510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION MEMORANDUM

A. 510(k) Number:

K162977

B. Purpose for Submission:

To introduce hardware modifications to the previously cleared ADVIA® 2120/2120i Autoslide System to conform to the RoHS Directive, 2011/65EU of the European Parliament.

C. Manufacturer and Instrument Name:

Siemens Healthcare Diagnostics Inc., ADVIA® 2120/2120i

D. Type of Test or Tests Performed:

Quantitative complete blood count with leukocyte differential and body fluid analysis

Whole Blood

WBC, RBC, Hgb, CN-Free Hgb, calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV, Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#), Baso (%/#), LUC (%/#), Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr

Body Fluids (Pleural, Peritoneal, and Peritoneal Dialysate)

Total nucleated cell count (TNC) and red blood cell count (RBC)

Cerebrospinal Fluid (CSF)

WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#), and PMN (%/#)

E. System Descriptions:

1. Device Description:

   The ADVIA 2120/2120i is a fully automated differential cell counter and consists of an analytical module that aspirates, dilutes, and analyzes whole blood samples; an autosampler that automatically mixes, identifies, and presents samples for processing; a computer workstation that controls the instrument, provides primary user interface with the instrument and manages the data produced by the instrument; and a printer that optionally generates reports based on the instrument results.

2. Principles of Operation:

WBC Count

The whole blood sample is mixed with ADVIA 120/2120/2120i BASO reagent that contains acid and surfactant. The red blood cells are hemolyzed, and the white blood cells are then analyzed using two-angle laser light scatter signals.

Red Blood Cell and Platelet Counts

Red blood cells and platelets are analyzed by a single optical cytometer after appropriate dilution of the blood sample with ADVIA 120/2120/2120i RBC/PLT reagent (CBC TIMEPAC). The red blood cells are isovolumetrically sphered and lightly fixed to preserve the spherical shape. Red cells and platelets are counted from the signals from a common detector with two different gain settings.

Red Blood Cell and Platelet Size

Simultaneous measurement of laser light scattered at two different angular intervals is used to determine the size of red blood cells and platelets.

Hemoglobin

The hemoglobin method employs a modification of the manual cyanmethemoglobin method.

WBC Differential (DIFF) Method

The ADVIA 2120/2120i utilizes the Peroxidase and Basophil/Lobularity methods to quantitatively measure the following hematological parameters: neutrophils, lymphocytes, monocytes, eosinophils, large unstained cells, and basophils. With the Peroxidase method, leukocytes are classified by the characteristic properties exhibited by cell-specific constituents when the cells are treated with cytochemical stains. With the Basophil/Lobularity method, red blood cells are hemolyzed and the cytoplasm is stripped from all white blood cells except basophils. The sample is then analyzed by two-angle laser light scattering detection using a laser diode. The white cells are classified into three categories: basophils, mononuclear (MN) cells, and polymorphonuclear (PMN) cells.

Reticulocyte Count and Size

To determine the reticulocyte count, the ADVIA120/2120/2120i autoRETIC reagent isovolumetrically spheres the erythroid cells and stains cellular RNA. Low-angle laser light scatter, high-angle laser light scatter, and absorption characteristics of all cells are counted and measured. The absorption data are used to classify each cell as a reticulocyte or mature red blood cell based on its RNA content. The method of sizing reticulocytes uses the simultaneous measurement of laser light scattered at two different angular intervals.

Cerebrospinal Fluid (CSF) Method

The CSF sample is mixed with ADVIA 120/2120/2120i CSF reagent, which spheres and fixes the cells. After a minimum 4-minute to 4-hour incubation period, the prepared sample is then aspirated directly into the ADVIA 120/2120/2120i system. The cells are then detected and enumerated based on light scatter and absorbance measurements using the ADVIA 120/2120/2120i laser optics. A scatter versus scatter and scatter versus absorbance cytogram is displayed with the thresholds and results automatically calculated for each sample. Reportable parameters are WBC and RBC counts along with absolute and percentage counts for neutrophils, lymphocytes, monocytes, polymorphonuclear (PMN), and mononuclear (MN) cells.

