

# Certificate of Analysis

Product: <b>Essential II Control</b>	Cat.No. <b>213287</b>	Lot No.: <b>QCS025004</b>	Expiration date: <b>2025-03-15</b>
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Origin: human erythrocytes from blood group A and B  
 Manufacturing Date: 27 JAN 2025  
 Preservative: Neomycin & Chloramphenicol  
 Storage: 2-8 °C  
 Manufacturing size: 2 x 2 x 6 ml

Criterion	Method	Specification	Results
<b>Tube QCS1, lot QCS125004</b>			
Specificity	Blood group testing by DG Gel	Blood group A ccddee, K positive	Blood group A ccddee, K positive
	Blood group testing by tube technique	Blood group A ccddee, K positive	Blood group A ccddee, K positive
	Reverse-Typing by DG Gel	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative
	Reverse-Typing by tube technique	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative
	Direct Antiglobulin Test by DG Gel at release	negative	negative
	Direct Antiglobulin Test by tube technique at release	negative	negative
D Antibody screening	IAT test by DG Gel IgG	Ror cells: minimum weak positive; R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive; R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive; rr cells: negative	Ror cells: minimum weak positive; R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive; R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive; rr cells: negative
	IAT test by tube technique	Ror cells: minimum weak positive; R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive; R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive; rr cells: negative	Ror cells: minimum weak positive; R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive; R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive; rr cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	13.3 %
Hemolysis at release	Optical Density at 540nm	Absorbance ≤ 1.0 AU	Absorbance 0.010 AU

<b>Tube QCS2, lot QCS225004</b>			
Specificity	Blood group testing by DG Gel	Blood group B CcD.Ee, K negative, Fy <sup>a</sup> negative	Blood group B CcD.Ee, K negative, Fy <sup>a</sup> negative
	Blood group testing by tube technique	Blood group B CcD.Ee, K negative	Blood group B CcD.Ee, K negative
	Reverse-Typing by DG Gel	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative
	Reverse-Typing by tube technique	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative
	Direct Antiglobulin Test by DG Gel at release	negative	negative
	Direct Antiglobulin Test by tube technique at release	negative	negative
Fy <sup>a</sup> Antibody screening	IAT test by DG Gel with Screen-Cyte	Screening cells Fy <sup>a</sup> positive : positive Screening cells Fy <sup>a</sup> negative: negative	Screening cells Fy <sup>a</sup> positive : positive Screening cells Fy <sup>a</sup> negative: negative
	IAT test by tube technique with Screen-Cyte cells	Screening cells Fy <sup>a</sup> positive : positive Screening cells Fy <sup>a</sup> negative: negative	Screening cells Fy <sup>a</sup> positive : positive Screening cells Fy <sup>a</sup> negative: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	13.6 %
Hemolysis after filling	Optical Density at 540nm	Absorbance ≤ 1.0 AU	Absorbance 0.016 AU

**The product passed the internal Quality Control procedure.**

**All human source material used in the manufacture of this product were tested and found negative for HBsAg and antibodies to HCV, HIV-1/ HIV-2.**

Date: 29 January 2025



Sascha Feuerhahn  
Technical Director

Medion Grifols Diagnostics AG in Düringen, Switzerland, is certified according to EN ISO 13485.