

# PRODUCT TECHNICAL DATA SHEET

## LATEX CONTROLS

Rev. 1.1 - 2018.01.11

GENERAL INFORMATION	
<b>Name:</b> LATEX CONTROLS - QUALITY CONTROLS FOR ALIFAX ESR LINE ANALYZERS	
<b>Code:</b> SI 305.100-A	<b>Tubes:</b> 13x75 mm (Greiner)
<b>Classification:</b> IVD CE	Other In Vitro Diagnostic Devices
<b>Components:</b> The kit is made up of 3 test-tubes containing 3 ml of synthetic latex solution: 1 x Latex Control level 2 ("LATEX Test tube L 2") 1 x Latex Control level 3 ("LATEX Test tube L 3") 1 x Latex Control level 4 ("LATEX Test tube L 4")	
<b>Cap's colour:</b> White / Yellow	
<b>Method:</b> 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-195.220/BCL-195.230/SDL-195.240/YDL-195.250/MDL-195.260/XDL MicroTEST1 analyzer: Ref SI 199.101-LC ROLLER 20 analyzer: Ref SI R20-LC/R20-PN/R20-MC ROLLER 10 analyzer: Ref SI R10/R10-PN JO-PLUS analyzer: Ref SI 804.100	
<b>Tests N°:</b> up to 6; (the exceeding amount is automatically discarded by the analyzer)	
<b>Sample container:</b> REF SI 305.100-A Tubes 13x75 mm (Greiner).	
<b>EAN13 code:</b> 8056040141212	
<b>GMDN code:</b> 30531 - A DEVICE INTENDED FOR MEDICAL PURPOSES FOR USE IN A TEST SYSTEM TO ESTABLISH POINTS OF REFERENCE OR VERIFY THE PERFORMANCE CHARACTERISTICS OF A DEVICE USED IN THE DETERMINATION OF HEMATOLOGY CELL PARAMETERS (HAEMATOLOGY/HISTOLOGY/CYTOLOGY, HAEMATOLOGY REAGENTS, HAEMATOLOGY CONTROL/CALIBRATOR).	
<b>EDMA code:</b> 13015090 - Other Haematology Controls	
Waste disposal should be in accordance with the applicable national legislation. Having regard to the type of product is suggested to treat it as biological waste (E.W.C. code 18.01.03).	
SHELF LIFE	
<b>From the production date:</b>	6 months if kept properly. NOTE: in case of use of expired tubes, their contents are automatically discarded by the analyzer
<b>From the 1st piercing:</b>	6 weeks if stored between 4 ÷ 8 °C
STORAGE CONDITIONS	
<b>Temperature:</b>	4 ÷ 25 °C
<b>Warnings:</b>	1. Keep protected from light. 2. DO NOT FREEZE. Freezing may cause irreversible aggregation. 3. Humidity from 5% to 95% without condensed water.
WORKING SPECIFICATIONS	
<b>Usable with:</b>	ALIFAX line ESR analyzers upgraded with software for latex management (version 6.01A or upper for TEST1, MicroTEST1, ROLLER 20; 1.00A or upper for ROLLER 10, version 4.03A or upper for ROLLER 10-PN and 1.00.08 for JO-PLUS)

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<b>Temperature:</b>	Room temperature
<b>Sample Volume:</b>	291 ul (of which 116 ul for priming) from "LATEX Test tube L 2", 175 ul from "LATEX Test tube L 3" and "LATEX Test tube L 4"; approx. 3 ml of distilled water from the washing tubes (not supplied).
<b>Analysis Time:</b>	20" per sample
<b>Test results:</b>	Three ESR values
<b>Measure unit:</b>	mm/h
<b>PERFORMANCES</b>	
<b>Intra-lot Repeatability:</b>	CV% < 10%
<b>Inter-lot Reproducibility:</b>	CV% < 15%
<b>REAGENT COMPOSITION</b>	
<b>Composition:</b>	Aqueous dispersion of a polymer based on styrene and butadiene at 3 different concentrations (L2, L3, L4)
<b>Solid Content:</b>	1% - 8,5%
<b>TRANSPORT CONDITIONS</b>	
<b>Temperature:</b>	Not controlled as long as it does not go below 0 °C.
<b>PACKAGING DIMENSIONS</b>	
<b>Height:</b>	120 mm
<b>Width:</b>	132,5 mm
<b>Depth:</b>	160 mm
<b>Weight:</b>	90 g
<b>Packaging:</b>	Expanded Polystyrene (EPS)
<b>Product's image:</b>	