Body Fluid Method

The ADVIA 2120/2120i Body Fluid Application uses the Basophil/Lobularity and RBC/Plt channels to enumerate the total nucleated (TNC) and RBC counts. The TNC count is derived from the Basophil/Lobularity channel. The ADVIA120/2120/2120i BASO reagent contains surfactant and phthalic acid which, in the presence of low heat in the Baso channel reaction chamber, lyses RBCs and strips the cytoplasmic membrane from all leukocytes except basophils. This cell suspension is subsequently passed through the flowcell. The cell suspension is intercepted by light from the laser diode where the low-angle light scatter (2° to 3°) and high-angle light scatter (5° to 15°) signals of each cell are counted.

The RBC count is derived from the RBC/Plt channel. The ADVIA120/2120/2120i RBC/Plt reagent spheres and fixes the RBCs. The same flowcell, low-angle and high-angle light scatter signals as the Basophil/Lobularity channel are used to count the RBCs.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ____X_____

4. Specimen Identification:

   Sample identification is performed by the following methods: manual entry, scanning with a barcode reader, automatic incremental numbering, and rack/position numbering in the autosampler mode.

5. Specimen Sampling and Handling:

   Body fluid and whole blood samples must be manually mixed by gentle inversion when analyzed in the manual open tube and manual closed tube modes.

   Whole blood samples aspirated in the automated closed tube mode are automatically mixed. The automated closed tube sampler rotates first to 45° then to 135°, staying at each orientation for a minimum of 0.6 seconds and a maximum of 15 seconds. A total of 25 mixer-cycles are required before aspiration. Fully mixed samples which have a dwell of over 15 seconds require an additional 20 mixer cycles before aspiration. If a dwell exceeds 5 minutes, the samples must be mixed again for 45 cycles before aspiration.

6. Calibration:

   The system must be calibrated for all parameters except %Retic. The ADVIA SETpoint Calibrator is recommended.

7. Quality Control:

   ADVIA TESTpoint Hematology Controls are the recommended assayed quality controls. Quality controls should be assayed at an interval selected by the laboratory, after a change in reagent lot number, and after the replacement of any part or component of the analytical module that may affect the analytical performance.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X____ or No_____

   The Hazard Analysis and Software Development processes were reviewed in premarket notification K102644.

F. Regulatory Information:

1. Regulation section:

   21 CFR § 864.5220, Automated differential cell counter

2. Classification:

   Class II

3 Product code:

GKZ, Counter, Differential Cell

4. Panel:

Hematology (81)

G. Intended Use:

1. Indication(s) for Use:

The ADVIA 2120/2120i with autoslide are quantitative, automated hematology analyzers that provide the following information for in vitro diagnostic use in clinical laboratories:

- A complete blood count (CBC) consisting of WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV
- A leukocyte differential count consisting of: Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#), Baso (%/#), LUC (%/#).
- A reticulocyte analysis consisting of Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.
- A nucleated red blood cell count consisting of NRBC (%/#).
- Enumeration of the total nucleated (TNC) count and RBC count for pleural, peritoneal, or peritoneal dialysis (PD) specimens.

Note: Above measurands are determined (in whole blood, pleural, peritoneal, or peritoneal dialysis specimens) with K2 and/or K3 EDTA anti-coagulants.

- Quantitative determination of blood cells in Cerebrospinal Fluid (CSF) consisting of WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#), PMN (%/#)

In addition, the system provides the added capability to automatically prepare and stain high quality blood smears on a glass microscope slide.

