

Instructions for Use

suPARnostic® TurbiLatex Calibrators

REF T002

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 **suPARnostic®**

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INTENDED PURPOSE

For professional laboratory use.

suPARnostic® TurbiLatex Calibrators are used to establish a calibration curve. This is used to interpolate the soluble urokinase Plasminogen Activator Receptor (suPAR) concentration in human K2-EDTA or lithium-heparin plasma samples in ng/mL when using the suPARnostic® TurbiLatex Reagents kit.

This kit should be used on automated chemical analysers from Roche Diagnostics, such as cobas c 501/2 and c 701/2.

REAGENTS AND MATERIALS

Calibrator 1, volume: 1 mL (Low)

Calibrator 2, volume: 1 mL

Calibrator 3, volume: 1 mL

Calibrator 4, volume: 1 mL

Calibrator 5, volume: 1 mL

Calibrator 6, volume: 1 mL (High)

Do not use NaCl or water as a blank sample.

COMPOSITION

suPARnostic® TurbiLatex Calibrators consist of six ready-to-use solutions of known suPAR concentrations in human plasma containing a preservative. The human plasma used tested negative for Anti-HBsAg, HIV-1 Ab, HIV-2 Ab, HIV-1 RNA, HCV Ab, HCV RNA, HBV DNA, and STS.

The concentrations can be found in the Certificate of Analysis and are reported in ng/mL.

MATERIALS REQUIRED BUT NOT PROVIDED

suPARnostic® TurbiLatex Reagents
suPARnostic® TurbiLatex Controls
Clinical chemistry analyser
Adjustable pipette with tips, 20 µL – 200 µL
Disposable gloves

STORAGE AND STABILITY

suPARnostic® TurbiLatex Calibrators should be stored frozen at temperatures of –18 to –20°C and are produced with a 4-month shelf life.

Five freeze/thaw cycles throughout the shelf life do not impact the quality of the calibrators. Exposing the calibrators to sun, heat or an excessive amount of light is not recommended.

ASSAY PROCEDURE

Each laboratory should establish its calibration frequency. In any case, it is recommended to repeat calibration at least once a month, and it is mandatory to recalibrate when a new batch of suPARnostic® TurbiLatex Reagents is used.

Thaw the calibrators approximately 30 minutes before use and equilibrate them to room temperature. It is recommended to avoid thawing the calibrators by exposing them to the sun or heat. Before pipetting into the measuring cuvettes, the calibrators should be mixed thoroughly (preferably with a vortex mixer). Transfer the appropriate volume of mixed calibrators into the cuvette and perform the calibration. Dispose of the calibrators according to local regulations.




The calibration method should be the same as for measuring samples, according to the application parameters provided in suPARnostic® TurbiLatex Reagents Instructions for Use.

PRECAUTIONS

- Do not use kit components beyond the expiration date.
- Do not switch caps on calibrator containers, as this may cause contamination or mix-up.
- Do not mix calibrators from different kit lots.
- Do not mouth pipette or ingest any of the calibrators.
- Do not smoke, eat or drink when performing the calibration or in areas where calibrators are handled.
- Do not ingest, expose to open wounds, or breathe in aerosols.
- Wear protective gloves and properly dispose of biological samples.
- All solutions supplied should be handled carefully and disposed of following national and local regulations.
- Calibrators should be treated as infectious material; therefore, the required safety precautions must be taken.

WASTE HANDLING

Please note that calibrators are produced from biological material and should be treated as infectious. Discard unused calibrators and waste following country, federal, state and local regulations.

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| REF |  |  |
| Catalogue No. | Biological Risk | Use by |
| IVD |  | LOT |
| In vitro diagnostic medical device | Temperature Limits | LOT No. (Batch No.) |