510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:
k091313

B. Purpose for Submission:
Modification of device for inclusion of body fluid mode.

C. Manufacturer and Instrument Name:
Sysmex America, Inc.
Sysmex® XT-4000i

D. Type of Test or Tests Performed:
Quantitative, Automated Hematology Analyzer

WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG% / #, RDW-CV, RDW-SD, MPV, RET%/#, IRF, RET-He

Body Fluid Mode:
WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF#

E. System Descriptions:

1. Device Description:
   The XT-4000i is the same as the XT-2000i which is part of the XT-Series and has a body Fluid mode the same as the XE-5000. It is an automated hematology analyzer which consists of four principle units: (1) Main Unit which aspirates, dilutes, mixes, and analyzes whole blood and body fluid samples; (2) Sampler Unit which supplies samples to the Main Unit automatically; (3) IPU (Information Processing Unit) which processes data from the Main Unit and provides the operator interface with the system; (4) Pneumatic Unit which supplies pressure and vacuum from the Main Unit.
   The Body Fluid (BF) analysis mode of the XT-4000i uses the 4DIFF scattergram and the RBC distribution obtained from a specialized analysis sequence to calculate and display the WBC (WBC-BF) counts, mononuclear cell (MN) / polymorphonuclear cell (PMN) counts and percentages, TC-BF (Total Count) & RBC (RBC-BF) counts found in the body fluid.
2. Principles of Operation:
   Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.
3. Modes of Operation:
   (1) Manual Mode: the caps of the sample tubes are manually removed and each sample is aspirated via the whole blood aspiration pipette.
   (2) Sampler Mode: The sampler automatically mixes, aspirates and analyzes samples without removing their caps. Up to 50 samples can be loaded at a time and analyzed automatically.
   (3) Manual Closed Mode: The sampler is used to aspirate the sample without opening the cap of the sample tube. This mode is basically the same as the manual mode; mixing and continuous analysis cannot be performed

automatically.
(4) Capillary Mode: an analysis is performed after diluting the sampe to 1:5 ratio. This mode is used in analyzing a minute amount of blood collected from the earlobe or fingertip. The method used to aspirate the sample is the same as that used in manual and body fluid modes.
(5) Body Fluid Mode: The body fluid mode is used exclusively for measuring the number of blood cells contained in body fluid. Sample aspiration is performed in the same method as for the manual mode.

4. Specimen Identification:
   Specimen information is managed by four menu lists and specimen identification input is manual (operator entered) or by barcode reader.
5. Specimen Sampling and Handling:
   Specimens are processed manually.
6. Calibration:
   Calibration is carried out by entering calibration values into the unit. This calibration is performed for the WBC, RBC, HGB, HCT, PLT and PLT-O parameters. WBC Diff parameters are factory calibrated prior to shipment and verified by Sysmex technical representative on installation. The instrument does not need to be calibrated in the laboratory.
7. Quality Control:
   Body fluid controls are not available. Whole blood control materials are recommended.
8. Software:
   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:
   Yes__X__ or No_____

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:
   81 Hematology

G. Intended Use:

1. Indication(s) for Use:
   The Sysmex XT-400i is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patients found in clinical laboratories. The XT-4000i classifies and enumerates the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CV. RDW-SD, MPV, RET%/#, IRF, RET-He, and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF# parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Serous and synovial fluids should be

collected in K_2EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is not required or recommended.

2. Special Conditions for Use Statement(s):
   None

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
   Sysmex XT-Series k021241
   Sysmex XE-5000 k071967 (Body Fluid Mode)
2. Comparison with Predicate Device:

Similarities			
Item	**Device XT-4000i**	**Predicate 1 XT-Series (K061150)**	**Predicate 2 XE-5000 (K071967)**
Intended Use	The Sysmex® XT-4000i is a quantitative multi-parameter automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XT-4000i classifies and enumerates the following parameters for whole blood: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, IG%/#, RDW-CD, RDW-SD, MPV, RET%/#, IRF, RET-He and has a Body Fluid mode for body fluids. The Body Fluid mode enumerates the WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF parameters in cerebrospinal fluids (CSF), serous fluids (peritoneal, pleural) and synovial fluids. Serous and Synovial fluids should be collected in K_2 EDTA to prevent clotting of fluid. The use of anticoagulants with CSF specimens is not required or recommended.	The Sysmex® XT-Series, Hematology Analyzer, is a quantitative automated hematology analyzer and leukocyte differential counter for *in vitro* diagnostic use in clinical laboratories. The XT-Series Body Fluid Application adds a quantitative, automated procedure for analyzing body fluids such as cerebrospinal fluid, serous fluid an synovial fluid to the XT-Series, providing enumeration of the WBCs and the RBCs.	The Sysmex® XE-5000 is an automated hematology analyzer intended for *in vitro* diagnostic use in screening patient populations found in clinical laboratories. The XT-5000 classifies and enumerates the same parameters as the XE-2100 using whole blood as described below, cord blood for HPC and has a Body Fluid mode for body fluids. The Body Fluid mode analyzes WBC-BF, RBC-BF, MN%/#, PMN%/# and TC-BF in body fluids CSF, serous fluids and synovial fluids with EDTA as needed). WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, NRBC, RDW-SD, RDW-CV, MPV, RET%/#, IRF, IG%/#, HPC#, RET-He, IPF, WBC-BF, RBC-BF, MN%/#, PMN%/#,TC-BF
Principle of Measurement	Performs hematology analyses according to the Hydro Dynamic Focusing (DC Detection), flow cytometry method (using a semiconductor laser), and SLS-hemoglobin method.	Same as XT-4000i	Same as XT-4000i with the addition of the RF/DC detection method
Calibrator	Calibrator (X Cal)	Same as XT-4000i	Same as XT-4000i
Sample types	Whole blood Body Fluids	Same as XT-4000i	Same as XT-4000i

Differences			
Item	**Device XT-4000i**	**Predicate 1 XT-Series (K061150)**	**Predicate 2 XE-5000 (K071967)**
IVD Parameters	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He# WBC-BF, RBC-BF, MN%/#, PMN%/#, TC-BF	WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, NEUT%/#, LYMPH%/#, MONO%/#, EO%/#, BASO%/#, RDW-CV, RDW-SD, MPV, RET%/#, IRF, IG%/#, RET-He# WBC-BF, RBC-BF	Same as XT-4000i
Quality Control	e-Check (XE) – 3 Levels	e-Check – 3 Levels	Same as XT- 4000i
Throughput	Approximately 80-100 whole blood specimens/hr depending on mode used. Approximately 38 body fluid specimens/hr	Approximately 80 whole blood and/or body fluid specimens/hr depending on mode used	Approximately 113-150 whole blood specimens/hr depending on mode used. Same body fluid throughput as XT-4000i
Software/ Hardware Differences	Has a Body Fluid Mode	Has a Body Fluid Application	Same as XT-4000i
Reagents	CELLPACK™ (Diluent) STROMATOLYSER-FB™ (Lyse) STROMATOLYSER-4DL™ (Lyse) STROMATOLYSER-4DS™ (Stain) SULFOLYSER (Lyse) RET-SEARCH II (Diluent) RET-SEARCH II (Stain)	Same as XT-4000i	Same as XT-4000i and in addition uses: CELLSHEATH™ (Diluent) STROMATOLYSER-NR™ (Diluent) STROMATOLYSER-NR™ (Stain) STROMATOLYSER-IM™ (Lyse)
Dimensions (HxWxD) mm	630 x 520 x 720	Same as XT-4000i	711 x 706 x 535
Weight (kg)	59	Same as XT-4000i	81

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

1. CLSI Document C28-A2 "How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline—Second Edition. 2008. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898.
2. CLSI Document C49-A. "Analysis of Body Fluids in Clinical Chemistry; Approved Guideline". 2007. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898.

3. CLSI Document. EP5-A2. Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline—Second Edition". 2004. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898.
4. CLSI Document EP9-A2. "Method Comparison and Bias Estimation Using Patient Samples; Approved Guidelines—Second Edition". 2002. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898.
5. CLSI EP10-A3, *Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline 3rd Edition* CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898.
6. CLSI Document EP15-A2. "User Demonstration of Performance for Precision and Accuracy; Approved Guideline—Second Edition". 2005CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898.
7. CLSI Document H56-A. "Body Fluid Analysis for Cellular Composition; Approved Guideline". 2006. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898.
8. FDA. 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. Issued December 4, 2001.
9. ICSH. Guidelines for the evaluation of blood cell analyzers including those used for differential leukocyte and reticulocyte counting and cell marker applications. *Clin Lab. Haemat. 1994, 16, 157-174.*
10. Kjelksberg C. and Knight J. *Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids.* 3rd edition. Chicago, IL: ASCP Press, 1993.

