

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K061150

B. Purpose for Submission:

Added indication on the Sysmex® XT Series Automated Hematology Analyzer

C. Measurand:

White Blood Cell Count (WBC) and Red Blood Cell Count

D. Type of Test:

The XT-Series Body Fluid Application adds a quantitative, automated procedure for analyzing body fluids such as cerebrospinal fluid, serous fluid, and synovial fluid to the XT-Series, providing enumeration of the WBCs and RBCs.

E. Applicant:

Sysmex America, Inc.

F. Proprietary and Established Names:

Body Fluid Application for the XT-Series Automated Hematology Analyzer

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5220, Automated differential cell counter

2. Classification:

Class II

3. Product code:

GKZ

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

The Sysmex XT-Series Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for *in vitro* diagnostic use in clinical laboratories.

2. Indication(s) for use:

The XT-Series Body Fluid Application adds a quantitative, automated procedure for analyzing body fluids such as cerebrospinal fluid, serous fluid and synovial fluid to the XT-Series, providing enumeration of the WBCs and the RBCs.

3. Special conditions for use statement(s):

These matrices have been validated on the XT-Series: Cerebrospinal fluid, serous fluid (peritoneal, pleural, ascites, dialysate, pericardial, paracentesis, abdominal thoracentesis, trach aspiration, and bronchial fluid) and synovial fluid.

4. Special instrument requirements:

Sysmex Automated Hematology Analyzer, XT-Series.

I. Device Description:

The XT-Series Body Fluid Application adds a quantitative, automated procedure for analyzing body fluids such as cerebrospinal fluid, serous fluid and synovial fluid to the XT-Series, providing enumeration of the WBCs and the RBCs.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Sysmex XE-2100 Series Body Fluid Application

2. Predicate 510(k) number(s):

K040073

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	To provide a quantitative determination of blood cells in body fluids such as cerebrospinal fluid, serous fluid, and synovial fluid.	Same
Methodology	Cell count is performed on an automated hematology analyzer.	Same
Specimen Type	Body fluids such as cerebrospinal fluid, serous fluid, and synovial fluid.	same

Differences		
Item	Device	Predicate
Reagents	Cellpack, Sulfolyser Stromatolyser-FB Stromatolyser-4DL Stromatolyser-4DS Stromatolyser-NR Stromatolyser-IM Cellsheath Ret-Search II	Cellpack Sulfolyser Stromatolyser-FB Stromatolyser-4DL Stromatolyser-4DS Ret-Search II
Accuracy	Comparison to the XE-2100 Series Body Fluid Application demonstrated excellent correlation.	Performance was established in a previous 510(k) using a manual method.

K. Standard/Guidance Document Referenced (if applicable):

Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Cells; Final Guidance for Industry and FDA, December 4, 2001

L. Test Principle:

Fluorescent flow cytometry using lateral scattered light and lateral fluorescent light are used to determine the White Blood Cell count. The Direct Current (DC) detection method is used for the Red Blood Cell count.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

1. Within-run precision was determined by using samples that were run in the open mode ten times consecutively. Conclusion: The average CV% results for WBC samples $\geq 0.05 \times 10^3/\mu\text{L}$ and for RBC samples $\geq 0.01 \times 10^6/\mu\text{L}$ were acceptable.

2. Between-day precision using e-Check was monitored for the time period of the evaluation. Results were within acceptable ranges for e-Check as stated in the manufacturer's specifications.

b. Linearity/assay reportable range:

WBC and RBC linearity were evaluated by diluting body fluid samples with instrument diluent to obtain results at low levels of detection. R squared values for WBCs ranged from 0.9974 to 1.0. R squared values for RBCs ranged from 0.9655 to 0.9990. Conclusion: The WBC and RBC parameters were linear at low levels for body fluid specimens.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

N/A

d. Detection limit:

N/A

e. Analytical specificity:

N/A

f. Assay cut-off:

N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

Table 1: Accuracy of XT vs. XE White Blood Cell Counts

Fluid Type	N=	R	Slope	Intercept
CSF	47	1.00	1.0348	-0.0022
Serous*	150	1.00	0.9705	0.0625
Synovial	33	1.00	0.9703	0.1571
Body Fluids combined	228	1.00	0.9709	0.0644
Body Fluids $\geq 0.05 \times 10^3 / \mu\text{L}$	193	1.00	0.9706	0.0766

*Serous fluid included peritoneal, pleural, ascites, dialysate, pericardial, paracentesis, abdominal, thoracentesis, trach aspiration, and bronchial fluid samples.

Table 2 : Accuracy of XT vs XE Red Blood Cell Counts

Fluid Type	N=	R	Slope	Intercept
Body Fluids combined	209	1.00	1.0224	-0.0028
Body Fluids $\geq 0.01 \times 10^6 / \mu\text{L}$	89	1.00	1.0205	-0.0069

Table 3 : Accuracy of XT vs XE and Manual WBC and RBC Counts

Fluid Type	N=	R	Slope	Intercept
WBC Body Fluids Combined	97	1.00	0.9454	0.229
WBC $\geq 0.05 \times 10^3 / \mu\text{L}$ Body Fluids combined	65	1.00	0.9441	0.2972
RBC Body fluids	71	1.00	0.6632	0.007

- b. *Matrix comparison:* All three body fluid types (CSF, Serous, Synovial) provide strong positive correlations when comparison is made between the manual counts with the automated counts.

3. Clinical studies:

- a. *Clinical Sensitivity:*

N/A

- b. *Clinical specificity:*

N/A

- c. Other clinical supportive data (when a. and b. are not applicable):

Carryover: Carryover data was collected by analyzing a high sample three consecutive times then analyzing a low sample three times. Conclusion: Carryover was $\geq 1\%$ as stated in the manufacturer specification.

Table 4: WBC and RBC Carryover (%)

% Carryover	WBC	RBC	Manufacturer Specification
CSF	0.08	0.00	$\geq 1\%$
	0.00	0.00	$\geq 1\%$
	0.14	0.00	$\geq 1\%$
	0.00	0.00	$\geq 1\%$
Serous Fluid	0.12	0.00	$\geq 1\%$
	0.08	0.00	$\geq 1\%$
	0.16	0.00	$\geq 1\%$
Synovial Fluid	0.32	0.00	$\geq 1\%$
	0.12	0.00	$\geq 1\%$
	0.10	0.00	$\geq 1\%$
	0.27	0.00	$\geq 1\%$
	-0.21	0.00	$\geq 1\%$

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Due to the unavailability of obtaining normal body fluid samples, it is difficult for laboratories to establish expected values: therefore all laboratories will reference textbook values as their expected values as was the case with these study sites.

Table 5: Adult Expected Values for Body Fluids

Body Fluid Type	WBC	RBC
CSF	<5 mononuclear cells/ μ L	NA
Peritoneal fluid	<500/mL	NA
Pleural fluid	NA (WBCs have limited value)	NA
Synovial fluid	<200/ μ L	NA

SOURCE: Kjelksberg C. and Knight J. Body Fluids: Laboratory Examination of Cerebral, Seminal, Serous, & Synovial Fluids. 3rd ed. Chicago, IL: ASCP Press, 1993.

N. Proposed Labeling:

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

O. Conclusion:

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