Urine Lambda Light Chains (uLLC) – Immunoturbidimetric method

IVD CE

For Konelab - Indiko® systems

Instructions for Use (IFU)

ORDERING INFORMATION

Format	Code	Composition
Kit 1 x 30 mL – 1 x 4 mL	REF B78282279	n° 1 vials x 30 mL R:A n° 1 vials x 4 mL R:B n°1 vial x 60 mL R.C*

* In case of use on Indiko Analyser transfer the content into the additional empty vial

INTENDED USE

Diagnostic immunoturbidimetric test for the quantitative determination IVD of Lambda Light Chains (uLLC) in human urine. All results must be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE

The organism normally eliminates small amounts of proteins in the urine and their presence is generally known as "physiological proteinuria". Higher, transitory levels of proteinuria can be detected, among other situations, following energetic physical activity or after prolonged exposure to cold temperatures (benign or functional albuminuria). On the other hand, the persistent presence in the urine of protein levels higher than 150 mg/24 h is an indication of a pathological condition. Proteinuria can be divided into different types: pre-renal, due to extra-renal disease characterized by the elimination of low molecular weight proteins such as Bence-Jones proteins; renal (glomerular and tubular), due chiefly to glomerular and tubular lesions with consequent lack of reabsorbance of microglobulins, and characterized by the release of higher molecular weight proteins; post-renal due to inflammatory processes in the descending urinary tract and again characterized by the release of high molecular weight proteins.
From a diagnostic viewpoint it is therefore necessary to perform a preliminary rapid, accurate selection of the urine samples as such, in order to identify those cases of physiological proteinuria, differentiating these from the pathological situations, especially if these are characterized by low protein concentrations, as occurs in some forms of Bence-Jones proteinuria.
An accurate quantitative determination of the various plasma components and their respective ratios in weight, can also constitute a useful diagnostic tool, either alone or associated with other analytical techniques, to perform a diagnosis.
In this respect, the immunoturbidimetric quantitative test of the concentration of Kappa (uKLC) and Lambda (uLLC) light chains and their ratio in the urine, can constitute a valid instrument in the diagnosis of myelomas, Waldeström disease, primary amylosis or lymphomas, which can present with the elimination of light chains of Lambda or Kappa immunoglobulins (Bence-Jones proteins).

PRINCIPLE OF THE METHOD

Immunoturbidimetric method. The uLLC contained in the test sample reacts with the specific antibodies, resulting in immunocomplexes. The turbidity formed in this way is read photometrically at λ 340nm and it is proportional to the uLLC concentration in the sample. The quantitative analysis is obtained by interpolation of this photometric value with those found by testing known concentrations of uLLC.

Storage and stability

= **Storage temperature 2-8 °C**

If stored at 2-8°C avoiding direct light, the intact reagents remain stable until the expiration date, printed on the label. Slight variations in composition among batches will not affect test results.

Concentrations

Reagent A			
		Conc.	**U.M.**
Urinary Proteins Buffer	TRIS pH 8.3	150	mmol/L
	NaCl	100	mmol/L
	EDTA	10	mmol/L
	NaN_3	< 0.1	%
Reagent B			
Latex Particles coated with antibodies against LLC	NaN_3	< 0.1	%
Reagent C			
Sample Diluent	PBS	0,015	mol/L
	NaN_3	< 0,1	%

Materials included in the kit
Reagent as described above.
Necessary materials not included in the kit
Controls and calibrators.

PRECAUTIONS and WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. Reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Regulation 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. Do not use the reagent if it is visibly degraded (e.g. presence of corpuscles).
5. All human samples shall be handled and disposed of as potentially infectious material.
6. The kit should only be used by qualified and properly trained technical personnel.
7. Diagnoses shall be carried out exclusively by authorised and qualified personnel.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that complies with current regulations.

Reporting of serious incidents

In the event of a serious incident in relation to the use of the device, please inform the manufacturer (via your distributor) and the competent authority of the European Union member state where the incident occurred. For other jurisdictions, reporting must be made in accordance with regulatory requirements. Reporting serious incidents helps provide more information about the safety of the diagnostic medical device.

PREPARATION OF THE REAGENT

The Reagents are liquid, ready for use. After opening, the Reagents are stable until the expiry date if kept as indicated in "Storage and stability".

