Instructions for Use
suPARnostic® TurbiLatex Controls

REF **T003**

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 PURPOSE

For professional laboratory use.
suPARnostic® TurbiLatex Controls are used to verify the calibration curve and the performance of suPARnostic® TurbiLatex Reagents.
suPARnostic® TurbiLatex Reagents are used to determine the soluble urokinase Plasminogen Activator Receptor (suPAR) concentration in human K2-EDTA and lithium-heparin plasma samples in ng/mL.

This kit should be used on automated chemical analysers, e.g. Roche Diagnostics, Siemens Healthcare A/S, and Abbott.

REAGENTS AND MATERIALS

Control 1, volume: 1 mL (Low)
Control 2, volume: 1 mL (Medium)
Control 3, volume: 1 mL (High)

COMPOSITION

suPARnostic® TurbiLatex Controls contains three ready-to-use solutions of suPAR in human plasma with preservatives. The human plasma tested negative for Anti-HBsAg, HIV-1 Ab, HIV-2 Ab, HIV-1 RNA, HCV Ab, HCV RNA, HBV DNA, and STS.
The concentrations and ranges can be found in the Certificate of Analysis and are reported in ng/mL.

MATERIALS REQUIRED BUT NOT PROVIDED

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

STORAGE AND STABILITY

suPARnostic® TurbiLatex Controls should be stored 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 quality. Exposing the control samples to sun, heat, or excessive light is not recommended.

ASSAY PROCEDURE

Quality control of suPARnostic® TurbiLatex Reagents should be performed using suPARnostic® TurbiLatex Controls (T003) according to hospital guidelines and after each calibration. Quality control ranges and limits should be adapted to specific laboratory experience and knowledge with suPARnostic® TurbiLatex Reagents. The laboratory should undertake corrective actions if the values exceed the established upper/lower range.

Thaw the controls approximately 30 minutes before use and equilibrate them to room temperature. It is recommended to avoid thawing the controls by exposing them to the sun or heat. Before pipetting into the measuring cuvettes, the controls should be mixed thoroughly (preferably with a vortex mixer). Transfer the appropriate volume of mixed control into a cuvette and perform the test.
The method for Quality Control measures should be the same as when measuring clinical 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 control containers, as this may cause contamination or a mix-up.
- Do not mix controls from different kit lots.
- Do not mouth pipette or ingest any of the controls.
- Do not smoke, eat or drink when performing the measurement or in areas where controls are handled.
- Do not ingest, expose to open wounds, or breathe in aerosols.
- Wear protective gloves and adequately dispose of biological samples.
- Controls should be treated as infectious material; therefore, safety precautions must be taken.

WASTE HANDLING

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

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