ViroGates

suPARnostic® TurbiLatex Reagents
Instructions for Use

REF T013

CE IVD

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This product is protected by one or more US, European, and/or foreign patents.
The T013 product is validated on the automated Beckman Coulter 5800 instrument, and this instruction for use is dedicated to this biochemistry analyser.
Refer to the webpage http://www.virogates.com for instructions for other biochemistry analysers and languages. Alternatively, contact your local distributor for instructions in your language.

INTENDED PURPOSE
For in vitro diagnostic use.
The suPARnostic® TurbiLatex Reagents are an in vitro diagnostic assay used to determine the soluble urokinase Plasminogen Activator Receptor (suPAR) level in human K2-EDTA and Lithium Heparin plasma on automated biochemistry analysers. The suPARnostic® TurbiLatex is a quantitative test measuring the suPAR level in ng/mL. It is intended to aid in the detection and evaluation of inflammatory disorders and immune activation.

INTENDED USER AND PATIENT
For professional use.
Typical users are laboratory technicians in central laboratories.
The typical patients present in the Emergency Departments (ED) or the Intensive Care Units (ICU).

Acute Medicine
For unselected acute care patients, suPARnostic® TurbiLatex is used to identify the level of inflammation and immune activation to support triage decisions in conjunction with clinical findings and the results of other laboratory tests.

COVID-19
In patients with confirmed COVID-19 virus, suPARnostic® TurbiLatex is used to identify the level of inflammation and immune activation to aid in determining the risk of respiratory failure with a need for mechanical ventilation in conjunction with clinical findings and the results of other laboratory tests.

suPAR IS A MARKER OF DISEASE PROGRESSION

suPAR is the soluble form of urokinase Plasminogen Activator Receptor (uPAR). The amount of suPAR is a measure of immune activation and inflammation.[1] suPAR is a biomarker increased by disease presence and severity.

In unselected ED patients, suPAR has a high negative predictive value for ruling out disease progression[2]. This means that patients with a low (<4 ng/mL) suPAR level have a good prognosis and a low risk of readmission and mortality[3], supporting the decision to discharge the patient. Conversely, a high suPAR level (>6 ng/ml) is a strong measure of chronic inflammation and the underlying risk of adverse outcomes, including short-term mortality (in hospital, 30 days, or 90 days)[2] supporting the decision of further examination of the patient.

The use of suPAR in clinical routine adds significant additional knowledge to the standard assessment based on early warning score systems and standard parameters in pre-admission of acute medical patients. Hence, suPAR is a broadly applicable biomarker, e.g., in the ED, especially concerning discharge decisions of patients and identifying non-diagnosed inflammatory diseases.

A cluster-randomised interventional study showed that up- or down-triaging patients based on suPAR levels increased the number of patients discharged (low risk) by 34%[4] and reduced hospital bed days[5].

In patients with confirmed COVID-19, suPAR levels below 4 ng/mL suggest a low risk of developing respiratory failure and can be discharged for home quarantine.[6]

TEST PRINCIPLES

The suPARnostic® TurbiLatex test is a Particle Enhanced Turbidimetric Immunoassay (PETIA) that quantitatively determines suPAR in human plasma samples. The latex-enhanced particles coated with anti-suPAR antibodies (Mouse/Rat) in the reagent agglutinates with the suPAR present in the sample. During the incubation time, an antigen-antibody complex is formed. The size of the complex is estimated using spectrophotometric technology at a wavelength of 570 nm. The degree of turbidity caused by the agglutination is a measure of suPAR in the sample. The higher suPAR, the higher the turbidity.

REAGENTS AND MATERIALS

Reagents provided:

- Reagent 1: Dilution Buffer (Glycine-Buffer solution (pH 8.2) and preservatives)
- Reagent 2: Latex Particle Reagent (Phosphate buffer solution (pH 6.1), latex particles coated with anti-suPAR antibodies and preservatives)

This kit consists of a ready-to-use Reagent 1 dilution buffer and a ready-to-use Reagent 2 solution of latex particles coated with anti-suPAR antibodies.

The volume below is provided for a 15 mL cassette for the Beckman Coulter 5800 chemistry analyser.