J. Performance Characteristics*:*

1. **Analytical Performance:**

a. Accuracy:

Accuracy studies were performed on 389 samples at three sites and run on the XE-5000 and the XT-4000i for the WBC-BF, RBC-BF, TC-BF, MN%/# and PMN%/# parameters. Unselected residual body fluid specimens were collected and consisted of 100 cerebrospinal fluid (CSF), 70 synovial fluid, 85 pleural fluid and 134 peritoneal fluid specimens. Each body fluid specimen was run once on the XE-5000 and then the XT-4000i according to CLSI EP09-A2.

Conclusion: Method comparison testing for all parameters met manufacturer's specifications. Regression analysis demonstrated that WBC-BF, RBC-BF, TC-BF, MN# and PMN# slopes were within 1.01 – 1.05, intercepts were within -0.01 – 0.01, and correlation coefficients >0.990. MN% and PMN% slopes were within 0.98 – 0.99, intercepts were within -1.1 – 2.6, and correlation coefficients >0.93.

<u>Bias</u>

Bias studies were performed on 392 samples across three sites and run on the XE-5000 and the XT-4000i for the WBC-BF, RBC-BF, TC-BF, MN%/# and PMN%/# parameters. Studies were performed in accordance with CLSI EP09-A2, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* Unselected residual body fluid specimens were collected and consisted of 100 cerebrospinal fluid (CSF), 72 synovial fluid, 87 pleural fluid and 133 peritoneal fluid specimens. Each body fluid specimen was run once on the XE-5000 and then the XT-4000i. Estimation of Bias was determined for all sites combined. Acceptance criteria for each parameter are listed in the table below and all parameters were found to be within manufacturer's specifications.

Bias performance criteria

Parameter	Units	Analysis Range	Bias%
WBC-BF	x $10^3/\mu L$	0.004-10.000	± 15%
RBC-BF	x $10^6/\mu L$	0.001-5.000	± 500 or ± 6.0%
TC-BF	x $10^3/\mu L$	0.004-10.000	± 15%
MN#	x $10^3/\mu L$	0.004-10.000	± 3SD
MN%	%	0.00-100.00	± 3SD
PMN#	x $10^3/\mu L$	0.004-10.000	± 3SD
PMN%	%	0.00-100.00	± 3SD

Bias by Body Fluid Type

Site	Fluid Type	Parameter	Units	Mean Difference	%Difference or SD	Bias Limits
ALL SITES COMBINED	CSF	WBC-BF	x $10^3/\mu L$	0.0148	5.9	± 15%
		TC-BF	x $10^3/\mu L$	0.0162	6.4	± 15%
		RBC	x $10^6/\mu L$	0.0005	0.4	± 500 or ± 6%
		PMN#	x $10^3/\mu L$	0.0098	1SD	± 3 SD
		PMN%	%	1.5	1SD	± 3 SD
		MN#	x $10^3/\mu L$	0.0049	1SD	± 3 SD
		MN%	%	-1.4	1SD	± 3 SD
	Pleural	WBC-BF	x $10^3/\mu L$	0.0570	6.5	± 15%
		TC-BF	x $10^3/\mu L$	0.0404	4.2	± 15%
		RBC	x $10^6/\mu L$	0.0005	0.6	± 500 or ± 6%
		PMN#	x $10^3/\mu L$	0.0333	1SD	± 3 SD
		PMN%	%	1.3	1SD	± 3 SD
		MN#	x $10^3/\mu L$	0.0237	1SD	± 3 SD
		MN%	%	-1.3	1SD	± 3 SD
	Peritoneal	WBC-BF	x $10^3/\mu L$	0.0040	1.0	± 15%
		TC-BF	x $10^3/\mu L$	0.0042	1.0	± 15%
		RBC	x $10^6/\mu L$	-0.0005	-3.8	± 500 or ± 6%
		PMN#	x $10^3/\mu L$	0.0004	1SD	± 3 SD
		PMN%	%	3.59	1SD	± 3 SD
		MN#	x $10^3/\mu L$	-0.0023	1SD	± 3 SD
		MN%	%	-3.59	1SD	± 3 SD
	Synovial	WBC-BF	x $10^3/\mu L$	0.1128	5.3	± 15%
		TC-BF	x $10^3/\mu L$	0.1055	4.8	± 15%
		RBC	x $10^6/\mu L$	0.0002	0.1	± 500 or ± 6%

