

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 (2)
Initial accreditation

August 12, 2020
March 26, 2018

Y. Iizuka, President

Japan Accreditation Board

Accreditation Certificate
Appendix

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

Name of reference material producer	Laboratory of Assay Value Assignment, Ono Factory, Sysmex International Reagents Co., Ltd.																																				
Address	Zip	675-1322	Address 17, Takumidai, Ono City, Hyogo, JAPAN																																		
<ul style="list-style-type: none"> • Applied Scope of Accreditation Code of Field Category Class (1) Class (2) • Type of reference Material • Name of reference material • Test method • Range of property values • The expanded uncertainties of property values 	<p>Code Field: B4.1 Category: B Biological and clinical properties Class (1): B4 Hematology and Cytology Class (2): B4.1 Complete Blood Counts</p> <p>Name of Reference material: XN CAL (WBC, RBC, PLT, HGB, HCT) and XN CAL PF (PLT-F)</p> <p>Test method: Company Quality Control Standard (HIB1601)</p> <p>Range of property values:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td>Erythrocyte count (RBC)</td> <td style="text-align: right;">(3.800 ~ 4.900) 10¹²/L</td> </tr> <tr> <td>Leucocyte count (WBC)</td> <td style="text-align: right;">(5.800 ~ 10.200) 10⁹/L</td> </tr> <tr> <td>Platelet count (PLT)</td> <td style="text-align: right;">(185.00 ~ 275.00) 10⁹/L</td> </tr> <tr> <td>Platelet count (PLT-F)</td> <td style="text-align: right;">(160.00 ~ 280.00) 10⁹/L</td> </tr> <tr> <td>Hemoglobin concentration (HGB)</td> <td style="text-align: right;">(100.0 ~ 155.0) g/L</td> </tr> <tr> <td>Hematocrit level (HCT)</td> <td style="text-align: right;">(30.00 ~ 45.00) %</td> </tr> </table> <p>The relative expanded uncertainties of property values:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Item</th> <th style="text-align: right;">Relative expanded uncertainty *</th> </tr> </thead> <tbody> <tr> <td>Erythrocyte count (RBC)</td> <td style="text-align: right;">1.6 %</td> </tr> <tr> <td>Erythrocyte count (RBC-O)</td> <td style="text-align: right;">2.7 %</td> </tr> <tr> <td>Leucocyte count (WBC-N)</td> <td style="text-align: right;">3.1 %</td> </tr> <tr> <td>Leucocyte count (WBC-D)</td> <td style="text-align: right;">3.1 %</td> </tr> <tr> <td>Leucocyte count (WBC-P)</td> <td style="text-align: right;">3.7 %</td> </tr> <tr> <td>Hemoglobin concentration (HGB)</td> <td style="text-align: right;">1.9 %</td> </tr> <tr> <td>Hematocrit level (HCT)</td> <td style="text-align: right;">2.3 %</td> </tr> <tr> <td>Platelet count (PLT)</td> <td style="text-align: right;">4.7 %</td> </tr> <tr> <td>Platelet count (PLT-O)</td> <td style="text-align: right;">6.1 %</td> </tr> <tr> <td>Platelet count (PLT-F)</td> <td style="text-align: right;">4.5 %</td> </tr> </tbody> </table>			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) %	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 %
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*: Relative expanded uncertainty is calculated with coverage factor of $k=2$.

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