

Certificate of Analysis

Product: Extended IV Control	Cat.No. 213286	Lot No.: QCX021017	Expiration date: 2021-10-02
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Origin: human erythrocytes from blood group A₂B, A, B and O

Manufacturing Date: 16 AUG 2021

Preservative: Neomycin & Chloramphenicol

Storage: 2-8 °C

Manufacturing size: 4 x 6 ml

Criterion	Method	Specification	Results
Tube QCX1, lot QCX121017			
Specificity	Blood group testing by DG Gel	Blood group A ₂ B CcD.Ee, K positive	Blood group A ₂ B CcD.Ee, K positive
	Blood group testing by MDmulticard (Lateral Flow)	Blood group AB CcD.Ee, K positive	Blood group AB CcD.Ee, K positive
	Blood group testing by tube technique	Blood group AB CcD.Ee, K positive	Blood group AB CcD.Ee, K positive
	Reverse-Typing by DG Gel	A ₁ cells: negative A ₂ cells: negative B cells: negative O cells: negative	A ₁ cells: negative A ₂ cells: negative B cells: negative O cells: negative
	Reverse-Typing by tube technique	A ₁ cells: negative A ₂ cells: negative B cells: negative O cells: negative	A ₁ cells: negative A ₂ cells: negative 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
Antibody screening	IAT Test by DG Gel with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
	IAT test by tube technique with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	13.5 %
Hemolysis at release	Photometry at 540nm	≤ 30.0 mg/dl of Hemoglobin	2.19 mg/dl of Hemoglobin

Tube QCX2, lot QCX221017			
Specificity	Blood group testing by DG Gel	Blood group A CC ^w D. ee, Fy ^a negative	Blood group A CC ^w D. ee, Fy ^a negative
	Blood group testing by MDmulticard (Lateral Flow)	Blood group A CC ^w D. ee	Blood group A CC ^w D. ee
	Blood group testing by tube technique	Blood group A CC ^w D. ee, Fy ^a negative	Blood group A CC ^w D. ee, Fy ^a negative
	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
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 %	13.0 %
Hemolysis after filling	Photometry at 540nm	≤ 30 mg/dl of Hemoglobin	1.46 mg/dl of Hemoglobin
Tube QCX3, lot QCX321017			
Specificity	Blood group testing by DG Gel	Blood group B ccD. EE	Blood group B ccD. EE
	Blood group testing by MDmulticard (Lateral Flow)	Blood group B ccD. EE	Blood group B ccD. EE
	Blood group testing by tube technique	Blood group B ccD. EE	Blood group B ccD. EE
	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
Antibody screening	IAT Test by DG Gel with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
	IAT test by tube technique with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	14.6 %
Hemolysis after filling	Photometry at 540nm	≤ 30 mg/dl of Hemoglobin	2.19 mg/dl of Hemoglobin

Tube QCX4, lot QCX421017			
Specificity	Blood group testing by DG Gel	Blood group O ccddee, K negative	Blood group O ccddee, K negative
	Blood group testing by MDmulticard (Lateral Flow)	Blood group O ccddee, K negative	Blood group O ccddee, K negative
	Blood group testing by tube technique	Blood group O ccddee, K negative	Blood group O ccddee, K negative
	Reverse-Typing by DG Gel	A ₁ cells: positive A ₂ cells: positive B cells: positive O cells: negative	A ₁ cells: positive A ₂ cells: positive B cells: positive O cells: negative
	Reverse-Typing by tube technique	A ₁ cells: positive A ₂ cells: positive B cells: positive O cells: negative	A ₁ cells: positive A ₂ cells: positive 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 ₁ R ₁ cells: minimum weak positive R ₂ R ₂ cells: minimum weak positive rr cells: negative	Ror cells: minimum weak positive R ₁ R ₁ cells: minimum weak positive R ₂ R ₂ cells: minimum weak positive rr cells: negative
	IAT test by tube technique	Ror cells: minimum weak positive R ₁ R ₁ cells: minimum weak positive R ₂ R ₂ cells: minimum weak positive rr cells: negative	Ror cells: minimum weak positive R ₁ R ₁ cells: minimum weak positive R ₂ R ₂ cells: minimum weak positive rr cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	13.0 %
Hemolysis after filling	Photometry at 540nm	≤ 30 mg/dl of Hemoglobin	2.19 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: 20 August 2021



Sascha Feuerhahn
Technical Director

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