		PMN#	x 10^3/µL	0.0691	1SD	± 3 SD
		PMN%	%	0.4	1SD	± 3 SD
		MN#	x 10^3/µL	0.0350	1SD	± 3 SD
		MN%	%	-0.4	1SD	± 3 SD

b. *Precision/Reproducibility:*

Repeatability Testing

Residual body fluids that covered the whole measuring range for each of the body fluid types for the WBC-BF, RBC-BF and TC-BF parameters were assayed 10 consecutive times at the upper and lower range. The mean, standard deviation and coefficient variance were calculated. Specimen with clots or that had insufficient volume were rejected. The specimens were comprised of CSF (N=4), Synovial fluid (N=4), Pleural fluid (N=5) and Peritoneal fluid (N=4) specimens. Each body fluid specimen was run 10 consecutive times on the XT-4000i. Studies were performed in accordance with CLSI EP10-A3, *Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline 3rd Edition.* Acceptance criteria for each parameter are listed in the tables below and were found to be within manufacturer's specifications.

Repeatability WBC, RBC, TC

CSF	UNITS	MEAN	SD	CV%	LIMIT CV%	RANGE*
WBC-BF	x $10^3/\mu L$	0.0049	0.0007	15.1	≤30	0.0049-10.6662
	x $10^3/\mu L$	10.6662	0.2111	2.0	≤30	
RBC-BF**	x $10^6/\mu L$	0.0048	0.0004	8.8	≤40	0.0048-7.1082
	x $10^6/\mu L$	7.1082	0.0251	0.4	≤40	
TC-BF	x $10^3/\mu L$	0.0049	0.0007	15.1	≤30	0.0049-10.6724
	x $10^3/\mu L$	10.6724	0.2115	2.0	≤30	
PLEURAL						
WBC-BF	x $10^3/\mu L$	0.0507	0.0041	8.1	≤30	0.0507-10.8865
	x $10^3/\mu L$	10.8865	0.1557	1.4	≤30	
RBC-BF**	x $10^6/\mu L$	0.0068	0.0004	6.2	≤40	0.0068-4.5363
	x $10^6/\mu L$	4.5363	0.0189	0.4	≤40	
TC-BF	x $10^3/\mu L$	0.0507	0.0041	8.1	≤30	0.0507-6.2611
	x $10^3/\mu L$	6.2611	0.1101	1.8	≤30	
PERITONEAL						
WBC-BF	x $10^3/\mu L$	0.5559	0.0204	3.7	≤30	0.5559-11.9384
	x $10^3/\mu L$	11.9384	0.1774	1.5	≤30	
RBC-BF**	x $10^6/\mu L$	0.0134	0.0007	5.2	≤40	0.0134-5.7646
	x $10^6/\mu L$	5.7646	0.0205	0.4	≤40	
TC-BF	x $10^3/\mu L$	0.5571	0.0205	3.7	≤30	0.5571-12.07
	x $10^3/\mu L$	12.072	0.1762	1.5	≤30	
SYNOVIAL						
WBC-BF	x $10^3/\mu L$	0.2743	0.182	6.6	≤30	0.2743-10.9545
	x $10^3/\mu L$	10.9545	0.3467	3.2	≤30	
RBC-BF**	x $10^6/\mu L$	0.0050	0.0000	0.0	≤40	0.0050-7.3403
	x $10^6/\mu L$	7.3403	0.0438	0.6	≤40	
TC-BF	x $10^3/\mu L$	0.2756	0.0184	6.7	≤30	0.2756-8.3766
	x $10^3/\mu L$	8.3766	0.1725	2.1	≤30	

Repeatability (MN%, MN#, PMN%, PMN#)

