

# INSTRUCTIONS FOR USE

## LATEX CONTROLS

Rev. 1.3 - 2016.07.29

**REF** SI 305.100-A/SI 305.102-A/SI 305.300-A/SI 305.302-A



**IVD** In vitro use only

### 6/30 TESTS KIT

#### AIM OF THE TEST

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

#### INTRODUCTION

The ESR determination is susceptible to several variables (temperature, performing, sample state, results reading). Since the phenomenon of erythrocyte sedimentation is confined to fresh blood and is transient, quality control procedures are based on the comparison of the results with the reference method performed on fresh samples.

According to these remarks, the traditional control materials are not able to reproduce correctly the phenomenon. For laboratory quality control needs it is then important to have at disposal a control system reproducible and easy to handle.

#### PRINCIPLE OF METHOD

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.

#### KIT DESCRIPTION

The 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")

The control tubes are ready to use, their volume (approx 3 ml) allows up to 6 checks and so does each triplet. The traceability is assured by the lot number and the barcode carried on each tube.

#### KIT COMPOSITION

Turbidimetric standards are suspensions of synthetic latex at different concentrations.

#### TUBES IDENTIFICATION

• Plastic tube with screw cap, that can be 13x75 mm Greiner REF SI 305.100-A / SI 305.300-A or 66x11,5 mm Sarstedt REF SI 305.102-A / SI 305.302-A.

• Liquid state.

• Identification label indicating the rack (or rotor) loading position number and the barcode including the standard turbidimetric value.

#### 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, contact with eyes, skin and clothes.

• Do not use if the packaging is damaged.

• Do not use the product 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

The daily use of the control kit is recommended.

- 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:

- Prepare three washing tubes containing at least 3 ml of distilled water.

- Load the three tubes of a single column of the kit and the washing tubes on the rack in the case of TEST1 analyzer, or on the rotor in the case of Roller 10/20 or MicroTEST1 analyzers, verifying the loading position number indicated on the test tubes, according to the following scheme:

1. Washing tube - position N°1

2. LATEX Test tube L 2 - position N°2 Please verify that the three control

3. LATEX Test tube L 3 - position N°3 tubes belong to the same column

4. LATEX Test tube L 4 - position N°4 in the packaging (only for 30 tests kit)

5. Washing tube - position N°5

6. Washing tube - position N°6

On TEST1 analyzer with the Internal Barcode Reader (IBCR) the tubes must be placed with the labels on the right way for the barcode 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 check. After closing the front door, the analysis of controls will be started automatically.

- In case of use on analyzers MicroTEST1 and Roller 10/20 with the external barcode reader (EBCR), execute the reading of the barcode of each single test-tube just before the loading on the rack or on the mixing rotor.

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

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

Please be sure that the barcoded last three numbers are the same on all three tubes used taken from the same column. Otherwise the analyzer will give an error and won't perform the analysis of the controls.

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

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

- The three ESR resulting values will have to be evaluated according to the "Results" paragraph down below.

#### 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". 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%.

#### 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

