 900 standalone instrument and one site using DxH 900−3S. A total of 735 venous samples collected in K2EDTA from pediatric (≤21 years) and adult subjects including a wide variety of disease states/clinical conditions. The tested samples covered the AMR and at MDLs for various analytes. Testing was performed within eight hours of sample collection in two replicates on both the devices and first replicate was used for analysis. Samples were tested in random on the UniCel DxH 900 Coulter Cellular Analysis System and the predicate within one hour of each other.

A Passing-Bablok regression analysis was performed. Bias at medical decision points were evaluated for all sites combined. All results were within the predefined acceptance criteria. Overall, the UniCel DxH 900 Coulter Analysis System demonstrated comparable performance to the predicate device, UniCel DxH 800 Coulter Cellular Analysis System in an intended use population in a clinical laboratory setting.

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)
WBC ($10^3/\mu L$)	723	0.08 − 282.90	1.000	1.006 (1.003, 1.009)	0.003 (-0.009, 0.015)

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)
RBC ($10^6/\mu L$)	734	0.93 − 8.06	0.999	0.994 (0.990, 0.997)	0.005 (-0.006, 0.016)
HGB (g/dL)	734	2.97 − 19.64	1.000	0.995 (0.992, 0.997)	0.035 (0.009, 0.060)
HCT (%)	734	8.40 − 60.67	0.999	0.987 (0.983, 0.992)	0.117 (-0.010, 0.243)
MCV (fL)	734	54.19 – 128.29	0.998	0.998 (0.990, 1.006)	-0.163 (-0.872, 0.546)
MCH (pg)	733	14.14 − 73.76	0.994	1.019 (0.999, 1.039)	-0.464 (-1.051, 0.124)
MCHC (g/dL)	733	26.09 − 57.50	0.952	1.024 (0.982, 1.066)	-0.571 (-1.970, 0.828)
RDW (%)	733	12.08 − 39.15	0.993	0.999 (0.967, 1.032)	0.004 (-0.501, 0.510)
RDW-SD (fL)	733	33.69 − 98.44	0.994	0.980 (0.966, 0.993)	0.761 (0.127, 1.394)
PLT ($10^3/\mu L$)	687	3.86 − 1449.60	0.999	1.000 (0.996, 1.004)	0.025 (-0.457, 0.507)
MPV (fL)	687	6.22 − 13.30	0.978	1.012 (0.991, 1.033)	-0.025 (-0.200, 0.151)
LYM# ($10^3/\mu L$)	673	0.05 − 257.91	1.000	1.003 (0.995, 1.011)	0.003 (-0.009, 0.003)
LYM (%)	681	0.62 − 98.09	0.998	1.001 (0.996, 1.005)	-0.002 (-0.117, 0.112)
MON# ($10^3/\mu L$)	670	0.00 − 58.59	0.998	0.994 (0.985, 1.003)	0.003 (0.001, 0.004)
MON (%)	678	0.32 − 97.62	0.996	1.005 (0.992, 1.018)	-0.058 (-0.174, 0.057)
NEU# ($10^3/\mu L$)	673	0.01 − 94.69	0.995	1.010 (1.004, 1.017)	0.000 (0.000, 0.000)
NEU (%)	681	1.02 − 97.62	0.998	1.001 (0.997, 1.005)	-0.050 (-0.321, 0.221)
EOS# ($10^3/\mu L$)	647	0.00 − 1.92	0.847	1.008 (0.986, 1.029)	0.000 (0.000, 0.000)

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)
EOS (%)	655	0.01 − 18.26	0.993	0.985 (0.969, 1.000)	0.016 (-0.013, 0.046)
BAS# ($10^3/\mu L$)	666	0.00 − 1.21	0.684	1.010 (0.940, 1.080)	0.000 (-0.001, 0.002)
BAS (%)	674	0.03 − 6.34	0.818	0.888 (0.709, 1.066)	0.078 (-0.022, 0.177)
IRF (%)	723	0.03 − 0.83	0.934	0.985 (0.955, 1.015)	0.008 (-0.006, 0.023)
RET# ($10^6/\mu L$)	726	0.00 − 0.89	0.987	1.028 (1.016, 1.040)	0.000 (0.000, 0.000)
RET (%)	727	0.04 − 23.79	0.992	1.014 (0.984, 0.098)	0.044 (-0.011, 0.992)
MRV (fL)	727	83.20 − 169.45	0.972	1.001 (0.980, 1.021)	-0.025 (-3.571, 1.161)
NRBC # ($10^3/\mu L$)	616	0.00 − 34.92	0.999	0.834 (0.746, 0.922)	0.000 (0.000, 0.000)
NRBC (%)	619	0.01− 130.63	0.998	1.115 (0.876, 1.354)	-0.075 (-0.174, 0.023)

Body Fluid Studies

Method comparison studies were performed to assess the performance of the UniCel DxH 900 Coulter Cellular Analysis System to the predicate UniCel DxH 800 Coulter Cellular Analysis System. The study was conducted at three sites with two sites using DxH 900 standalone instrument and one site using DxH 900−3 S. A total of 204 residual body fluid samples (serous, synovial and diluted whole blood) collected from pediatric (≤21 years) and adult subjects including a wide variety of disease states/clinical conditions were tested across three clinical sites. Body fluids samples were stored at room temperature and tested in random order on UniCel DxH 900 Coulter Cellular Analysis System and UniCel DxH 800 Coulter Cellular Analysis System within one hour of each other.