2. Special Conditions for Use Statement(s):

For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

ADVIA® 2120/2120i Hematology Auto-Analyzers (K102644)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	The ADVIA 2120i RoHS/REACH compliant instrument will have the same intended use as the ADVIA 2120i instrument (including the Autoslide additional option). The products are quantitative, automated hematology analyzers that provide the following information for in vitro diagnostic use in clinical laboratories: • A complete blood count (CBC) consisting of WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV. • A leukocyte differential count consisting of: Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#), Baso (%/#), LUC (%/#). • A reticulocyte analysis consisting of Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr. • A nucleated red blood cell count consisting of NRBC (%/#). • Enumeration of the total nucleated (TNC) count and RBC count for pleural, peritoneal, or peritoneal dialysis (PD) specimens. Note: Above measurands are determined (in whole blood, pleural, peritoneal, or peritoneal dialysis specimens) with K2 and/or K3 EDTA anti-coagulants. • Quantitative determination of blood cells in Cerebrospinal Fluid (CSF) consisting of WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#), PMN (%/#) In addition, the system provides the added capability to automatically prepare and stain high quality blood smears on a glass microscope slide.	Same
Throughput	120 samples/hour	Same
Sample type(s)	Whole blood, pleural, peritoneal, or peritoneal dialysis fluid collected in K_2EDTA and K_3EDTA	Same
Sample volume	175 µL	Same

Similarities		
Item	Device	Predicate
Sampling modes	Manual open tube sampler (MOTS) Manual closed tube sampler (MCTS) Automated closed tube sampler (ACTS)	Same
Reagents	CBC TIMEPAC CN-Free CBC TIMEPAC DIFF TIMEPAC autoRetic EZ KLEEN SHEATH/RINSE	Same
Calibrators	ADVIA OPTIpoint ADVIA SETpoint	Same
Quality controls	ADVIA TESTpoint Low ADVIA TESTpoint Normal ADVIA TESTpoint High ADVIA TESTpoint Retic Low ADVIA TESTpoint Retic High ADVIA TESTpoint 3-in-1 Abnormal1 ADVIA TESTpoint 3-in-1 Normal ADVIA TESTpoint 3-in-1 Abnormal2	Same

Differences		
Item	Device	Predicate
Signal Processor PCB	New VHDL implementation of signal processing and monitor/keyboard interface design. No onboard software.	Existing non-RoHS compliant Signal Processing PCB. No onboard software.
Autosampler Control PCB DAA	New VHDL implementation of former used discrete components and includes SMC4 motor control. No change to predicate software	Dropped in SMC4 motor controller. Onboard motion control software for 80186 (CPU).
Autosampler Control PCB SAA	New VHDL implementation of former used discrete components and includes SMC4 motor control.	Dropped in SMC4 motor controller. Onboard motion control software for 80186 (CPU).
Reference preAmplifier	No onboard software or firmware.	No onboard software or firmware. Contains some non-RoHS compliant components.
PreAmp Power Supply	No onboard software or firmware. Uses the predicate sensors	No onboard software or firmware. Contains some non-RoHS compliant components.
Laser Diode Driver 1	No onboard software or firmware. Contains some minor RoHS component changes.	No onboard software or firmware. Contains some non-RoHS compliant components.
Dual Servo Pump	New VHDL implementation of former used discrete components. Uses original software.	Uses original Software
Valve Driver Board	New VHDL implementation of former used discrete components. Uses original software.	Uses original Software

Differences		
Item	Device	Predicate
Parallel Node	New VHDL implementation of former used discrete components. Uses original Software.	Uses original Software
HGB Interface	New VHDL implementation of former used discrete components. Uses original Software.	Uses original Software
Perox Optics Scrambler	No onboard software or firmware. Contains some minor RoHS component changes.	No onboard software or firmware. Contains some non-RoHS compliant components.
Sensor Amplifier	No onboard software or firmware. Contains some minor RoHS component changes.	No onboard software or firmware. Contains some non-RoHS compliant components.
Rack Sensor LED	No onboard software or firmware. Contains some minor RoHS component changes.	No onboard software or firmware. Contains some non-RoHS compliant components.
Indicator Assy DAA	No onboard software or firmware. Contains some minor RoHS component changes.	No onboard software or firmware. Contains some non-RoHS compliant components.
Indicator Assy SAA	No onboard software or firmware. Contains some minor RoHS component changes.	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.
Input/Output Q I/O PCBA	No onboard software or firmware. Contains some minor RoHS component changes.	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.
CAN Scrambler	No onboard software or firmware. Contains some minor RoHS component changes.	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.
Baso Optics Scrambler o Optics Scrambler	No onboard software or firmware. Contains some minor RoHS component changes.	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.
Pneu Valve Scrambler Board Valve Scrambler Board	No onboard software or firmware. Contains some minor RoHS component changes.	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.
UFC Illumination Board Illumination Board	No onboard software or firmware. Contains some minor RoHS component changes.	Provides cosmetic lighting. No onboard software or firmware. Contains some non-RoHS compliant components.
Switch Panel Interface Panel Interface	No onboard software or firmware. Contains some minor RoHS component changes.	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.
ID Reader Interface	No onboard software or firmware. Contains some minor RoHS	Interconnect board. No onboard software or firmware.