PROCEDURE

Quality Control

Use the Sclavo Diagnostics Int. Controls: Urinary Proteins Control Low REF B47182223 and High REF B47182224 for your quality control purposes at least once a day. Repeat the analysis also after calibration. Obtained values must be within the range of acceptability.

ANALYTICAL TECHNIQUE

For automatic procedures, consult the instruction manual and applicable notes for the Konelab® - Indiko®. analyzers. All applications not specifically approved by Sclavo Diagnostics Int. cannot be guaranteed in terms of performance and must be evaluated by the user.

Calibration

For calibration, use the Sclavo Diagnostics Int. Urine Proteins Single Level Calibrator REF B47182222, in accordance with methodology applying to Konelab® - Indiko® series.

Traceability

The uLLC value has been determined according to the IFCC using the reference material.

SAMPLE

Sample types and storage

Samples are represented by normal urine specimens that are routinely delivered to the laboratory; the tests can be performed on both early morning specimens and on 24-hour collections. No special preparation of the patient is necessary.
The samples must be pre-diluted 1:10 before analysis.
Urine samples must be brought to room temperature before testing, and centrifuged at 2500 rpm for 15 minutes. The clear supernatant is used for the analysis. .

Calculation of results on Konelab® - Indiko® systems

Results are automatically calculated by analyzer based on the calibration curve. The analyzer automatically performs serial dilutions from a primary standard according to the method protocol. The calibration curve is obtained by interpolating the values obtained with an appropriate algorithm.

REFERENCE RANGE

0 – 9 mg/L;
0 – 5,1 mg/g Creatinine;
0 – 0,56 mg/mmole Creatinine.
As sex, age, geographical location and other factors can influence the normal values found in the population, each laboratory should determine its own normal, medium and pathological values for its own population.

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CHARACTERISTICS/PERFORMANCE

Analytical Range – Antigen excess

The analytical range was tested using a strongly positive sample and serial dilutions in saline solution. The method guarantees a correct response throughout the minimal detectable measurement range and the calibrator higher concentration.
The present method does not show Antigen Excess until 1000 mg/L.

Trueness

The Trueness of the analytical results has been determined according to the CLSI EP15-A2 guideline, using human urine samples. The data obtained are shown in the following table (confidence interval 95%).

Level	Replicates	Mean (mg/L)	SD	CV%
Low	25	19.988	1.6986	8.5
High	25	60.714	4.6037	7.6

Specificity

The method is 100% specific for Urine Kappa Light Chains (uLLC).

Interferences

The influence of the following substances on the analytical response was tested up to the concentrations reported below:
Bilirubin 50 mg/dL, Ascorbic Acid 50 mg/dL, EDTA 10 mM, Hemoglobin 500 mg/dL, Sodium citrate 1000 mg/dL, Sodium Heparin 40 mg/mL, Triglycerides 2%, Rheumatoid Factor 2000 IU/mL.
No appreciable interference was found in any case, and the variations observed were within the expected precision range. Higher concentrations were not tested.
However, in view of the wide heterogeneity of potentially interfering substances and pharmaceuticals, for diagnostic purposes the results of this test must always be taken into consideration in conjunction with the clinical history of the patient, other clinical tests and medical investigations.

Precision

The Precision of the analytical results has been determined as Repeatability and Total Precision according to the CLSI EP15-A2 guideline, using human urine samples. The data obtained are shown in the following table (confidence interval 95%).

Within-run Precision – Repeatability				
Level	**Replicates**	**Mean (mg/L)**	**DS**	**CV%**
Low	25	19.988	0.334	1.7
High	25	60.714	1.059	1.7
Total Precision (Within-lab Precision)				
Level	**Replicates**	**Mean (mg/L)**	**DS**	**CV%**
Low	25	19.988	1.855	9.3
High	25	60.714	5.021	8.3

Limits of sensitivity

The Sensitivity limit has been measured using serial dilutions of high concentrated urine. The smallest measurable concentration is 3.1 mg/L.

Comparison between methods

The present method was compared with another commercially available method following the guidelines of the CLSI EP09-A2-IR, analyzing 48 human urines with a concentration between 0.32 e 110.145 mg/L. The correlation data between the two methods are reported in the table below.

Parameter	Estimation
Intercept	1.4415
Slope	1.021
Correlation Coeff. (R)	0.990

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

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REVISION	DATE	CHANGE
Rev.E	06/2024	New Issue for IVDR Regulation (UE) 2017/746 compliance

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