INSTRUCTIONS FOR USE
LATEX CONTROLS

EN

Rev. 2.1bis – 2023-12-06

REF SI 305.100-A; SI 305.102-A; SI 305.300-A; SI 305.302-A

6/30 TESTS KIT

CE IVD

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.

DEVICE DESCRIPTION
Latex Control is provided in ready-to-use plastic capped tubes filled with 3ml aqueous suspension of synthetic latex at different known concentrations:
- 13x75mm Greiner Tube: REF: SI 305.100-A (6 test); SI 305.300-A (30 test)
- 11,5x66mm Sarstedt Tube: REF: SI 305.102-A (6 test); SI 305.302-A (30 test)

Each triplet allows up to 6 checks. The traceability is assured by the lot number and the barcode carried on each tube. The identification of the tubes is by an identification label indicating the rack (or rotor) loading position number and the barcode including the standard turbidimetric value.

PRINCIPLE OF THE METHOD
Good laboratory practices require the use of stable reference materials to verify the accuracy and precision of testing equipment and procedures. The technology applied by Alifax's ESR analyzers is Quantitative Capillary Photometry, which allows to obtain the ESR result of the sample, expressed in mm/hour, as per guidelines and reference method. For laboratory quality control needs it is then important to have at disposal a control system reproducible and easy to handle.
The Control kit is based on the use of three samples with known turbidity values, on which the analyzer performs transmittance measurements related to ESR values. The results obtained should fit the expected ranges. Otherwise the calibration of the instrument shall be verified.

MATERIALS PROVIDED
Each kit is made up of 1 or 5 triplets containing each the following 3 test-tubes:
No.1 Latex Control level 2 (“LATEX Test tube L 2”)
No.1 Latex Control level 3 (“LATEX Test tube L 3”)
No.1 Latex Control level 4 (“LATEX Test tube L 4”)

MATERIALS REQUIRED BUT NOT PROVIDED
Washing tubes containing 3ml distilled water

COMPATIBILITY
ALIFAX ESR line analyzers upgraded with software (SW) for latex management
- SW 6.01A onward: TEST1: (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); MicroTEST1 (REF: SI 199.101-LC); ROLLER 20 (REF: SI R20-LC)
- *SW 1.0.0 onward: TEST1 2.0: (REF: SI 195.210/THL)*
- SW 1.00A onward: ROLLER 20 (REF: SI R20-PN)
- SW 4.01A onward: ROLLER 20 (REF: SI R20-MC)
- SW 4.03A onward: ROLLER 10 PLUS NEEDLE (REF: SI R10-PN)
- SW 1.00.08 onward: JO-PLUS (REF: SI 804.100)

WARNINGS AND PRECAUTIONS
- For in-vitro diagnostic use only
- Do not use if the packaging is damaged.
- Do not use if product shows aggregations
- Handle with caution, avoiding ingestion, inhalation, contact with eyes, skin and clothes.
- Do not reuse the product more than six times

BENEFITS AND LIMITATIONS
The product can be used only with ALIFAX ESR line analyzers.

REACTIVE INGREDIENTS
Polymer based on styrene and butadiene.

PROCEDURE
The daily use of the control kit is recommended.
All kit components must be brought to room temperature prior to performing the test.
Perform the washing procedure according to the instrument operative manual.
Take three control tubes (for 30 test kit, verify that the three control tubes belong to the same column in the packaging) *and perform the control procedure according to the instrument operative manual.*
After the analysis of the control standards, the results obtained will be *displayed/*printed as ESR values (mm/h) in increasing order.
Only for SI R20-PN, check conformity of the 2 values (SENS1 and SENS2) for each level and if necessary calculate and record the average.
Store the kit at 4-8°C immediately after use.

RESULTS
The three ESR resulting values should fit the ranges reported both on the *display/*print itself and on the outer label in the table “REFERENCE VALUES”. If the obtained values are outside the expected ranges, the calibration of the instrument shall be verified. In this case, call the technical service to recalibrate the instrument.

QUALITY CONTROL
Quality Control can be done by processing repeatability tests on the same instrument and monitoring the results obtained with turbidimetric standards on which the percentage Standard Deviation (% RSD) for each value is calculated. The average value must be under 10%.

STORAGE AND STABILITY CONDITIONS
The kit is stable until the expiration date shown on the label when stored in the original packaging, between 4-25°C. Do not use after the expiration date. Do not freeze the product (freezing can cause irreversible aggregations) or expose it to direct light during storage. The tubes are stable for 6 weeks since the first opening if properly stored at 4-8°C in the original packaging. No controlled temperature transport required provided that the temperature doesn’t decrease under 0°C.

DISPOSAL
Reagents and samples disposal is under user’s responsibility according to their specific features and to local law requirements.

BIBLIOGRAPHY

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SYMBOLS GLOSSARY

REF	Catalogue Number	IVD	For in vitro diagnostic use
	Manufacturer		Temperature Limit
	Use-by date yyyy-mm-dd	LOT	Batch Code
eIFU Indicator	Consult electronic instructions for use		Caution
Cont.	Kit content		Contains sufficient for <n> tests
	Keep away from sunlight	℞ ONLY	*For US Only: Caution: US Federal Law restricts this device to sale by or on the order of the licensed practitioner.*
	Do not use if package is damaged		

NOTICE TO THE USER [REGULATION (EU) 2017/746]

Any **serious incident** that has occurred in relation to the device shall be reported to the manufacturer *(email: vigilance@alifax.com)* and the competent authority of the Member State in which the user and/or the patient is established.

Text written in italic blue identifies an addition or modification to the previous version

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