



INSTRUCTIONS FOR USE LATEX CALIBRATORS

EN

Rev. 2.1bis – 2023-12-06

REF

SI 305.400-A; SI 305.402-A

CE

IVD

6 TESTS KIT

INTENDED USE

Latex Calibrators are intended for in-vitro diagnostic professional use only by the technical service authorised by Alifax for the calibration of ALIFAX ESR line analyzers.

DEVICE DESCRIPTION

Latex Calibrators 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 305.400-A (6 test);
- 11,5x66mm Sarstedt Tube: REF: SI 305.402-A (6 test);
and in disposable washing tubes filled with 3ml distilled water:

- 13x75mm Greiner Tube: REF: SI 305.400-A (6 test);
- 11,5x66mm Sarstedt Tube: REF: SI 305.402-A (6 test);

The kit allows up to 6 calibrations. 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

The CALIBRATION kit is the final step in reference to latex controls application for ALIFAX ESR line analyzers. Latex controls allow the user to monitor analyzer performances pointing out any deviations that can be solved by the technical service by using the CALIBRATION kit. The CALIBRATION kit is in fact a rapid tool easy to handle that enables to bring back the analyzer to the original performances.

The CALIBRATION kit is based on the use of three samples with known turbidity values, on which the instrument performs transmittance measurements related to ESR values. The correction of the calibration, that must be done exclusively by the technical service, occurs by realigning the results obtained with the turbidimetric standards expected values.

MATERIALS PROVIDED

The kit is made up of 21 tubes:

No.1 Latex Calibrator level 2 ("LATEX Test tube L 2")
No.1 Latex Calibrator level 3 ("LATEX Test tube L 3")
No.1 Latex Calibrator level 4 ("LATEX Test tube L 4")
N°6 Washing tubes for rack position 1 (disposable)
N°6 Washing tubes for rack position 5 (disposable)
N°6 Washing tubes for rack position 6 (disposable)

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

All kit components must be brought to room temperature prior to performing the calibration.

Perform the washing procedure according to the instrument operative manual.

Take the kit tubes and perform the calibration procedure according to the instrument operative manual.

- At the end of analysis, the expected values and the results obtained will be *displayed*/printed out as ESR values (mm/h) in an increasing order.

- If the results obtained fit the expected ranges, *it means that the analyzer is calibrated correctly and the current calibration can be confirmed according to the instrument technical manual.*

- If the obtained values are outside the expected ranges, *save the new calibration according to the instrument technical manual.*

- The ESR values before and after the calibration will be *displayed*/printed out in sequence. These last values will have to be evaluated according to the "Results" paragraph down below.

- Perform at least *three* calibrations, verifying each time the deviation of Model Fact (difference between prior and after calibration). If the deviation of Model Fact is greater than 50 points on the *three* or more calibrations performed, it is advisable to verify the capillary conditions and check the statistical trends. *For TEST1 2.0 analyzers it is advisable to verify the CPS manifold.*

- The calibration will modify only the MODEL FACT, parameter that manages latex, keeping unchanged the BOOSTER Y, parameter that manages blood samples. For keeping the blood samples results aligned with the ones historically obtained it is necessary to act on Booster Y.

- 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". In case the obtained values after calibration keep staying outside the expected ranges, it

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will be necessary to check the instrument hardware. In this case please refer to the technical manual of the analyzer model under calibration.

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%.

METROLOGICAL TRACEABILITY

No international traceable reference materials are available for the measurement of ESR. The setpoint values of the calibrators were obtained by assaying representative samples of the entire lot on a photometer calibrated using primary standards.

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

	Catalogue Number		For in vitro diagnostic use
	Manufacturer		Batch Code
	Use-by date yyyy-mm-dd		Temperature Limit
	Kit contents		Do not re-use
	Do not use if package is damaged		Contains sufficient for <n> tests

	Keep away from sunlight
	Caution

	eIFU Indicator	Consult electronic instructions for use
	Rx ONLY	For US Only: Caution: US Federal Law restricts this device to sale by or on the order of the licensed practitioner.

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](mailto: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