

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

A. 510(k) Number: K081610

B. Purpose for Submission: Extension of Mean Cell Volume stability to 48 hours

C. Manufacturer and Instrument Name: Sysmex America, Inc., Sysmex® XS-1000iC Automated Hematology Analyzer

D. Type of Test or Tests Performed: Mean Cell Volume (MCV)

E. System Descriptions:

1. Device Description:

The Sysmex® XS-1000iC Analyzer is a quantitative, automated hematology analyzer for *in vitro* diagnostic use. The instrument analyzes and provides 21 parameters of a blood sample: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, MPV, RDW-SD, RDW-CV, NEUT%, NEUT#, LYMPH%, LYMPH#, MONO%, MONO#, EO%, EO#, BASO%, and BASO#.

The system is comprised of an analyzer and a reagent system. The reagent system consists of diluent, lyse, and stain. The analyzer provides two modes of blood sampling: whole blood and capillary. The XS-1000iC consists of three principle units: (1) Main Unit, which processes, and analyzes blood samples, (2) Auto Loader, which supplies samples to the Main Unit automatically, and (3) Information Processing Unit, which processes data generated from the Main Unit. The analyzer provides two options: CBC and CBC with Differential. Graphic printer and barcode reader are optional.

2. Principles of Operation:

The Sysmex® XS-1000iC Analyzer performs analysis of CBC and 5-part differential using the following methods:

- WBC and differential: flow cytometry method using a semiconductor laser
- RBC and platelets: RBC detector using the Hydro Dynamic Focusing method
- Hemoglobin: HGB detector based on the Sodium Lauryl Sulfate hemoglobin detection method

3. Modes of Operation: Manual Mode, Capillary Mode, and Sampler Mode.

4. Specimen Identification: Manual or by barcode reader.

5. Specimen Sampling and Handling:
 - a. Manual Mode and Capillary Mode: whole blood tubes and diluted blood are manually mixed prior to sampling.
 - b. Sampler Mode: whole blood tubes are mixed automatically.
6. Calibration: Manual and automatic calibration using fresh blood.
7. Quality Control: Specified commercial control blood and normal blood sample are used to monitor the performance of the analyzer. The following QC methods are used:
 - a. Control material: X-bar control and L-J control.
 - b. Normal blood samples: X-barM.
8. Software:

FDA has reviewed applicant's Hazard Analysis and Verification and Validation documentation for this line of product types:

Yes or No

F. 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)

G. Intended Use:

1. Indication(s) for Use: The Sysmex® XS-1000iC is an automated hematology analyzer for *in vitro* diagnostic use in clinical laboratories and reference laboratories. The XS-1000iC will extend MCV stability to 48 hours.
2. Special Conditions for Use Statement(s): N/A

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers: Sysmex® XE-2100DC, K051459

2. Comparison with Predicate Device:

Similarities		
Item	Device XS-1000iC	Predicate XE-2100DC
Intended Use	The Sysmex® XS-1000iC is an automated hematology analyzer for <i>in vitro</i> diagnostic use in clinical laboratories and reference laboratories. The XS-1000iC will extend MCV stability to 48 hours.	Same as XS-1000iC
Methodology	Sheath Flow DC Detection, Flow Cytometry Methods using a Semiconductor Laser and LSL-hemoglobin method	Same as XS-1000iC
Sample type	EDTA	Same as XS-1000iC
Software/ Hardware	A modification kit was installed for >48-hours sample analysis, which includes software and hardware changes and a modified reagent Cellsheath (C). This kit only impacts the RBC/PLT dilution step.	Same as XS-1000iC

Differences		
Item	Device XS-1000iC	Predicate XE-2100DC
Reagents	Diluent: CELLSHEATH (C) Lyse: STROMATOLYSER-4DL SULFOLYSER Stain: STROMATOLYSER-4DS	Diluent: CELLPACK CELLSHEATH (C) STROMATOLYSER-NR Lyse: STROMATOLYSER-FB STROMATOLYSER-4DL STROMATOLYSER-IM SULFOLYSER Stain: STROMATOLYSER-4DS STROMATOLYSER-NR

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

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy:* 255 normal and abnormal samples with various disease states and conditions were used to evaluate the performance of the XS-1000iC to the

predicate XE-2100DC, most specifically the MCV parameter. The MCV results are as follows:

Correlation Coefficient	Slope	Intercept
0.9527	1.024	-0.22

- b. *Precision/Reproducibility:* 5 blood samples were assayed 20 consecutive times for MCV precision. Manufacturer specification: $\leq 1.5\%$.

Sample	Mean	SD	CV
1	97.33	0.19	0.2
2	98.38	0.55	0.6
3	63.27	0.35	0.6
4	118.16	0.45	0.4
5	79.28	0.19	0.2

- c. *Linearity:* RBC linearity was evaluated on the XS-1000iC over the range of 0.300 to $7.910 \times 10^6 / \mu\text{L}$, using 6 levels of dilution of Range Check Linearity Kit. Replicate of three was measured at each level. The results were linear with the slope of 1.000, the intercept of 0.013, and within Allowable Systematic Error of $0.36 \times 10^6 / \mu\text{L}$.
- d. *Carryover:* Carryover was evaluated by assaying a sample with a high cell count three consecutive times, followed immediately by testing a low count sample consecutively three times. Zero carryover result was generated for RBC, HGB, HCT, and PLT.
- e. *Interfering Substances:* N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

- a. *Stability:* To evaluate the stability of the MCV parameter to 48 hours, 29 samples with normal and abnormal MCV were used. Each sample was split into two aliquots, one was stored at room temperature ($18^\circ\text{-}26^\circ\text{C}$) and the other was stored at low temperature (4°C). Each aliquot was analyzed at baseline (0 hrs), 24 hrs, and 48 hrs. Percent deviation from the baseline was used to determine the MCV stability. Data indicated that the MCV parameter was stable up to 48 hours for samples stored at room temperature and 4°C . Manufacturer specification: $\leq 8\%$ deviation.
- b. *Reference Intervals:* To verify the reference interval, 20 samples were analyzed and compared to the existing reference values, which were established on the XS-1000. Normal samples from this study fell within these established reference ranges. The manufacturer recommends that each

laboratory establishes or verifies its own expected reference intervals.

K. Proposed Labeling:

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

L. Conclusion:

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

