Instructions for Use
suPARnostic® TurbiLatex Controls
Soluble Urokinase Plasminogen Activator Receptor

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 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 Controls are intended for verification of the calibration curve performance.

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

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

STORAGE AND STABILITY
The suPARnostic® TurbiLatex Controls 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 Controls to sun, heat or excessive amount of light.

WARNINGS AND PREACAUTIONS
- For professional users.
- Do not use kit components beyond the indicated kit expiration date.
- Do not switch caps on controls containers as it may cause contamination or 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 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.
- Controls should be treated as infectious material and therefore required safety precautions have to be taken.

COMPOSITION
The suPARnostic® TurbiLatex Controls contains three 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 Reagent REF T001
- suPARnostic Turbilatex Calibrator REF T002
- Clinical chemistry analyser
- Adjustable pipette with tips, 20 µL – 200 µL
- Disposable gloves

ASSAY PROCEDURE
Quality control of TurbiLatex Reagents should be performed with the use of suPARnostic TurbiLatex Controls T003 after each calibration. Quality control ranges and limits should be fitted if needed to specific laboratory's experience and knowledge with the TurbiLatex Reagents. If the values exceed established upper/lower range the laboratory should undertake corrective actions.

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

Transfer the appropriate volume of mixed control into cuvette and perform the test as if it were a patient sample. After the process dispose the controls according to regulations.
Method for Quality control measurement should be the same as for measuring the clinical samples according to application parameters which are given in suPARnostic® TurbiLatex Reagent Instruction for use.

WASTE HANDLING
Note that Controls are produced from biological material and should be treated as infectious. Discard unused Controls 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.)