Product/Buffer	Reagent 1	Reagent 2	No. tests
T013	13 mL	5 mL	150*

*No. of tests refers to the measurements available for sample testing when all reagent is transferred to empty bottles. Reagent volumes include the bottle's dead volumes and 12 tests used for calibration. The bottles are for one-time use.

Material required but not provided:

- suPARnostic® TurbiLatex Calibrators
- suPARnostic® TurbiLatex Controls
- Beckman Coulter 5800 analyser
- Empty bottles for Beckman Coulter 5800
- General laboratory equipment

PRECAUTIONS

For professional laboratory use.
For in vitro diagnostic use. Exercise the standard precautions required for handling all laboratory reagents. Disposal of all waste material should follow local guidelines. The safety data sheet is available for professional users upon request.

- Do not use kit components beyond the indicated kit expiration date.
- Do not freeze any of the kit components.
- Do not mix reagents from different kit lots.
- Do not switch caps on reagent containers as it may cause contamination or mix-up.
- Do not mouth pipette or ingest any of the reagents.
- Do not smoke, eat, or drink when performing the assay or in areas where samples or reagents are handled.
- Do not mix plasma samples from different patients or different blood samplings of the same patient.
- Human samples may be contaminated with infectious agents. Therefore, do not ingest, expose to open wounds, or breathe aerosols.
- Wear protective gloves and dispose of biological samples according to the regulations.
- Be aware of possible dilution of suPAR in the case of a transfusion, infusion or similar.

STORAGE AND HANDLING

The suPARnostic® TurbiLatex Reagents kit should be stored at 2-8°C - do not freeze.
Before use, check the expiry date on the label.
The suPARnostic® Reagents are produced with a 2-year shelf life from the production date.
The reagents have 8 weeks of onboard stability when kept at 2-8°C and with a minimum of monthly calibration.
The reagent's stability may be affected if not stored correctly, and inefficient and misleading results may be obtained. If any colouring or precipitation appears, discard the Reagents.

SAMPLE COLLECTION AND PREPARATION

Blood samples collected in K2-EDTA and Lithium-Heparin have been validated.

Collecting blood samples should be performed by authorised personnel using approved venipuncture techniques.
To prepare plasma samples, draw whole blood into a blood collection tube containing either K2-EDTA or Lithium Heparin anticoagulant. Then, centrifuge the blood at 3,000 x g between 1-10 minutes or until blood cells and plasma have separated.

Ensure the samples, calibrators, and controls are at room temperature before measurement.
Due to possible evaporation effects when loaded on the instrument, samples, calibrators, and controls should be analysed within 2 hours.

NOTE: Do not use hemolysed, contaminated, or hyperlipemic sample specimens.

ASSAY PROCEDURE

1) Install the suPARnostic® method using the application parameters provided at the end of this note onto the Beckman Coulter 5800 analyser.
2) Transfer the suPARnostic® TurbiLatex Reagents to Beckman Coulter 5800 appropriate empty bottles before loading on the equipment. Transfer Reagent 1 to a 15 mL bottle and place it in the R1 refrigerator tray at the fixed position. Transfer Reagent 2 to a 15 ml empty bottle and place it in the R2 refrigerator tray at the fixed position.
   For more information, refer to the Beckman Coulter 5800 Instruction for use.
   Note. When the reagent bottles do not have a barcode, you must assign the reagent position (Fixed reagent position).
3) Load reagents on the analyser.
4) If fully automated, load blood sample directly on the analyser or isolate plasma before loading.
5) The assay run time is 10 minutes with:
   1st incubation: 75 µL of Reagent 1 with 5 µL of the sample.
   2nd incubation: 25 µL of Reagent 2 is added to the mixture, and antigen-antibody complexes are formed.
6) The turbidity of the sample is measured in set time intervals at a wavelength of 570 nm.
7) Results are determined via a calibration curve generated by measuring a subset of calibrators (Cal 0 Blank and Cal 5 of the suPARnostic® TurbiLatex Calibrator kit #T007) with a known suPAR concentration.
8) The measurement result is calculated by determining the difference in absorbance values at 2 read points. The analyser automatically calculates the analyte concentration of each sample in ng/mL.