Differences		
Item	Device	Predicate
	component changes.	Contains some non-RoHS compliant components.
UFC Valve Scrambler PCB	No onboard software or firmware. Contains some minor RoHS component changes.	Interconnect board. No onboard software or firmware. Contains some non-RoHS compliant components.

I. Special Control/Guidance Document Referenced (if applicable):

CLSI EP05-A3, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Third Edition

CLSI EP15-A3, User Verification of Precision and Estimation of Bias; Approved Guideline - Third Edition

CLSI EP09-A3, Measuring Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition

CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition

ISO 14971, Medical Devices - Application of Risk Management to Medical Devices

J. Performance Characteristics*:*

1. Analytical Performance:

a. Method Comparison:

To assess the performance of the ADVIA 2120i® RoHS/REACH compliant system compared to the ADVIA 2120i® (K102644), 110 whole blood samples, 40 cerebrospinal (CSF) samples, and 40 body fluid (BF) samples were analyzed on four different system configurations. Configurations 2 and 4 consisted of the candidate device, whereas configurations 1 and 3 consisted of the predicate device, ADVIA 2120i (K102644).

Device Configurations

Predicate Device		Candidate Device	
Configuration 1	**Configuration 3**	**Configuration 2**	**Configuration 4**
Cyanide-free CBC TIMEPAC	Cyanide containing CBC TIMEPAC	Cyanide-free CBC TIMEPAC	Cyanide containing CBC TIMEPAC
Dual aspirate autosampler	Single aspirate autosampler	Dual aspirate autosampler	Single aspirate autosampler

Whole Blood Method Comparison – All Sites

Parameter	Correlation Coefficient	Slope	Intercept	Mean	
				Predicate	Candidate
WBC ($x10^3/\mu L$)	0.999	0.99	-0.01	10.66	10.55
RBC ($x10^6/\mu L$)	0.996	0.99	0.04	3.38	3.37
Hgb (g/dL)	0.999	0.97	0.0	10.2	10.2
MCV (fL)	0.993	0.99	0.9	93.3	93.2
CHCM (g/dL)	0.981	0.97	1.2	32.0	32.1
RDW (%)	0.997	0.99	0.1	16.2	16.1
HDW (g/dL)	0.981	0.99	0.0	2.97	2.90
Plt ($x10^3/\mu L$)	0.997	1.00	-1.0	182	184
MPV (fL)	0.902	0.99	-0.4	9.2	9.7
Neut %	0.991	1.02	-1.9	65.6	65.1
Lymph %	0.981	1.03	-0.2	19.9	20.3
Mono %	0.920	1.10	-0.5	6.8	6.9
Eos %	0.947	0.96	-0.2	2.3	2.1
Baso %	0.884	1.00	0.0	0.8	0.8
LUC %	0.988	1.00	0.2	4.7	5.0
Retic %	0.966	1.17	-0.1	2.1	2.4
CHr (pg)	0.950	1.02	-0.7	31.7	31.6
NRBC %	0.996	1.10	-0.5	14.2	13.7

