

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY**

**A. 510(k) Number:**

k081890

**B. Purpose for Submission:**

Addition of IG and RET-He parameters to the Sysmex<sup>®</sup> XT-Series, Automated Hematology Analyzer.

**C. Measurand:**

IG%/#: Immature Granulocyte Percent and Count

RET-He: Reticulocyte Hemoglobin

**D. Type of Test:**

IG: Metamyelocytes, Myelocytes, and Promyelocytes

RET-He: hemoglobin of reticulocytes

**E. Applicant:**

Sysmex America, Inc.

**F. Proprietary and Established Names:**

Sysmex<sup>®</sup> XT-Series IG Parameter

Sysmex<sup>®</sup> XT-Series RET-He Parameter

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.5220, Automated Differential Cell Counter

2. Classification:

II

3. Product code:

GKZ, Counter, differential cell

4. Panel:

Hematology, 81

**H. Intended Use:**

1. Intended use(s):

The IG parameter on the Sysmex<sup>®</sup> XT-Series, Automated Hematology Analyzer, is intended for in vitro diagnostic use to classify and count immature granulocytes cells in EDTA anti-coagulated blood. The RET-He parameter on the Sysmex<sup>®</sup> XT-Series, Automated Hematology Analyzer, determines the hemoglobin of reticulocytes for in vitro diagnostic use in EDTA anti-coagulated blood.

- IG%/#: Immature Granulocyte Percent and Count
- RET-He: Reticulocyte Hemoglobin

2. Indication(s) for use:

Same as the Intended Use

3. Special conditions for use statement(s):

For use with EDTA anti-coagulated blood

4. Special instrument requirements:

For use only on Sysmex<sup>®</sup> XT analyzers with:

- IG%/#: Sysmex<sup>®</sup> XT-Pro and IG Master Software
- RET-He: Sysmex<sup>®</sup> XT-Pro and RET Master Software

**I. Device Description:**

The XT-Series is an automated hematology analyzer using Hydrodynamic Focusing, flow cytometry method, and SLS-hemoglobin method for analysis of IG and RET-He in EDTA anti-coagulated blood samples. The IG parameter is measured in the DIFF channel, cells are detected by a combination of side scattered, forward scatter, and fluorescent intensity. Abnormal and immature cells are clustered and indistinguishable in the DIFF scattergram. The RET-He parameter is measured in the reticulocyte channel; cells are stained with polymethine dye which stains RNA differentiating reticulocytes from mature RBCs. The reticulocyte parameters are derived from the reticulocyte histogram, which is generated by the forward light signals.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
 Sysmex<sup>®</sup> XE-2100, IG parameter  
 Sysmex<sup>®</sup> XE-2100, RET-He parameter
2. Predicate K number(s):  
 k032039  
 k050589
3. Comparison with predicate:

<b>Similarities</b>		
Item	Device: Sysmex <sup>®</sup> XT-Series	Predicate: Sysmex <sup>®</sup> XE-2100
Intended Use	The IG parameter is intended for in vitro diagnostic use to classify and count immature granulocytes cells, the RET-He parameter determines the hemoglobin of reticulocytes.	Same
Methodology	IG: measured in the DIFF channel using the combination of side scatter, forward scatter, and fluorescent intensity of nucleated cells. RET-He: reticulocyte parameters are derived using the reticulocyte measurement channel and a propriety Sysmex calculation equation.	Same
Specimen Type	EDTA anti-coagulated blood	Same

<b>Differences</b>		
Item	Device	Predicate
Software	XT-Pro & IG Master Software XT-Pro & RET Master Software	XE-Pro & IG Master Software XE-Pro & RET Master Software

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

None provided

**L. Test Principle:**

IG parameter: When blood is diluted and stained with Stomatolyzer-4DL, mature leukocytes and red blood cells are selectively lysed, leaving immature granulocytes intact due to its lower phospholipid content. In the optical detector block, the sample is analyzed via flow cytometry method utilizing a semiconductor laser.

RET-He parameter: When blood is stained with polymethine dye in the reticulocyte channel, the sample is analyzed by automated fluorescent flow cytometry method. The analyzer measures the mean value of the forward light scatter histogram of mature red blood cells and reticulocytes.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Quality control and residual samples were used. E-Check Quality Control materials, 3 levels, were assayed for 20 days. Five residual samples were assayed 10 consecutive times. Results met manufacturer specification and testing criteria as follows:

Parameter	Specification	Testing Criteria
IG%	CV% ≤25%, or within ±1.5 IG%	IG% ≥ 2%, WBC ≥ 4.00 x 10 <sup>3</sup> /μL
IG#	CV% ≤25%, or within ±0.12 x 10 <sup>3</sup> /μL	IG#: 0.1 x 10 <sup>3</sup> /μL
RET-He	CV% ≤5%	RET#: ≥ 0.020 x 10 <sup>6</sup> /μL

b. *Linearity/assay reportable range*

Not applicable

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

Stability: Samples should be stored at room temperature (18-26°C) and refrigerated temperature (2-8°C). The variation from 0 hour after the blood collection to 24 hours was calculated and met manufacturer specification.

- 30 normal samples were used in the IG stability study. The variation IG from was within ± 2 IG%
- 30 samples with RET-He ≥ 0.010 x 10<sup>6</sup> /μL were used in the RET-He stability study. The variation for RET-He was within ± 8%.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

272 samples were collected and analyzed at two sites. The study included abnormal samples with a variety of disease states such as anemia, iron deficiency, thalassemia, immature granulocytes, blast forms, left shift, atypical/abnormal lymphocytes, high WBC counts, lipemia, NRBCs, etc. Results met manufacturer specification, r ≥0.90, as follows:

Parameter	Correlation Coefficient	Slope	Intercept
IG #	0.9846	0.947	-0.0103
IG %	0.9833	1.024	-0.13822
RET-He	0.9277	1.049	1.43

- b. *Matrix comparison:*  
Not applicable.
3. Clinical studies:
- a. *Clinical Sensitivity:*  
Not applicable.
- b. *Clinical specificity:*  
Not applicable.
- c. Other clinical supportive data (when a. and b. are not applicable):  
Not applicable.
4. Clinical cut-off:  
Not applicable
5. Expected values/Reference range:  
40 specimens were tested and compared to verify the existing reference intervals established for the Sysmex XE-2100. Sysmex recommends that each laboratory establish its own expected reference intervals based upon the laboratory's patient population and use NCLSI C28-A2 for guidelines.

	IG%	IG#	RET-He
Mean	0.2	0.016	34.265
SD	0.159	0.0139	2.2
Range	0-0.518	0-0.0438	29.9-38.7

**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.