CALIBRATION

Together with the suPARnostic® TurbiLatex Reagents kit, the suPARnostic® TurbiLatex Calibrators (#T007) must be used for calibration. For the Beckman Coulter 5800 analyzer, only the Cal 0 Blank and the Cal 5 of the Calibrator kit are used. See the settings at the back of the instruction. It is recommended to repeat the calibration at least once a month. In addition, recalibration is required when a new batch of the suPARnostic® TurbiLatex Reagents is used. Calibration is performed according to the instruction provided with the suPARnostic® TurbiLatex Calibrators.

QUALITY CONTROL

Quality control of the suPARnostic® TurbiLatex Reagents must be performed with the suPARnostic® TurbiLatex Controls (#T003) as a minimum after each calibration and according to the laboratory guidelines. If the QC values exceed the established upper/lower range, the laboratory should undertake corrective actions.

INTERPRETATION OF RESULTS

suPAR levels and cut-offs

Acute care medical patients and risk of 90-day mortality

The cut-offs for interpreting results from acute care patients were established based on suPAR baseline measurements of 990 patients attending the ED in a Spanish multicenter trial.[14] The median age was 68 years (53-81), 50.8% were men, median suPAR was 3.8 ng/mL (Interquartile range 2.8-6.0). In total, 47 died during the 90-day follow-up. Out of the 990 patients, 520 (52.5%) had suPAR below 4.0 ng/mL. Patients with suPAR <4.0 ng/mL had a low risk of 90-day mortality (N=5, 0.96%), resulting in a negative predictive value (NPV) of 99.0%, a sensitivity of 89.4% and a specificity of 54.6%. In patients with suPAR >6.0 ng/mL (N=245 (24.8%), 33 patients died during the 90-day follow-up (13.5%), resulting in a positive predictive value (PPV) of 13.5%, a sensitivity of 70.2% and a specificity of 77.5%.

	90 Days follow-up				
	Died	Survived	Total	PPV	NPV
High risk (suPAR >6.0 ng/mL)	33	212	245	13.5%	
Medium Risk (suPAR 4.0– 6.0 ng/mL)	9	216	225		
Low risk (suPAR <4.0 ng/mL)	5	515	520		99.0%
Total	47	943	990		
Sensitivity/specificity (<4.0 ng/mL)	89.4%	54.6%			
Sensitivity/specificity (>6.0 ng/mL)	70.2%	77.5%			

Table 1: 90-day Mortality according to suPAR cut-offs in Spanish multicenter study.

COVID-19 and risk of respiratory failure

For patients who tested positive for the COVID-19 virus, suPAR baseline measurements were taken within 48 hours after patients presented at the hospital[6]. Respiratory failure was defined as the need for mechanical ventilation within 2 weeks. The study included 57 patients, of whom 21 developed respiratory failure. None of the patients with suPAR below 4.0 ng/mL developed respiratory failure resulting in an NPV of 100%, a sensitivity of 100% and a specificity of 36.1%. Of the 21 patients who developed respiratory failure, 18 had baseline suPAR levels above 6.0 ng/mL resulting in a PPV of 85.7%, a sensitivity of 85.7%, and a specificity of 81.3%.

suPAR level	Interpretation, ED and COVID-19
<4.0 ng/mL	**Low Risk** - Supports the decision of discharge. - The underlying health condition is good, and the prognosis for survival is high. - Low risk of respiratory failure and need of mechanical ventilation in patients with COVID-19.
4.0-6.0 ng/mL	**Medium Risk** - Some disease activity or co-morbidity is present.

	- Some readmissions and mortality are expected after six months of follow-up. - Medium risk of respiratory failure and need of mechanical ventilation in patients with COVID-19.
>6.0 ng/mL	**High Risk** - Clinical attention is needed - high risk of mortality. - Supports the decision of admission and treatment - High risk of respiratory failure and need of mechanical ventilation in patients with COVID-19.

Table 2: Simplified suPAR clinical decision scheme[6, 14].