CSF	UNITS	MEAN	SD	CV%	LIMIT CV%	RANGE*
MN#	x 10^3/µL	5.0415	0.0942	1.9	≤30	0.0021-5.0415
	x 10^3/µL	0.0021	0.0006	27.0	≤30	
MN%	%	47.29	0.40	0.8	≤30	43.33-47.29
	%	43.33	11.22	25.9	≤30	
PMN#	x 10^3/µL	5.6247	0.1306	2.3	≤30	0.0028-5.6247
	x 10^3/µL	0.0028	0.0008	28.2	≤30	
PMN%	%	52.74	0.37	0.7	≤30	52.74-56.67
	%	56.67	11.22	19.8	≤30	
PLEURAL						
MN#	x 10^3/µL	2.5882	0.0434	1.7	≤30	0.0137-2.5882
	x 10^3/µL	0.0137	0.0028	20.4	≤30	
MN%	%	41.43	0.57	1.4	≤30	27.30-41.43
	%	27.30	6.34	23.2	≤30	
PMN#	x 10^3/µL	3.6576	0.0821	2.2	≤30	0.0370-3.6576
	x 10^3/µL	0.0370	0.0056	15.1	≤30	
PMN%	%	58.57	0.57	1.0	≤30	58.57-72.70
	%	72.70	6.34	8.7	≤30	
PERITONEAL						
MN#	x 10^3/µL	4.6729	0.0703	1.5	≤30	0.2456-4.6729
	x 10^3/µL	0.2456	0.0139	5.7	≤30	
MN%	%	38.72	0.54	1.4	≤30	38.72-44.20
	%	44.20	1.72	3.9	≤30	
PMN#	x 10^3/µL	7.3957	0.1560	2.1	≤30	0.3103-7.3957
	x 10^3/µL	0.3103	0.0141	4.5	≤30	
PMN%	%	61.28	0.54	0.9	≤30	55.83-61.28
	%	55.83	1.76	3.1	≤30	
SYNOVIAL						
MN#	x 10^3/µL	4.7317	0.0926	2.0	≤30	0.1180-4.7317
	x 10^3/µL	0.1180	0.0073	6.2	≤30	
MN%	%	56.44	0.47	0.8	≤30	43.10-56.44
	%	43.10	2.75	6.4	≤30	
PMN#	x 10^3/µL	3.6514	0.1026	2.8	≤30	0.1563-3.6514
	x 10^3/µL	0.1563	0.0159	10.2	≤30	
PMN%	%	43.56	0.47	1.1	≤30	43.56-56.90

Reproducibility

Three (3) levels of low, medium and high range quality controls were assayed 10 consecutive times in the Body Fluid mode. The mean, standard deviation and coefficient variance was calculated. Studies were performed in accordance with CLSI EP10-A3, *Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline 3rd Edition.* All results met the acceptable limits of the Manufacturer's Calibration/Verification Specifications for precision as indicated in the table below.

Precision (Reproducibility) WBC-BF, RBC-BF, MN#/%, PMN#/%
Quality Control Low, Medium, High

Analyte	Sample	N	Mean	SD	CV%	Manufacturer Spec CV%	PASS/FAIL
WBC-BF	QC 1	10	2.9301	0.0510	1.7	≤3.0%	PASS
WBC-BF	QC 2	10	6.6443	0.1161	1.7	≤3.0%	PASS
WBC-BF	QC 3	10	17.0886	0.2866	1.7	≤3.0%	PASS
RBC-BF	QC 1	10	2.2536	0.0110	0.5	≤1.5%	PASS
RBC-BF	QC 2	10	4.3244	0.0072	0.2	≤1.5%	PASS
RBC-BF	QC 3	10	5.2748	0.0177	0.3	≤1.5%	PASS
MN#	QC 1	10	0.9241	0.0336	3.6	≤20.0%	PASS
MN#	QC 2	10	2.5049	0.1132	4.5	≤20.0%	PASS
MN#	QC 3	10	5.3420	0.1577	3.0	≤20.0%	PASS
MN%	QC 1	10	31.87	0.83	2.6	≤20.0%	PASS
MN%	QC 2	10	37.71	1.61	4.3	≤20.0%	PASS
MN%	QC 3	10	32.75	0.94	2.9	≤20.0%	PASS
PMN#	QC 1	10	1.9834	0.0494	2.5	≤8.0%	PASS
PMN#	QC 2	10	4.1394	0.1344	3.2	≤8.0%	PASS
PMN#	QC 3	10	11.5464	0.2306	2.0	≤8.0%	PASS
PMN%	QC 1	10	68.11	0.78	1.1	≤8.0%	PASS
PMN%	QC 2	10	62.29	1.61	2.6	≤8.0%	PASS
PMN%	QC 3	10	67.25	0.94	1.4	≤8.0%	PASS
TC-BF	QC 1	10	2.9336	0.0503	1.7	≤3.0%	PASS
TC-BF	QC 2	10	6.6582	0.1165	1.7	≤3.0%	PASS
TC-BF	QC 3	10	17.1101	0.2874	1.7	≤3.0%	PASS

c. Linearity:

