Creatinine – Colorimetric method Jaffè
Instructions for use (IFU)

IVD CE

ORDERING INFORMATION

	Code	Composition
OPEN KONELAB INDIKO	REF B75182519	n° 6 vials x 54 mL (R.A) n° 4 vials x 18 mL (R.B)
	REF B75182520	n° 8 vials x 18 mL (R.A) n° 2 vials x 16 mL (R.B)
CHEMILAB	REF B81180091	n° 2 vials x 33 mL (R.A) n° 1 vials x 8 mL (R.B)
	REF B81180092	n° 8 vials x 32 mL (R.A) n° 4 vials x 7 mL (R.B)

INTENDED USE

Product for use in the quantitative determination in vitro of the Creatinine concentration in human serum or urine. The results of the test must always be interpreted in conjunction with the clinical context. FOR PROFESSIONAL USE ONLY.

CLINICAL SIGNIFICANCE

Creatinine is synthesized in the kidneys, the liver and the pancreas, and is subsequently transported in the blood to other organs such as the muscles and the brain. As the production of endogenous Creatinine is proportional to the muscular mass, it varies according to age and sex. The influence of the amount of meat taken in daily in the diet can be considered to be approximately 10%. In general, however, daily fluctuations in the Creatinine present in the diet cause only minor variations in the daily excretion levels. High Creatinine levels are seen in cases of acute or chronic renal insufficiency and in dehydration.

PRINCIPLE OF THE METHOD

Method colorimetric with the detection system Jaffè. Jaffé was the first to describe the reaction which takes place between Creatinine and an alkaline picrate solution, with formation of a coloured compound. Subsequently the method used for the determination of serum Creatinine was modified to improve its specificity. Creatinine reacts with alkaline picrate, forming a coloured compound which is measured at 500-520 nm. The rate of the colour formation is proportional to the creatinine concentration.

Storage and stability

= storage temperature 2-8°C

If stored closed at 2-8 ° C, avoiding direct light, the intact reagents are stable until the expiration date, printed on the label.

Composition

Reagent A			
	Conc.	**U.M.**	
Picric Acid	20,5	mmol/L	*GHS05
Reagent B			
Sodium Hydroxide 5%	1,25	mmol/L	*GHS05

Signal word: **DANGER**

RB: Contains: Sodium hydroxide (CAS 1310-73-2)

H314 - Causes severe skin burns and eye damage.

P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 - Immediately call a POISON CENTER/doctor.

P321 - Specific treatment (see on this label).

P501 - Dispose of contents/container in accordance with local / regional/national/international regulations.

Reagents included in the kit

The reagent is described above.

Materials required but not supplied in the kit

Controls, calibrators and pipettes with adequate volume.

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.

PROCEDURE

Quality control

Control sera with a known titer of Creatinine are commercially available for quality control, with values and confidence limits included. Sclavo Diagnostics Normal and pathological control sera are available: Clinicontrol N 5x5mL cod. B35181700 and Clinicontrol A 5x5 mL code B35181701. The values obtained must be within the acceptability range.

Calibration

For calibration use the "Calibrator serum Sclavo" code B35181702.

Traceability

The Creatinine traceability is reported in the package insert supplied with the "Calibrator Serum".

SAMPLE

Type of sample and storage

Creatinine in serum or urine samples is stable for 24 hours when stored at 2-8°C. Use fluoride or fluoride with thymol as preservatives to keep creatinine at room temperature for about 5 days. If frozen at – 10°C, creatinine is stable in serum for a few months. Use undiluted serum or urine collected within 24 hours diluted 1:100 with distilled water.

PREPARATION OF THE REAGENT

Add 1 volume of Reagent B to 9 volumes of Reagent A, mix by inversion. The reagent is thus ready for use. The stability of the reagents thus prepared is 5 days if closed and kept at a temperature of 2-8 ° C away from direct light. Their slight variation in color, from batch to batch, does not affect the test results.

Automation

The kit can be used with all automatic analyzers that can meet the operating conditions of the reagent while maintaining the volumetric ratios R1 / R2 / C. Validated applications are available for Sclavo Konelab® - Indiko® and CHEMILAB instruments. Applications not approved by Sclavo Diagnostics do not guarantee the performance of the reagent and must therefore be approved under the responsibility of the user.