EXPECTED VALUES IN HEALTHY INDIVIDUALS

All individuals have a measurable suPAR level. In healthy blood donors (N=9305), the median suPAR level for men aged 18-65 years is 2.2 ng/mL (25-75% interval from 1.8-2.9 ng/mL)[7], for women aged 18-65 years is 2.6 ng/mL (25-75% interval from 2.1-3.2 ng/mL)[7], patients attending ED the suPAR level is around 3.0-6.0 ng/mL[2,3,8]. In patients with severe disease and organ failure, suPAR is often double-digits[9,10]. The higher the level, the higher the risk of disease progression and the worse the prognosis.

CLINICAL PERFORMANCE

Validation of cut-offs

Acute care medical patients

The clinical validation data are from a prospective observational study of unselected acute medical patients attending the ED at Mikkeli Hospital in Finland.[11] A total of 1747 acute medical patients were included and had suPAR measured using suPARnostic® TurbiLatex. The median age was 70 (IQR: 57-79), and 51.4% were men. Among patients with suPAR below 4.0 ng/mL (N=804, 46.0%), 8 (1.0%) died within 90-day follow-up, resulting in a negative predictive value of 99.0% and a sensitivity of 94.2% and a specificity of 47.9%. Among patients with suPAR above 6.0 ng/mL (N=429, 24.6%), 87 patients (20.3%) died within 90-day follow-up, resulting in a positive predictive value of 20.1%, a sensitivity of 63.0% and a specificity of 78.7%. Data for 90-day follow-up are shown in Table 3.

	90-day follow-up				
	Died	Survived	Total	PPV	NPV
High risk (suPAR >6.0 ng/mL)	87	342	429	20.3%	
Medium Risk (suPAR 4.0– 6.0 ng/mL)	43	471	514		
Low risk (suPAR <4.0 ng/mL)	8	796	804		99.0%
Total	138	1609	1.747		
Sensitivity/specificity (< 4.0 ng/mL)	94.2%	49.5%			
Sensitivity/specificity (> 6.0 ng/mL)	63.0%	78.7%			

Table 3: 90-day mortality in acute medical patients in Finish validation study.

COVID-19
The clinical validation data are from a prospective observational study at Mikkeli Central Hospital in Finland using the suPARnostic® TurbiLatex on a cobas c 501. The study included 100 acute medical patients who tested positive for SARS-CoV-2 at the Emergency Department at Mikkeli Central Hospital in Finland.[15]

Results of suPAR validation for stratification of COVID-19 patients regarding the risk of developing severe respiratory failure and requiring mechanical ventilation are shown in Table 4.

	90-day follow-up				
	Died	Survived	Total	PPV	NPV
High risk (suPAR >6.0 ng/mL)	5	44	49	10.2%	
Medium Risk (suPAR 4.0– 6.0 ng/mL)	0	27	27		
Low risk (suPAR <4.0 ng/mL)	0	24	24		100%
Total	5	95	100		
Sensitivity/specificity (< 4.0 ng/mL)	100%	25.3%			
Sensitivity/specificity (> 6.0 ng/mL)	100%	53.7%			

Table 4: 90-day development of respiratory failure in COVID-19 patients according to suPAR cut-offs.

LIMITATIONS
Clinical prognostication must not be based on the results of the suPARnostic® TurbiLatex test alone. Instead, the results must be interpreted considering the patient's clinical history and other diagnostic test results.

ANALYTICAL PERFORMANCE

SAMPLE STABILITY
Blood samples should be added to the instrument for automated sampling within 2 hours of sampling to avoid hemolysis.

Samples should preferably be analysed as soon as possible, but K2-EDTA and Lithium Heparin plasma samples are stable for:
- 24 hours at room temperature (20-25°C).
- 3 days at 2-8°C.

REQUIRED TRAINING
To use the suPARnostic® TurbiLatex Reagents, the user must be fully trained to operate the chemistry analyser.

PERFORMANCE CHARACTERISTICS
The results presented below were obtained with the use of the suPARnostic® TurbiLatex Reagents on the Beckman Coulter 5800 analyser.