Linearity testing was performed at two sites, using serial dilutions of body fluid samples made to represent the full range of linearity. The expected values were plotted against obtained results and both low and high values were calculated. Specimens that represented the high end of the reportable range and had sufficient volume were selected for testing. Specimens with clots or insufficient volume were rejected. For WBC-BF, RBC-BF, TC-BF, the following specimen types were included in the study: CSF (N=2), Synovial fluid (N=3), Pleural fluid (N=2)

and Peritoneal fluid (N=2). For MN and PMN parameters: CSF (N=2), Synovial fluid (N=2), Pleural fluid (N=2) and Peritoneal fluid (N=2). Each linearity dilution was assayed twice.
All results met manufacturer's specifications as described in the tables below and were within manufacturer's specifications for all parameters.

Linearity acceptance criteria

Linearity - Body Fluid Mode	Acceptance Criteria
WBC-BF	Within $\pm$ 0.01 x10^3/uL (0.001-0.050 x10^3/uL) Within $\pm$ 20% (0.050-10.000 x10^3/uL)
RBC-BF	Within $\pm$ 3% or $\pm$ 0.03 x10^6/uL (0.001-5.000 x10^6/uL)
TC-BF	Within $\pm$ 0.01 x10^3/uL (0.001-0.050 x10^3/uL) Within $\pm$ 20% (0.050-10.000 x10^3/uL)
MN#	Within $\pm$ 0.01 x10^3/uL (0.001-0.050 x10^3/uL) Within $\pm$ 20% (0.050-10.000 x10^3/uL)
PMN#	Within $\pm$ 0.01 x10^3/uL (0.001-0.050 x10^3/uL) Within $\pm$ 20% (0.050-10.000 x10^3/uL)

Linearity Results

CSF	**UNITS**	**r^2**	**r**	**Slope**	**Intercept**	**Range ***
WBC-BF	x 10^3/µL	1.000	1.000	0.988	-0.002	0.001-11.394
RBC-BF	x 10^6/µL	1.000	1.000	1.007	-0.001	0.001-6.852
TC-BF	x 10^3/µL	1.000	1.000	0.989	-0.003	0.001-11.556
MN#	x 10^3/µL	1.000	1.000	0.9887	0.0072	0.002-17.148
PMN#	x 10^3/µL	1.000	1.000	1.0092	-0.0063	0.000-11.373
Pleural						
WBC-BF	x 10^3/µL	1.000	1.000	1.002	0.000	0.001-10.416
RBC-BF	x 10^6/µL	1.000	1.000	1.000	0.000	0.001-4.510
TC-BF	x 10^3/µL	0.999	0.999	0.997	-0.024	0.001-10.414
MN#	x 10^3/µL	1.000	1.000	0.9818	0.0074	0.001-11.003
PMN#	x 10^3/µL	1.000	1.000	1.0018	-0.0034	0.000-8.487
Peritoneal						
WBC-BF	x 10^3/µL	1.000	1.000	1.007	-0.002	0.001-7.853
RBC-BF	x 10^6/µL	1.000	1.000	1.003	0.000	0.001-5.048
TC-BF	x 10^3/µL	1.000	1.000	1.007	-0.002	0.001-7.942
MN#	x 10^3/µL	1.000	1.000	0.9858	-0.0034	0.001-14.341
PMN#	x 10^3/µL	1.000	1.000	1.0098	-0.0046	0.000-8.772
Synovial						
WBC-BF	x 10^3/µL	0.9900	1.00	1.0082	0.0178	0.001-11.201
RBC-BF	x 10^6/µL	1.0000	1.00	0.9980	0.0006	0.002-6.226
TC-BF	x 10^3/µL	1.000	1.000	1.017	-0.008	0.001-8.308
MN#	x 10^3/µL	1.000	1.000	1.0170	-0.0110	0.002-9.343
PMN#	x 10^3/µL	1.000	1.000	0.9762	0.0046	0.001-11.448

d. Carryover:

Body fluid counts (WBC, RBC and TC) with High to Low carryover were measured at two sites. Three (3) body fluid samples with a high cell count were analyzed three consecutive times (H1, H2, H3) followed immediately by testing a sample with a low cell count consecutively three times (L1, L2, L3) for each body fluid type. Specimens that represented the high and low end of the reportable range and had sufficient volume were selected. Specimen with clots or had insufficient volume were rejected. Carryover studies were performed using the following specimen types: CSF (N=3), Synovial fluid (N=3), Pleural fluid (N=2) and Peritoneal fluid (N=1).

The studies indicate that the device met the manufacturer's acceptance criteria for each parameter as listed below.

WBC-BF: $\leq$0.3%, or 0.001 x10^3/uL
RBC-BF: $\leq$0.3%, or 0.003 x10^6/uL
TC-BF#: $\leq$0.3%, or 0.001 x10^3/uL

e. Interfering Substances:

The sponsor provided reference publications to support claims of interfering substances. Fat globules, crystals and high viscous synovial fluids may cause erroneous or misleading results. (Source: Kjeldsberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebrospinal, Seminal, Serous & Synovial Fluids. 3rd Ed. Chicago, IL: ASCP Press, 1993. Pages 266-270.)

2. Other Supportive Instrument Performance Data Not Covered Above:

Limit of Blank

The instrument diluent (Cellpack) was used as a blank and run 60 consecutive times in the body fluid analysis mode. Samples with target concentrations were run 60 consecutive times. Limits of Blank (LoB) and Limits of Detection (LoD) were determined using a protocol based on CLSI EP17-A. Specimens containing clots or insufficient volume were rejected. The LoB studies were performed with the following specimen types: CSF fluids (N=3), Synovial (N=3), Serous fluid (N=3). Sixty replicates were tested for each LoB and LoD at a single site.

The Mean, SD and LoB were calculated from the WBC-BF, TC-BF, RBC-BF, MN# and PMN# results. The LoB was calculated as: LoB = Mean + (1.645 x SD). Results for LoB studies are found in the table below.

Limit of Blank				
Diluent	**WBC-BFand TC-BF cells/µL**	**RBC-BFx10^6/µL**	**MN#**	**PMN#**
Mean	0.166	0	0.16	0
SD	0.38	0	0.38	0.2
LOB	0.78	0	0.6	0.5

Limit of Detection and Limit of Quantitation

The data in the Limit of Detection (LoD) table was obtained from running samples with the target WBC-BF and TC-BF values of 3, 5 and 10 cells/µL and target RBC-BF values of 2 and 5 cells x 10^3/µL, MN# target values of 1 and 5 cells/µL and PMN# target values of 3 and 5 cells/µL. Specimens were analyzed 60 consecutive times in the Body Fluid Mode. The Mean, SD and limit of detection were calculated from the WBC-BF, TC-BF, RBC-BF, MN# and PMN# results. The limit of detection was calculated as: LoD=LoB + (1.645 x SD). The estimate of bias and imprecision was determined using the mean and standard deviation results from the LoD study. The estimate of total error was less than the manufacturer's goal of 5 cells/µL for the WBC-BF, TC-BF, RBC-BF, MN# and PMN# and therefore the Limit of Quantitation (LoQ) is equal to the LoD.

Limit of Detection and Limit of Quantitation

	WBC-BF and TC-BF Target = 3cells/µL	**WBC-BF and TC-BF** Target = 5 cells/µL	**WBC-BF (or TC-BF)** Target =10 cells/µL	**RBC-BF** Target = 2 x10^3/µL	**RBC-BF** Target = 5 x10^3/µL	**MN#** Target = 1 cells/µL	**MN#** Target = 5 cells/µL	**PMN#** Target = 3 cells/µL	**PMN#** Target = 5 cells/µL
Mean	2.47	4.88	9.83	1.82	3.90	1.32	4.97	3.62	4.87
SD	1.23	1.52	1.74	0.39	0.40	1.03	1.38	1.35	1.44
LoD	2.80	3.28	3.64	0.64	0.66	2.30	2.86	2.83	2.83
LoQ*	2.80	3.28	3.64	0.64	0.66	2.30	2.86	2.83	2.83

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.