GRIFOLS

Certificate of Analysis

Product:	Cat.No.	Lot No.:	Expiration date:
Essential II Control	**213287**	**QCS022011**	**2022-05-14**

Origin: human erythrocytes from blood group A and B
Manufacturing Date: 28 MAR 2022
Preservative: Neomycin & Chloramphenicol
Storage: 2-8 °C
Manufacturing size: 2 x 2 x 6 ml

Criterion	Method	Specification	Results
Tube QCS1, lot QCS122011			
Specificity	Blood group testing by DG Gel	Blood group A ccddee, K positive	Blood group A ccddee, K positive
	Blood group testing by MDmulticard (Lateral Flow)	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_1 cells: negative A_2 cells: negative B cells: positive O cells: negative	A_1 cells: negative A_2 cells: negative B cells: positive O cells: negative
	Reverse-Typing by tube technique	A_1 cells: negative A_2 cells: negative B cells: positive O cells: negative	A_1 cells: negative A_2 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_1R_1 cells: minimum weak positive; R_2R_2 cells: minimum weak positive; rr cells: negative	Ror cells: minimum weak positive; R_1R_1 cells: minimum weak positive; R_2R_2 cells: minimum weak positive; rr cells: negative
	IAT test by tube technique	Ror cells: minimum weak positive; R_1R_1 cells: minimum weak positive; R_2R_2 cells: minimum weak positive; rr cells: negative	Ror cells: minimum weak positive; R_1R_1 cells: minimum weak positive; R_2R_2 cells: minimum weak positive; rr cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	13.2 %
Hemolysis at release	Photometry at 540nm	≤ 30.0 mg/dl of Hemoglobin	2.19 mg/dl of Hemoglobin

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Tube QCS2, lot QCS222011			
Specificity	Blood group testing by DG Gel	Blood group B CcD.Ee, K negative, Fy^a negative	Blood group B CcD.Ee, K negative, Fy^a negative
	Blood group testing by MDmulticard (Lateral Flow)	Blood group B CcD.Ee, K negative	Blood group B CcD.Ee, K 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_1 cells: positive A_2 cells: positive B cells: negative O cells: negative	A_1 cells: positive A_2 cells: positive B cells: negative O cells: negative
	Reverse-Typing by tube technique	A_1 cells: positive A_2 cells: positive B cells: negative O cells: negative	A_1 cells: positive A_2 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^a Antibody screening	IAT test by DG Gel with Screen-Cyte	Screening cells Fy^a positive : positive Screening cells Fy^a negative: negative	Screening cells Fy^a positive : positive Screening cells Fy^a negative: negative
	IAT test by tube technique with Screen-Cyte cells	Screening cells Fy^a positive : positive Screening cells Fy^a negative: negative	Screening cells Fy^a positive : positive Screening cells Fy^a negative: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	13.2 %
Hemolysis after filling	Photometry at 540nm	≤ 30 mg/dl of Hemoglobin	4.38 mg/dl of Hemoglobin

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: 30 March 2022



Sascha Feuerhahn
Technical Director

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