RESULTS

The 1-Point Linear calibration model calculates results with the AB model that uses the Cal 5 (#T007) and Cal 0 Blank (#T007) as blank.

The method must be validated if another calculation method is used. Control the curve fitting using the suPARnostic® TurbiLatex Controls and undertake corrective actions if results exceed the upper and lower limit.

MEASURING RANGE

The measuring range of the suPARnostic® TurbiLatex test is 1,8 ng/mL to 16.0 ng/mL on the Beckman Coulter 5800 analyser.

It is not recommended to dilute samples with the results above the measuring range.

ANALYTICAL LIMITS

The Limit of Blank (LoB) was determined as the 95th percentile of observed 60 blank measurements.

The Limit of Detection (LoD) was calculated from measurement precision of 60 low-level sample determinations with Type II error (false negatives - β) at 5%.

The Limit of Quantification (LoQ) was determined from the precision and accuracy of the 60 low-level sample determinations with TE (Total Error for the analyte) of 30% toward the suPARnostic® Turbilatex kit on Roche Cobas c111.

Plasma type	**LoB**	**LoD**	**LoQ**
K2-EDTA	0.1 ng/mL	0.4 ng/mL	0.4 ng/mL
Lithium Heparin	0.4 ng/mL	0.7 ng/mL	0.7 ng/mL

All analytical limits were estimated following the guidelines of CLSI (Clinical and Laboratory Standard Institute) EP-17A protocol.

INTERFERENCE

Samples with abnormally elevated haemoglobin levels, lipids, or bilirubin may interfere with assay performance and sensitivity.

No interference was observed for the following concentrations.

Substance:	Concentration:
Bilirubin	350 µmol/L
Hemoglobin	1.4 g/L
Triglycerides	3.3 g/L
Rheumatoid Factor	>440 IU/mL
HAMA	Titer >640*

The interference studies were performed using a modified CLSI EP07-A2 protocol[13]. The interference study has been conducted on the Roche cobas c111 and the Siemens Atellica instrument.

Rheumatoid Factor and HAMA solutions were prepared by adding concentrated rheumatoid and HAMA solutions to human plasma pools.

In rare cases, gammopathy may produce inaccurate results, especially type IgM (Waldenström's

macroglobulinemia). Patients with a confirmed diagnosis of anti-TPO or other autoimmune-related diseases have been shown to interfere in a few cases.

Although precautions have been taken to minimise interference caused by heterophilic antibodies, erroneous results can be observed. Therefore, any suPAR value above 10 ng/mL should be carefully investigated, and unusually high results, e.g. above 20 ng/mL may be false-positive results caused by interference.

LINEARITY

The suPARnostic® TurbiLatex Reagents test is linear from 1.8 ng/mL to 26.5 ng/mL.

HOOK EFFECT

The suPARnostic® TurbiLatex Reagents test showed no prozone effect in concentrations up to 70 ng/mL.

PRECISION

Low, medium, and high samples were measured with two replicates in two separate runs per day for 20 days.

K2-EDTA plasma	Mean suPAR level (ng/mL)	Repeatability (CV)	Within-day precision (CV)	Between-day precision (CV)	Within-laboratory precision (CV)
Low	3.8	7,2 %	1.3%	5.5%	9.0%
Medium	5.6	6.6%	2.7%	4.9%	8.1%
High	8,7	6.0%	2.4%	6.3%	8.6%

Lithium Heparin Plasma	Mean suPAR level (ng/mL)	Repeatability (CV)	Within-day precision (CV)	Between-day precision (CV)	Within-laboratory precision (CV)
Low	4.1	6.1%	0.0%	5.9%	8.4%
Medium	5.9	6.2%	3.6%	4.1%	7.1%
High	9.0	6.8%	2.9%	3.7%	7.4%

The intermediate precision study was performed according to the CLSI EP05-A2 protocol.[13]

ACCURACY (METHOD COMPARISON)

Bias and correlation calculations toward the SuPARnostic® TurbiLatex Assay on Roche Cobas c111 were conducted with 105 samples measured with two lots of suPARnostic® TurbiLatex reagents over 21 days.