A Passing-Bablok regression analysis was performed. Bias at medical decision points were evaluated for all sites combined. All results were within the predefined acceptance criteria. Overall, all body fluid tested on UniCel DxH 900 Coulter Analysis System demonstrated comparable performance to the predicate device, UniCel DxH 800 Coulter Cellular Analysis System.

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)
BF RBC (cells/mm^3)	130	1085.99 – 6034566.00	1.00	0.998 (0.991, 1.005)	-18.721 (-95.808, 58.367)
BF TNC (cells/mm^3)	195	25.01 – 56066.86	1.00	1.014 (1.000, 1.027)	1.101 (-1.626, 3.827)

UniCel DxH 690T Coulter Cellular Analysis System

Whole Blood Studies

Method comparison studies was conducted to evaluate the performance of the UniCel DxH 690T Coulter Cellular Analysis System compared to the predicate device, UniCel DxH 800 Coulter Cellular Analysis System. A total of 382 adult whole blood samples collected in K2EDTA were analyzed on DxH690T, and predicate device. The study was performed in the automatic mode using CDR test panel. 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 to estimate regression parameters, and Deming analysis was performed for all the other whole blood parameters. Bias at medical decision points were evaluated for all parameters. All results were within the predefined acceptance criteria. Overall, UniCel DxH 690T Coulter Analysis System demonstrated comparable performance to the predicate device, UniCel DxH 800 Coulter Cellular Analysis System.

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)
WBC (10^3/µL)	368	0.06 – 148.83	0.999	0.994 (0.992, 0.997)	0.000 (-0.002, 0.002)
RBC (10^6/µL)	369	1.68 – 8.49	0.999	1.008 (1.004, 1.012)	-0.039 (-0.053, -0.025)
HGB (g/dL)	367	4.95 – 24.84	1.000	0.985 (0.982, 0.989)	0.130 (0.092, 0.168)
MCV (fL)	367	66.15 – 115.06	1.001	1.001 (0.994, 1.008)	-0.342 (-0.872, 0.546)
RDW (%)	367	11.93 – 27.60	0.993	1.003 (0.991, 1.034)	-0.072 (-0.269, -0.124)
RDW-SD (fL)	367	35.88 – 92.31	0.994	1.017 (1.001, 1.034)	-0.672 (-1.411, 0.158)

Parameter	N	Result Range	Correlation Coefficient	Slope (95% CI)	Intercept (95% CI)
PLT ($10^3/\mu L$)	334	7.80 – 788.70	0.999	1.012 (1.001, 1.024)	-0.854 (-2.236, 0.527)
MPV (fL)	335	6.58 – 12.21	0.995	9.995 (0.970, 1.020)	0.117 (-0.065, 0.298)
LYM (%)	340	1.03 – 98.00	0.998	1.012 (1.004, 1.020)	0.117 (-0.065, 0.298)
MON (%)	340	0.00 – 92.73	0.996	0.972 (0.959, 0.986)	0.158 (0.025, 0.290)
NEU (%)	340	0.66 – 96.2.0	0.998	1.002 (0.996, 1.004)	-0.428 (-0.832, -0.023)
EOS (%)	340	0.00 – 20.30	0.995	0.992 (0.972, 1.012)	0.011 (-0.029, 0.050)
BAS (%)	340	0.00 – 3.61	0.473	1.481 (0.383, 2.579)	-0.275 (-0.275, -0.275)
IRF (%)	371	0.00 – 0.77	0.924	1.018 (0.971, 1.065)	-0.014 (-0.038, 0.009)
RET (%)	371	0.03 – 15.20	0.985	1.031 (0.987, 1.074)	0.062 (-0.004, 0.129)
MRV (fL)	371	76.42 – 170.24	0.965	0.996 (0.961, 1.030)	0.349 (-3.7921, 4.491)

2. Matrix Comparison:

K2EDTA versus K3EDTA Anticoagulant Comparison Study

Refer to the 510(k) submission K120771.

Venous versus Capillary Whole Blood

Refer to the 510(k) submission K120771.