CSF Method Comparison – All Sites

Parameter	Correlation Coefficient	Slope	Intercept	Mean	
				Predicate	Candidate
WBC (cells/µL)	0.999	0.93	1.3	83	78
RBC (cells/µL)	0.999	1.07	-4.1	455	482
Neut %	0.960	0.83	3.9	27.7	26.7
Lymph %	0.960	0.96	1.1	53.9	52.6
Mono %	0.901	0.98	2.1	17.7	19.5
MN %	0.958	0.85	11.2	71.6	72.1
PMN %	0.958	0.85	3.7	28.4	27.9

Body Fluid Method Comparison – All Sites

Parameter	Correlation Coefficient	Slope	Intercept	Mean	
				Predicate	Candidate
TNC (cells/µL)	0.999	1.03	-18	916	924
RBC ($x10^3/\mu L$)	0.998	0.96	12	377	375

b. Precision/Reproducibility:

To obtain measures of within-run (repeatability) imprecision (%CV and SD), normal and pathological whole blood samples were analyzed in the following modes of operation: autosampler (AS), manual closed tube sampler (MCT), and manual open tube sampler (MOT). At least 30 replicates were performed for each sample analyzed. The result for each whole blood parameter was within the predefined acceptance criteria for SD or %CV.

Within-run imprecision of CSF was evaluated in the MOT mode; whereas, body fluids were analyzed in the MOT and MCT modes. At least 30 replicates were performed for each sample analyzed. The results for each sample matrix and

parameter were within the predefined acceptance criteria for SD or %CV.

Whole Blood – Configuration 2

Parameter	Autosampler (AS)			Manual Closed-Tube (MCT)			Manual Open-Tube (MOT)		
	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
WBC P ($x10^3/\mu L$)	4.51	0.12	2.72	4.28	0.10	2.42	4.40	0.13	2.92
WBC B ($x10^3/\mu L$)	4.43	0.09	2.01	4.31	0.10	2.28	4.51	0.13	2.94
RBC ($x10^6/\mu L$)	4.55	0.02	0.53	4.58	0.03	0.74	4.71	0.04	0.89
Hgb (g/dL)	13.4	0.07	0.55	13.3	0.09	0.64	13.8	0.09	0.68
MCV (fL)	88.9	0.07	0.08	90.1	0.15	0.16	86.5	0.12	0.14
CHCM (g/dL)	33.0	0.04	0.11	32.1	0.07	0.22	34.3	0.07	0.21
RDW (%)	14.9	0.08	0.53	14.9	0.06	0.38	14.9	0.06	0.38
HDW (g/dL)	2.47	0.01	0.53	2.41	0.01	0.47	2.48	0.01	0.47
Plt ($x10^3/\mu L$)	277	7.34	2.65	281	6.58	2.34	286	8.30	2.91
Neut %	45.4	0.94	2.08	45.6	0.80	1.76	47.4	0.85	1.79
Lymph %	40.0	0.89	2.23	39.8	1.01	2.55	38.7	1.14	2.95
Mono %	9.5	0.86	9.06	9.6	0.58	6.07	9.3	0.58	6.23
Eos %	2.8	0.29	10.58	2.7	0.20	7.49	2.7	0.26	9.77
LUC %	1.9	0.21	10.95	1.8	0.30	16.35	1.4	0.20	14.7
Baso %	0.5	0.13	26.88	0.5	0.13	26.66	0.7	0.15	23.21
Retic %	1.2	0.10	8.53	1.2	0.08	6.57	0.7	0.07	9.69
MPV	7.8	0.11	1.41	8.0	0.13	1.59	8.8	0.11	1.28

