GRIFOLS

CERTIFICATE OF ANALYSIS

PRODUCT	CODE	LOT	EXP.DATE
Extended IV Control	**213286**	**QCX025016**	**2025-08-30**

Origin: Human erythrocytes of blood group A_2B, A, B and O
Preservative: Neomycin & Chloramphenicol
Storage: 2-8 ºC
Manufacturing size: 4 x 6 ml

TEST	METHOD	RESULT	SPECIFICATIONS
Tube QCX1			
Specificity	Blood group testing by DG Gel and Tube Technique	**Correct**	Blood group A_2B CcD.Ee, K positive
	Reverse-Typing by DG Gel and Tube Technique	**Correct**	A_1 cells: Negative A_2 cells: Negative B cells: Negative O cells: Negative
Antibody screening	IAT Test by DG Gel and Tube Technique	**Correct**	Screening cells: Negative
Tube QCX2			
Specificity	Blood group testing by DG Gel and Tube Technique	**Correct**	Blood group A $CC^wD.ee$, Fy^a negative
	Reverse-Typing by DG Gel and Tube Technique	**Correct**	A_1 cells: Negative A_2 cells: Negative B cells: Positive O cells: Negative
Fy^a Antibody screening	IAT Test by DG Gel and Tube Technique	**Correct**	Screening cells Fy^a positive: Positive, Screening cells Fy^a negative: Negative

This document has been electronically issued.

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Tube QCX3			
Specificity	Blood group testing by DG Gel and Tube Technique	**Correct**	Blood group B ccD.EE
	Reverse-Typing by DG Gel and Tube Technique	**Correct**	A_1 cells: Positive A_2 cells: Positive B cells: Negative O cells: Negative
Antibody screening	IAT Test by DG Gel and Tube Technique	**Correct**	Screening cells: Negative
Tube QCX4			
Specificity	Blood group testing by DG Gel and Tube Technique	**Correct**	Blood group O ccddee, K negative
	Reverse-Typing by DG Gel and Tube Technique	**Correct**	A_1 cells: Positive A_2 cells: Positive B cells: Positive O cells: Negative
D Antibody screening	IAT Test by DG Gel and Tube Technique	**Correct**	R_0r cells: Minimum weak positive R_1R_1 cells: Minimum weak positive R_2R_2 cells: Minimum weak positive rr cells: Negative
Direct Antiglobulin Test	Direct Antiglobulin Test by DG Gel and Tube Technique	**Correct**	Tube QCX1 to QCX4: Negative
Concentration of suspension	Determination of Hematocrit	**Correct**	Tube QCX1 to QCX4: 15.0 ± 2.0 %
Hemolysis at Release	Absorbance at 540nm	**Correct**	Tube QCX1 to QCX4: ≤ 1.0
Virus testing	Each donor unit used in the preparation of this product has been found nonreactive for HBsAG, anti-HIV-1+2 and anti-HCV.		

The product passed the internal Quality Control procedure.

Sascha Feuerhahn
Technical Director

Date of issue: 17/JUL/2025

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

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EN

Certificate of Analysis / Product / Code / Lot / Exp.Date / Origin / Human erythrocytes of blood group A_2B, A, B and O / and / Preservative / Neomycin & Chloramphenicol / Storage / Manufacturing size / Test / Method / Result / Specifications / Tube / Specificity / Blood group testing by DG Gel and Tube Technique / Reverse-Typing by DG Gel and Tube Technique / Correct / Blood group / Positive / cells / Negative / Antibody screening / IAT Test by DG Gel and Tube Technique / Minimum weak positive / Screening cells / Direct Antiglobulin Test by DG Gel and Tube Technique / to / Concentration of suspension / Determination of Hematocrit / Hemolysis at release / Absorbance at 540nm / Virus testing / Each donor unit used in the preparation of this product has been found nonreactive for HBsAG, anti-HIV-1+2 and anti-HCV / The product passed the internal Quality Control procedure / Technical Director / Date of issue / Medion Grifols Diagnostics AG in Düdingen, Switzerland, is certified according to EN ISO 13485 / This document has been electronically issued / Page / Telephone / Telefax

ES

Certificado de análisis / Producto / Código / Lote / Fecha de caducidad / Origen / Eritrocitos humanos del grupo sanguíneo A_2B, A, B y O / Conservante / Neomicina y cloranfenicol / Almacenamiento / Formato de fabricación / Prueba / Método / Resultado / Especificaciones / Tubo / Especificidad / Pruebas de grupo sanguíneo mediante la técnica DG Gel y técnica en tubo / Tipado inverso mediante la técnica DG Gel y técnica en tubo / Correcto / Grupo sanguíneo / Positivo / células / Negativo / Escrutinio de anticuerpos / Prueba IAT mediante la técnica DG Gel y técnica en tubo / mínimo positivo débil / Células de escrutinio / Prueba antiglobulina directa mediante la técnica DG Gel y técnica en tubo / a / Concentración de la suspensión / Determinación del hematocrito / Hemólisis en el momento de la liberación / Absorbancia a 540 nm / Pruebas de virus / Se ha comprobado que cada unidad donante utilizada en la preparación de este producto ha resultado no reactiva para HBsAG, anti-VIH-1+2 y anti-VHC / El producto pasó los controles de calidad internos / Director Técnico / Fecha de emisión / Medion Grifols Diagnostics AG, en Düdingen, Suiza, cuenta con la certificación EN ISO 13485 / Este documento ha sido emitido electrónicamente / Página / Teléfono / Telefax

PT

Certificado de análise / Produto / Código / Lote / Data de validade / Origem / Eritrócitos humanos do grupo sanguíneo A_2B, A, B e O / Conservante / Neomicina & Cloranfenicol / Armazenamento / Tamanho da fabricação / Teste / Método / Resultado / Especificações / Tubo / Especificidade / Teste de determinação de grupo sanguíneo por DG Gel e técnica de tubo / Técnica de Reverse Typing por DG Gel e técnica tubo / Correto / Grupo sanguíneo / Positivo / células / Negativo / D Triagem de anticorpos / Teste IAT por DG Gel IgG e tubo / mínimo fraco positivo / Células de triagem / Teste direto de antiglobulina pela técnica de gel e tubo DG / Concentração de suspensão / Determinação de hematócrito / Hemólise na liberação / Absorvância em 540nm / Teste de vírus / Cada unidade doadora utilizada na preparação deste produto foi considerada não reativa para HBsAG, anti-HIV-1+2 e anti-HCV / O produto passou pelo procedimento interno de controle de qualidade / Diretor Técnico / Data de emissão / A Medion Grifols Diagnostics AG em Düdingen, Suíça, é certificada de acordo com a EN ISO 13485 / Este documento foi emitido eletronicamente / Página / Telefone / Fax

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