



PRODUCT TECHNICAL DATA SHEET

LATEX CONTROLS

Rev. 3.1 – 2023-02-28

GENERAL INFORMATION

Name LATEX CONTROLS **REF** SI 305.300-A **Container** 13x75mm (Greiner) tube



Intended use Latex Controls are intended for in-vitro diagnostic professional use only in the quantitative control of the calibration status of ALIFAX ESR line analyzers. The control is performed on three samples with different known turbidity values analyzed for transmittance related to ESR values.

Cont.

Components

The kit is made up of 15 test-tubes containing 3 ml of synthetic latex solution:

5 x Latex Control level 2 ("LATEX Test tube L 2")

5 x Latex Control level 3 ("LATEX Test tube L 3")

5 x Latex Control level 4 ("LATEX Test tube L 4")

Principles of the examination method

The kit aims to the control of the calibration stability of ALIFAX ESR line analyzers and is based on the use of three samples with known turbidity values, on which the analyzer performs transmittance measurements related to ESR values.

TEST1 analyzer: Ref SI 195.210/THL; SI 195.220/BCL; SI 195.230/SDL; SI 195.240/YDL; SI 195.250/MDL; SI 195.260/XDL

TEST1 2.0 analyzer: Ref SI 195.210/THL

MicroTEST1 analyzer: Ref SI 199.101-LC

ROLLER 20 analyzer: Ref SI R20-LC; SI R20-PN; SI R20-MC

ROLLER 10 analyzer: Ref SI R10; SI R10-PN

JO-PLUS analyzer: Ref SI 804.100



Contains sufficient for 30 tests

The exceeding amount is automatically discarded by the analyzer

Classification IVD CE	Class A-Not Sterile
Regulation (EU) 2017/746	
BD/RDM Registration ID (IVDD 98/79/CE)	1301844
BD/RDM Registration ID (IVDR 746/2017)	2289213
CND Classification	W0103010599 - CONTROLLI EMATOLOGIA - ALTRI
GMDN Code	55972 Erythrocyte sedimentation rate (ESR) IVD, control
GIVD Code (previously known as EDMA)	13.01.50.90 - Other Haematology Controls
UDI-DI (GTIN13)	8056040141229

Waste disposal should be in accordance with the applicable national legislation. Having regard to the type of product, it is suggested to treat it as biological waste

SHELF LIFE

From the production date	6 months if kept properly. NOTE: in case of use of expired tubes, their contents are automatically discarded by the analyzer
From the first piercing	6 weeks if stored between 4 - 8 °C

TRANSPORT CONDITIONS

Temperature	Not controlled as long as it does not go below 0 °C.
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ESR_PTDS_SI305300_LATEXCONT30_3-1_EN

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STORAGE CONDITIONS

Temperature	4 - 25°C
Warnings and precautions	Keep protected from light. DO NOT FREEZE. Freezing may cause irreversible aggregation. Humidity from 5% to 95% without condensed water.

WORKING SPECIFICATION

Compatibility	ALIFAX line ESR analyzers upgraded with software for latex management (version 6.01A or upper for TEST1, MicroTEST1, R20-LC; version 1.0.0 or upper for TEST1 2.0 , version 1.00A or upper for R10, R20-PN, version 4.01A or upper for R20-MC, version 4.03A or upper for R10-PN and 1.00.08 for JO-PLUS)
Test results	Three ESR values
Measure Unit	mm/h

REAGENT COMPOSITION

Composition	Aqueous dispersion of a polymer based on styrene and butadiene at 3 different concentrations (L2, L3, L4)
Solid Content	1,0 - 8,5%

PRIMARY PACKAGING

Type	Greiner Tube
Material	Polyethylene terephthalate (PET)
Dimension (Ø x H)	13 (diameter) x 75 (Height) mm
Volume	4 ml
Colour	Transparent
Type	Cap
Material	Polyethylene (PE) with Polypropylene (PP) ring
Colour	White with Yellow ring

OUTER PACKAGE

Type	Box
Material	Expanded Polystyrene (EPS)
Dimension (LxWxH)	160 (Length) x 132,5 (Width) x 120 (Height) mm
Gross Weight	200 g
Colour	White

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PRODUCT PRESENTATION



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