Whole Blood – Configuration 4

Parameter	Autosampler (AS)			Manual Closed-Tube (MCT)			Manual Open-Tube (MOT)		
	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
WBC P ($x10^3/\mu L$)	6.18	0.11	1.71	7.57	0.20	2.58	7.27	0.15	2.03
WBC B ($x10^3/\mu L$)	5.69	0.10	1.68	7.38	0.15	2.07	6.99	0.13	1.87
RBC ($x10^6/\mu L$)	5.03	0.04	0.74	4.94	0.03	0.69	5.06	0.04	0.80
Hgb (g/dL)	14.9	0.07	0.48	16.4	0.09	0.55	16.7	0.12	0.72
MCV (fL)	87.2	0.23	0.26	93.3	0.07	0.08	92.7	0.12	0.13
CHCM (g/dL)	33.4	0.12	0.36	35.0	0.05	0.15	35.3	0.04	0.13
RDW (%)	12.9	0.11	0.83	13.0	0.08	0.64	13.0	0.11	0.83
HDW (g/dL)	2.34	0.01	0.61	2.54	0.01	0.46	2.56	0.01	0.42
Plt ($x10^3/\mu L$)	231	5.78	2.50	244	5.66	2.32	259	7.09	2.74
Neut %	56.4	0.60	1.07	60.8	0.63	1.03	60.5	0.59	0.98
Lymph %	27.8	0.70	2.52	25.9	0.68	2.61	25.7	0.58	2.27
Mono %	7.6	0.38	5.08	6.3	0.34	5.43	6.4	0.40	6.29
Eos %	6.0	0.25	4.16	3.1	0.24	7.83	3.2	0.23	7.27
LUC %	1.6	0.19	11.80	3.3	0.34	10.34	3.5	0.29	8.22
Baso %	0.6	0.09	16.37	0.8	0.10	12.37	0.8	0.11	14.40
Retic %	1.5	0.05	3.69	0.8	0.05	6.00	0.9	0.06	6.82
MPV	10.4	0.14	1.30	9.0	0.13	1.39	8.9	0.09	1.07

Low Abnormal Whole Blood – Autosampler (AS)

Parameter	Configuration 2			Configuration 4		
	Mean	SD	%CV	Mean	SD	%CV
WBC ($x10^3/\mu L$)	0.85	0.10	11.8	1.02	0.10	9.9
RBC ($x10^6/\mu L$)	2.15	0.01	0.6	2.19	0.02	0.8
Hgb (g/dL)	6.5	0.05	0.8	6.5	0.05	0.8
Plt ($x10^3/\mu L$)	39	1.7	4.5	36	1.6	4.4

Low Abnormal Whole Blood – Manual Closed-Tube (MCT)

Parameter	Configuration 2			Configuration 4		
	Mean	SD	%CV	Mean	SD	%CV
WBC ($x10^3/\mu L$)	0.80	0.11	14.3	0.99	0.10	10.2
RBC ($x10^6/\mu L$)	2.15	0.02	0.7	2.17	0.02	1.0
Hgb (g/dL)	6.5	0.05	0.8	6.5	0.04	0.6
Plt ($x10^3/\mu L$)	38	2.0	5.3	36	1.7	4.8

Low Abnormal Whole Blood – Manual Open-Tube (MOT)

Parameter	Configuration 2			Configuration 4		
	Mean	SD	%CV	Mean	SD	%CV
WBC ($x10^3/\mu L$)	1.14	0.09	8.2	1.32	0.09	7.1
RBC ($x10^6/\mu L$)	2.97	0.03	0.9	2.96	0.01	0.5
Hgb (g/dL)	8.7	0.05	0.5	8.6	0.06	0.7
Plt ($x10^3/\mu L$)	39	2.4	6.1	37	1.9	5.1

High Abnormal Whole Blood – Autosampler (AS)

Parameter	Configuration 2			Configuration 4		
	Mean	SD	%CV	Mean	SD	%CV
WBC ($x10^3/\mu L$)	373.13	8.63	2.3	381.23	8.95	2.3
RBC ($x10^6/\mu L$)	7.04	0.07	1.0	7.13	0.06	0.8
Hgb (g/dL)	21.5	0.17	0.8	22.0	0.16	0.7
Plt ($x10^3/\mu L$)	3470	69.5	2.0	3221	62.4	1.9

High Abnormal Whole Blood – Manual Closed-Tube (MCT)