MANUAL METHOD

The kit, in Open format, can be used manually through the use of spectrophotometer or photometer with the following parameters:

Reaction conditions

Wavelength (primary):	510 nm
Temperature:	37°C
Reaction	End Point (Increasing reaction)

Technique – Monoreactive method

Bring the reagents to reaction temperature and operate away from direct light.

	U.M.	Blank	Calibr. Serum	Sample
Reagent A+B	µL	1000	1000	1000
Sample	µL	-	40	-
Calibr. Serum	µL	-	-	40
Blank	µL	40	-	-

Mix well the solution and exactly 10 second after sample or standard addition, take the first reading. Exactly 1 minute after the first reading, repeat the reading. Measure the absorbances of sample and calibrator serum against reagent blank.

Reaction volumes may be varied proportionally without alteration of results.

Results

Creatinine concentration is calculated with the following formula:

$$\frac{\Delta \text{O.D. Sample}}{\Delta \text{O.D. Calibrator Serum}} \times \text{Conc. Calibrator Serum} = \text{Creatinine mg/dL}$$

$$\frac{\Delta \text{O.D. Sample}}{\Delta \text{O.D. Calibrator Serum}} \times \text{Conc. Calibrator Serum x 100} = \text{Creatinine in urine mg/dL}$$

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Automation
The results are automatically calculated by the analyzer based on the calibration line. The analyzer automatically performs calibration in accordance with the method protocol. The calibration line is calculated automatically by the different instruments.

REFERENCE RANGE
Serum:
- Male and female: 0.6 – 1.3 mg/dL (53-115 µmol/L)

Urine collected within 24 h:
-Male and female: 14 - 26 mg/ Kg weight/24 h

Each laboratory must establish its own normal-range values on the basis of its population

ANALYTICAL CHARACTERISTICS / PERFORMANCE
Linearity
The reaction is linear up to 22.6 mg/dL (1999µmol/L).
If the value in the sample exceeds the linearity limit of the method, dilute the sample with saline and multiply the result for the dilution factor.

Trueness
The Trueness of the analytical results has been determined accordingly to the CLSI guidelines, using commercial control sera. The data obtained are shown in the following table.

Serum – Plasma

Level	Replicates	Mean	SD	CV%	Recovery
Low	5	0.58	0.02	3.45	105,3 %
High	5	1.72	0.02	1.16	93 %

Urine

Level	Replicates	Mean	SD	CV%	Recovery
Low	5	60.30	0.50	4.20	102,03%
High	5	91.16	0.79	4.40	109,9 %

Interference

Interference	Limits
Glucose	**600 mg/dL**
Fructose	**200 mg/dL**
Acetone	**20 mg/dL**
Ascorbic Acid	**20 mg/dl**

Precision of the method

Accuracy in the series (Within-run precision) – Repeatability					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	1,44	0,03	2,08	30
High	mg/dL	5,86	0,08	1,37	30
Total precision (Within-lab precision)					
Range	U.M.	Mean	S.D.	C.V. (%)	No.
Low	mg/dL	1,31	0,042	3,21	30
High	mg/dL	5,55	0,082	1,48	30

Limit of Sensitivity
The limit of sensitivity was measured by analyzing scalar dilutions of a concentrated serum. Under the conditions established for this test the lowest detectable concentration is 0.04 mg/dL creatinine.

Comparison between methods
The method was compared with a similar commercially available method, analyzing 40 human serum and urine samples. The correlation data between the two methods are reported in the table below.

Serum:

Parameter	Estimation
Intercept	0,080
Slope	1,0111
Correlation Coeff. (R))	0.975

Urine:

Parameter	Estimation
Intercept	2,943
Slope	1,0181
Correlation Coeff. (R))	0.953

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	

REFERENCES

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5. **Clinical Laboratory Standards Institute (CLSI).** User Verification of Performance for Precision and Trueness; Approved Guideline – Second Edition. EP15-A2.
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8. **Clinical Laboratory Standards Institute (CLSI).** Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition – EP17.
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REVISION	DATE	CHANGE
Rev.A	01/2023	New Issue for IVDR Regulation (UE) 2017/746 compliance

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