Results:

Sample Type	No. of pairs	Slope	Intercept	Pearson correl.	Range value
K2-EDTA plasma	105	1.00	0.00	0.990	2.5-19.0 ng/mL

Lithium-Heparin plasma	105	1.00	-0.30	0.987	2.9-19.8 ng/mL

X = suPARnostic® Turbilatex on Roche Cobas c111 Y = suPARnostic® TurbiLatex on Beckman AU5800

ANTICOAGULANT EFFECT (METHOD COMPARISON)

The suPARnostic® TurbiLatex is calibrated for plasma samples with K2-EDTA anticoagulant. Therefore, bias and correlation calculations toward K2-EDTA-based plasma samples should be considered when a Lithium Heparin anticoagulant is used.

Therefore, 45 samples from the same individual were collected in K2-EDTA and Lithium Heparin samples drawn from a single subject were measured with one lot of suPARnostic® TurbiLatex reagents and the results were compared.

Sample Type	No. of pairs	Slope	y-Intercept	Pearson correl.	Range value
Lithium Heparin Plasma	45	1.12	-0.06	0.982	2.2-12.1 ng/mL

X = suPARnostic® TurbiLatex on K2-EDTA-plasma. Y = suPARnostic® TurbiLatex on Lithium Heparin Plasma. Studies were performed using Siemens Atellica® bioanaylser.

When using plasma with Lithium-Heparin anticoagulant, the following correction factor must be added to offset the inherent matrix:

Correlated result = (Obtained result for Lithium Heparin plasma) – 0.0571)/1.1219

WASTE HANDLING

Discard unused reagents and waste according to country, federal, state, and local regulations.

REF	Σ	
Catalogue no.	Contains sufficient for <n> tests	Use by
IVD	°C °C	LOT
In vitro diagnostic medical device	Temperature Limits	LOT no. (Batch No.)

REFERENCES

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APPLICATION PARAMETERS

For the Beckman Coulter 5800 instrument

Parameters	Specific Test Parameters
General	

Test Name: *1 | Type: Plasma | Operation: Yes

Sample Volume		5.0	µl	Dilution	0	µl	OD Limit			
Pre-Dilution Rate		1		Diluent Bottle	Outside			Min. OD	-2	Max OD 3
Reagent Volume	R1(R1-1)	75	µl	Dilution	0	µl	Reagent OD Limit			
	R1-2		µl	Dilution		µl	1st.	Low	-2	High 3
							Last	Low	-2	High 3
	R2(R2-1)	25	µl	Dilution	0	µl				
							Dynamic Range	Low	0.000	High 150
Common Reagent	Type	None		Name	None		Correlation Factor	A	1	B 0
Wavelength	Pri.	570	nm	Sec.	None	nm	Factor For Maker	A	1	B 0
Method		FIXED								
Reaction Slope		+		Last	27		Onboard Stability Period		56 Day	0 Hour
Measuring Point-1	1st.	14		Last						
Measuring Point-2	1st.									
Linearity Limit			%							
Lag Time Check										

Parameters	Calibration Parameters
Calibrators	Calibration Specifics
GENERAL	

Test Name: *1 | Type: Plasma | Cuvette:

Calibration Type: AB | Formula: Y = AX + B | Counts: 3

<Calibrator Parameters> | Slope Check:

	Calibrator	OD	Conc.	Factor Range Low	Factor Range High
Point-1	suPAR Cal 5		2*	-9999	9999
Point-2					
Point-3					
Point-4					
Point-5					
Point-6					

Allowable Range-Check
□ Reagent Black
□ Calibration

Advanced Calibration
Operation: Yes
Interval (RB/ACAL): Bottle/Bottle

<Point Cal. For Master Curve> | No. of Correction Points | Use Master Curve | □ Lot Calibration

	Calibrator	OD	Conc.	OD Range Low	OD Range High
Point-1					
Point-2					

Stability
Reagent Blank: 30 Day 0 Hour
Calibration: 30 Day 0 Hour

MB Type Factor | 1-Point Calibration Point | □ With conc-0

***1: User-defined value**

***2: Batch-specific concentrations - see CoA**

***3: User defin**