

Instructions for Use

suPARnostic® TurbiLatex Calibrators

Soluble Urokinase Plasminogen Activator Receptor

REF T002

CE **IVD**

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Refer to the webpage <http://www.virogates.com> for instructions in other languages. Alternatively contact your local distributor for instructions in your language.

INTENDED USE

FOR PROFESSIONAL USE

The suPARnostic® TurbiLatex Reagents are used for determination of soluble urokinase plasminogen activator receptor (suPAR) in human EDTA- and heparin plasma and serum in ng/mL.

The suPARnostic® Calibrators are used to establish a calibration curve which is used to interpolate the suPAR measurements.

KIT CONTENTS

- 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)

The Calibrators are ready to use solutions. Certificate of analysis with concentrations is provided with each suPARnostic® TurbiLatex Calibrators kit.

Do not use NaCl or water as blank sample.

STORAGE AND STABILITY

The suPARnostic® TurbiLatex Calibrators should be stored frozen at temperature -20°C or below.

Stability frozen: 3 months.

Five freeze/thaw cycles over the shelf-life do not have an impact on suPAR concentration. It is not recommended to expose the Calibrators to sun, heat or excessive amount of light.

WARNINGS AND PRECAUTIONS

- For professional users.
- Do not use kit components beyond the indicated kit expiration date.
- Do not switch caps on calibrator containers as it 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 aerosols. Wear protective gloves and dispose of biological samples properly.
- All solutions supplied should be handled carefully and disposed of in accordance with national and local regulations.
- Calibrators should be treated as infectious material and therefore required safety precautions have to be taken.

COMPOSITION

suPARnostic® TurbiLatex Calibrators consist of six ready to use solutions of suPAR in human plasma which contains preservative. The Human Plasma was tested negative for Anti HBsAg, HIV ½ Ab, HIV-1 RNA, HCV Ab, HCV RNA, HBV DNA & STS.

MATERIALS REQUIRED BUT NOT PROVIDED

- suPARnostic® TurbiLatex Reagents **REF** T001
- suPARnostic® TurbiLatex Controls **REF** T003
- Clinical chemistry analyzer
- Adjustable pipette with tips, 20 µL – 200 µL
- Disposable gloves

ASSAY PROCEDURE

Each laboratory should establish their own calibration frequency, but it is recommended to repeat the calibration at least once a month and it is required to recalibrate when a new batch of TurbiLatex Reagents is used.




The calibrators must be stored frozen, therefore approximately 30 minutes before calibration let the calibrators thaw and equilibrate to room temperature. It is recommended to avoid thawing the calibrators by exposing them to sun or heat. Before pipetting to measuring cuvettes, the calibrators should be mixed thoroughly (preferably with vortex mixer).

Transfer the appropriate volume of mixed calibrators into cuvette and perform the calibration. After the process dispose the calibrators according to regulations.

Method for calibration should be the same as for measuring the samples according to application parameters which are given in suPARnostic® TurbiLatex Reagents Instruction for use.

WASTE HANDLING

Note that Calibrators are produced from biological material and should be treated as infectious. Discard unused Calibrators and waste in accordance with country, federal, state, and local regulations.

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