Parameter	Configuration 2			Configuration 4		
	Mean	SD	%CV	Mean	SD	%CV
WBC ($x10^3/\mu L$)	376.60	7.91	2.1	418.2	10.52	2.5
RBC ($x10^6/\mu L$)	7.06	0.05	0.7	7.16	0.07	1.0
Hgb (g/dL)	21.6	0.09	0.4	22.1	0.20	0.9
Plt ($x10^3/\mu L$)	3478	58.9	1.7	3256	35.3	1.1

High Abnormal Whole Blood – Manual Open-Tube (MOT)

Parameter	Configuration 2			Configuration 4		
	Mean	SD	%CV	Mean	SD	%CV
WBC ($x10^3/\mu L$)	376.44	8.96	2.4	392.41	9.32	2.4
RBC ($x10^6/\mu L$)	7.52	0.07	0.9	7.48	0.06	0.9
Hgb (g/dL)	23.5	0.17	0.7	23.7	0.18	0.8
Plt ($x10^3/\mu L$)	3464	65.1	1.9	3217	46.8	1.5

Cerebrospinal Fluid (CSF) – Manual Open-Tube (MOT)

Parameter	N	Configuration 2			Configuration 4		
		Mean	SD	%CV	Mean	SD	%CV
WBC (cells/µL)	30	104	4.12	3.97	99	4.83	4.88
RBC (cells/µL)	30	199	7.60	3.82	225	7.38	3.28
MN %	30	48	3.62	7.59	49	4.05	8.23
PMN %	30	56	2.90	5.17	50	3.58	7.20

Body Fluid

Parameter	N	Manual Open-Tube (MOT)						Manual Closed-Tube (MCT)					
		Configuration 2			Configuration 4			Configuration 2			Configuration 4		
		Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV	Mean	SD	%CV
TNC (cells/µL)	30	1626.30	43.44	2.67	1270.82	38.50	3.03	4.31	0.08	1.92	1302.04	57.54	4.42
RBC ($x10^3$/µL)	30	76.27	2.81	3.68	59.20	2.43	4.11	4.58	0.03	0.76	58.31	4.42	4.06

To obtain measures of within-device imprecision (%CV and SD), three levels of ADVIA TESTpoint 3in1 Controls (Abnormal 1, Abnormal 2, and Normal) and two levels of CSF Controls (Level 1 and Level 2) were analyzed over 28 days, two runs per day and two replicates per run. The results of each study were within the predefined acceptance criteria for SD or %CV.

c. Linearity:

The linear ranges for the WBC, RBC, Hgb, PLT and %Retic parameters were established by testing two different sample sets (for each parameter with a wide overlap) prepared by diluting FDA cleared commercially available linearity materials to span the analytical measuring range (AMR). The linear ranges for the CSF RBC and body fluid (BF) RBC parameters were established by testing diluted samples prepared from anticoagulated whole blood. Results for each parameter were within the predefined acceptance criteria.

Parameter	Analytical Measuring Range
WBC ($x10^3$/µL)	0.02–400
RBC ($x10^6$/µL)	0.0–7.0
HGB (g/dL)	0–22.5
CN-Free HGB (g/dL)	1–22.5
%Retic	0.2–24.5
PLT ($x10^3$/µL)	5–3500
CSF WBC (cells/µL)	0–50
CSF RBC (cells/µL)	0–1500
BF TNC ($x10^3$/µL)	0.02–400
BF RBC ($x10^6$/µL)	0.01–6.76

d. Carryover:

Carryover studies for the WBC, RBC, HGB, and PLT parameters were conducted using pooled whole blood as high target value (HTV) samples and plasma as low target value (LTV) samples. Testing was conducted by aspirating a HTV whole blood

sample in triplicate followed by triplicate analysis of plasma-based LTV samples. Carryover was calculated according to the following calculation.

% Carryover = (LTV1 – LTV3)/(HTV3 – LTV3) x 100

The results of the carryover study were within the predefined specifications of ≤ 1.0% for WBC, RBC, HGB, and PLT in the autosampler, manual-open and manual-closed tube modes.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

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