

Reference Material Producer

# Accreditation Certificate

Accreditation No. RMP00030



**JAB**

***Laboratory of Assay Value Assignment, Ono Factory,  
Sysmex International Reagents Co., Ltd.***

***17, Takumidai, Ono City, Hyogo, JAPAN***

meets the following criteria. On the basis of this, Japan Accreditation Board (JAB) grants accreditation to the said reference material producer.

Applicable accreditation criteria	: JIS Q 17034:2018 (ISO 17034:2016)
Scope of accreditation	: As described in the appendix.
Premises covered by accreditation	: As described in the appendix.
Expiry date of accreditation	: March 31, 2022

Revised (1)  
Initial accreditation

June 21, 2019  
March 26, 2018

Y. Iizuka, President

## Japan Accreditation Board



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Scope of accreditation :

B Biological and clinical properties

B4 Hematology and Cytology

B4.1 Complete Blood Counts

Name of Reference material: XN CAL (WBC, RBC, PLT, HGB, HCT) and XN CAL PF (PLT-F)

Test method: Company Quality Control Standard (HIB1601)

Range of property values:

Erythrocyte count (RBC)	(3.800 ~ 4.900) $10^{12}/L$
Leucocyte count (WBC)	(5.800 ~ 10.200) $10^9/L$
Platelet count (PLT)	(185.00 ~ 275.00) $10^9/L$
Platelet count (PLT-F)	(160.00 ~ 280.00) $10^9/L$
Hemoglobin concentration (HGB)	(100.0 ~ 155.0) g/L
Hematocrit level (HCT)	(30.00 ~ 45.00) %

The relative expanded uncertainties of property values:

Item	Relative expanded uncertainty *
Erythrocyte count (RBC)	1.6 %
Erythrocyte count (RBC-O)	2.7 %
Leucocyte count (WBC-N)	3.1 %
Leucocyte count (WBC-D)	3.1 %
Leucocyte count (WBC-P)	3.7 %
Hemoglobin concentration (HGB)	1.9 %
Hematocrit level (HCT)	2.3 %
Platelet count (PLT)	4.7 %
Platelet count (PLT-O)	6.1 %
Platelet count (PLT-F)	4.5 %

\*: Relative expanded uncertainty is calculated with coverage factor of  $k=2$ .

**Japan Accreditation Board**