

REF SI 305.400-A/ SI 305.402-A



IVD In vitro use only

6 TESTS KIT

AIM OF THE TEST

The kit aims to the calibration 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

INTRODUCTION

The CALIBRATION 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.

PRINCIPLE OF METHOD

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 results obtained should fit the expected ranges, otherwise the calibration of the instrument shall be verified. The correction of the calibration that must be done by the technical service and occurs by realigning the results obtained with the turbidimetric standards expected values.

KIT DESCRIPTION

The kit is made up of the following 21 tubes:

No.1 Latex Calibrator of level 2 ("LATEX Test tube L 2")

No.1 Latex Calibrator of level 3 ("LATEX Test tube L 3")

No.1 Latex Calibrator of 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)

(the 18 washing tubes are laid out in 6 columns of 3 tubes each, one per position (1,5,6)). The calibrators are ready to use, their volume (approx 3 ml) allows up to 6 checks. The washing tubes (3 ml) must be used once. The traceability is assured by the lot number and the bar code carried on each tube.

KIT COMPOSITION

Turbidimetric standards are suspensions of synthetic latex at different concentrations. The washing tubes contain distilled water.

TUBES IDENTIFICATION

Washing tubes:

- Plastic tube with screw cap that can be 13x75 mm (Greiner) (REF SI 305.400-A) or 66x11,5 mm (Sarstedt) (REF SI 305.402-A).

- Liquid state.

- "STD WASHING TUBE AXT" identification label with the rack (or rotor) loading position number.

Calibration standards:

- Plastic tube with screw cap that can be 13x75 mm (Greiner) (REF SI 305.400-A) or 66x11,5 mm (Sarstedt) (REF SI 305.402-A).

- Liquid state.

- Bar-coded identification label indicating the standard turbidimetric value and the rack (or rotor) loading position number.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only.

- Suitable only with ALIFAX ESR line analyzers if upgraded with software for latex management (6.01A or upper for TEST1, MicroTEST1 and ROLLER 20-LC, version 1.00A or upper for ROLLER 10, ROLLER 20-PN, version 4.01A or upper for ROLLER 20-MC, version 4.03A or upper for ROLLER 10-PN, version 1.00.08 for JO-PLUS).

- Handle with caution, avoiding ingestion, inhalation and contact with eyes, skin and clothes.

- Do not use if the packaging is damaged.

- Do not use reagents after the expiration date.

- Do not reuse the product more times than indicated on the label.

- Do not freeze the product. Freezing can cause irreversible aggregations.

STORAGE CONDITIONS

The kit must be stored in a dark place (closed box), between 4 + 25 °C, until the expiration date. The tubes remain usable for 6 weeks since the first piercing if properly stored at 4 + 8 °C. It is not necessary to transport the product at controlled temperature provided that the temperature doesn't decrease under 0 °C.

PROCEDURE

- For analyzers upgraded with the following software versions, be sure that "Latex priming" is activated, otherwise activate it by following the instructions in the technical manual of the analyzer model under calibration: 6.51D or upper for TEST 1, 6.51C or upper for ROLLER 20-LC, 3.00A or upper for ROLLER 10 line analyzers (ROLLER 10, ROLLER 10-PN, ROLLER 20-PN, ROLLER 20-MC), 1.01.00 or upper for JO-PLUS.

- Perform the washing procedure according to the instrument operative manual.

- For TEST1 and Roller 20-LC analyzers:

From MAIN MENU press the key 6 and then the key 1 to start the procedure.

For ROLLER 20-PN analyzers:

From MAIN MENU, press "Main" (on the upper left corner), a scroll down menu will be displayed, then press "Standard" to start the procedure.

Common steps to follow for both analyzers:

- Load the kit tubes on a rack in the case of TEST1 analyzer, or on a rotor in the case of ROLLER 10/20 and MicroTEST1 analyzers, verifying the loading position number, according to the following scheme:

1. STD WASHING TUBE AXT 1 - position no. 1
2. LATEX Test tube L 2 - position no. 2
3. LATEX Test tube L 3 - position no. 3
4. LATEX Test tube L 4 - position no. 4
5. STD WASHING TUBE AXT 5 - position no. 5
6. STD WASHING TUBE AXT 6 - position no. 6

- On TEST1 analyzer with the Internal Bar Code Reader (IBCR) the tubes must be placed with the labels on the right way for the bar code reading.

Note: It is highly recommended to respect strictly the samples loading sequence as described in order to avoid a wrong instrument check.

- Following the analyzer menu driven instructions, open the loading door of the TEST1 instrument and insert the rack with the test-tubes prepared for the calibration. After closing the front door, the analysis of calibrators will be started automatically.

- In case of use on analyzers MicroTEST1 and Roller 20 with the external bar code reader (EBCR), execute the reading of the bar-code of each single test-tube just before the loading on the mixing rotor.

- If the analyzer is without any bar-code reader or the reader is not able to read the bar-codes on the test-tubes, the bar code indicated on each single test tube of the kit will need to be entered manually.

Note: it is necessary to enter the whole bar code carried on each single tube of the kit.

- Upon completed the mixing phase, the analyzer will perform the withdrawal and the analysis of the calibration standards.

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

- If the results obtained fit the expected ranges, activate the control function by pressing the key "1". The values found will be again printed out as ESR values (mm/h) as a confirmation of the current calibration.

- If the obtained values are outside the expected ranges, press "2" (Autoset Fact) to perform the automatic calibration of the analyzer. A password (66) that allows the procedure execution will be requested.

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

- Perform at least two 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 two or more calibrations performed, it is advisable to verify the capillary conditions and check the statistical trends.

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

RESULTS

The three ESR resulting values should fit the ranges reported both on the print itself ("Reference values") and on the outer label in the table "REFERENCE VALUES". In case the obtained values after calibration keep staying outside the expected ranges it 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%.

LIMITATIONS OF THE PROCEDURE

The product can be used only with ALIFAX ESR line analyzers upgraded with the software for latex management (6.01A or upper for TEST1, MicroTEST1 and ROLLER 20-LC, version 1.00A or upper for ROLLER 10, ROLLER 20-PN, version 4.01A or upper for ROLLER 20-MC, version 4.03A or upper for ROLLER 10-PN, version 1.00.08 for JO-PLUS).

PERFORMANCES







- Repeatability: CV% < 10%







- Reproducibility: CV% < 15%

WASTE DISPOSAL

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

INDEX OF SYMBOLS

Symbol	Meaning
	Product code
	Manufacturer
	Expire date
	Consult instructions for use
	Kit contents
	Protect from light

Symbol	Meaning
	In Vitro Diagnostic Medical Device
	Temperature limitation
	Lot number
	Attention, see instructions for use
	Contains sufficient for <n> tests
	Do not reuse more than six times