C Clinical Studies:

1. Clinical Sensitivity:

Sensitivity study was conducted to evaluate the flagging capabilities of the UniCel DxH 900 Coulter Cellular Analysis System and compare with that of UniCel DxH 800 Coulter Cellular Analysis System. The analysis was conducted using the flagging results from the method comparison studies performed at three clinical sites, in accordance with CLSI H20-A2 guideline. 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. All the distributional cases described in CLSI H20-A2 including important medical decision levels were analyzed for agreement analysis. The morphological agreement was based on DxH 800 (predicate) flagging for immature granulocytes, variant lymphocytes and left shift. Positive Percent Agreement (PPA), Negative Percent Agreement (NPA) and Overall Percent Agreement (OPA) with the 95% confidence intervals were calculated for all three sites combined.

Category of Abnormalities	N	TP	FP	FN	TN	NPA (95% CI)	PPA (95% CI)	OPA (95% CI)
Morphological Abnormalities	735	193	23	25	494	0.955 (0.934 − 0.970)	0.885 (0.836 − 0.921)	0.935 (0.914 − 0.950)
Distributional Study	735	419	35	22	259	0.881 (0.839 − 0.913)	0.9501 (0.926 − 0.967)	0.922 (0.901 − 0.940)

2. Clinical Specificity:

See Clinical Sensitivity

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Adult Whole Blood Reference Range
Studies to assess the adult reference range for whole blood samples were conducted on UniCel DxH 900 Coulter Cellular Analysis System per CLSI EP28-A3c to verify the reference intervals for male and female adults at one site. Forty whole-blood samples (male=20; female=20) were collected in K2EDTA from normal donors and tested in one replicate on two standalone UniCel DxH 900 Coulter Cellular Analysis Systems (DxH 900 instrument). The lower and upper limits of the 95% reference intervals were determined based on the 2.5th and 97.5th percentiles of all valid measurements for each sex group, respectively. 90% of the normal samples were within the established reference ranges on the predicate device DxH 800. The data supports that the

reference ranges established for the predicate device DxH 800 are applicable for the candidate device DxH 900. The reference intervals are summarized in table below:

Parameter	Female	Male
WBC ($10^3/\mu L$)	3.813 − 11.764	3.56 −10.21
RBC ($10^6/\mu L$)	3.63 − 4.92	4.06 − 5.63
HGB (g/dL)	10.86 − 14.27	12.47 − 16.33
HCT (%)	31.16 − 41.85	36.73 − 47.10
MCV (fL)	75.47 − 95.25	72.97 − 96.24
MCH (pg)	24.67 − 32.82	23.79 − 33.39
MCHC (g/dL)	33.34 − 34.61	33.47 − 36.26
RDW	12.34 − 17.69	12.06 − 16.17
RDW-SD (fL)	37.63 − 50.51	36.45 − 45.94
PLT ($10^3/\mu L$)	179.00 − 408.10	152.40 − 347.00
MPV (fL)	7.90 − 10.76	7.42 − 11.40
LYM# ($10^3/\mu L$)	1.13 − 3.05	0.97 − 3.23
LYM (%)	15.96 − 45.90	15.16 − 43.33
MON# ($10^3/\mu L$)	0.24 − 0.90	0.28 − 1.06
MON (%)	4.31 − 10.86	5.48 − 13.74
NEU# ($10^3/\mu L$)	1.86 − 8.21	1.75 − 7.56
NEU (%)	42.65 − 76.84	43.52 − 73.46
EOS# ($10^3/\mu L$)	0.03 − 0.53	0.04 − 0.46
EOS (%)	0.52 − 7.02	0.80 − 8.08
BAS# ($10^3/\mu L$)	0.01 − 0.09	0.01 − 0.09
BAS (%)	0.18 − 1.30	0.22 − 1.44
IRF (%)	0.26 − 0.52	0.30 − 0.54
RET# ($10^3/\mu L$)	23.00 − 93.51	18.84 − 108.56
RET (%)	0.51 − 2.17	0.42 − 2.23
MRV (fL)	96.40 − 118.01	97.53 − 122.66
NRBC # ($10^3/\mu L$)	0.00 − 0.02	0.00 − 0.02
NRBC (%)	0.00 − 0.33	0.02 − 0.61

Pediatric Whole Blood Reference Range
Refer to published literature; "Improving Laboratory Test Interpretation in Children (Beckman Coulter DxH 900–Core Laboratory Hematology System)." Am J Clin Pathol September 2020;154:330-341.

F Other Supportive Instrument Performance Characteristics Data:

Correlation between Sampling Modes

Please refer to 510(k) submission K120771

Correlation between analytical modes

Please refer to 510(k) submission K120771

Whole Blood Stability

Please refer to 510(k) submission K120771

Body Fluid Stability

Please refer to 510(k) submission K120771

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.