Creatinine

CYPRESS DIAGNOSTICS

CE

IVD

Jaffé. Colorimetric. Kinetic
without deproteinization
Liquid

Store at 2 - 25 °C

Configuration

REF	HB0080	HB0080A	HB0080M
VOL	2 x 125 mL	8 x 125 mL	8 x 30 mL
Reagent 1	1 x 125 mL	4 x 125 mL	4 x 30 mL
Reagent 2	1 x 125 mL	4 x 125 mL	4 x 30 mL
Standard	1 x 5 mL	4 x 5 mL	-

Intended use

The Cypress Diagnostics kit Creatinine is an in vitro diagnostic medical device intended to be used for the quantitative measurement of creatinine in human serum, heparinized plasma or urine. The device is not automated. The measurement of creatinine is intended to be used for the screening for and aid in diagnosis of kidney disease and the monitoring of the effectiveness of kidney disease treatment. This kit is intended to be used by healthcare professionals in a laboratory-based testing environment.
For *in vitro* diagnostic use only. For professional use only.

Clinical significance

Most of the creatine is found in muscle tissue where it is present as creatine phosphate and serves as a high energy storage reservoir for conversion to ATP. Creatinine, the waste product of this reaction, is transported to the kidneys and eliminated. Independent of the diet, serum creatinine concentration depends almost entirely upon its excretion rate by the kidneys. For this reason, its elevation is highly specific for kidney diseases.
Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle

Creatinine in a basic picrate solution forms a red complex as described by Jaffé. The Δ absorbance at predetermined times during conversion is proportional to the concentration of creatinine in the sample. The chosen time intervals for measurement avoid interferences from other serum constituents.

Reagent composition

Reagent 1	Picric Reagent Picric acid solution (25 mmol/L)
Reagent 2	Alkaline Reagent Sodium Hydroxide (0,29 mol/L)
Standard	Creatinine aqueous (see value on label)

Precautions

- Danger. H314: Causes severe skin burns and eye damage. P260: Do not breathe dust/fume/gas/mist/vapours/spray. P264: Wash hands and exposed skin thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P501: Dispose of contents/container in an appropriate container observing applicable local regulations.
- All body fluid samples should be considered potentially infectious materials and the appropriate precautions should be taken. Wear personal protective equipment such as gloves, safety glasses, lab coats or aprons when working with possible biohazard contaminants.
- Use Good Laboratory Practices (GLP) when handling this product.
- Please refer to the MSDS, available on our website, for further information.

Preparation

Mix proportionally 1:1 R1 Picric Reagent and R2 Alkaline Reagent. The working reagent is stable for 10 days at 15 - 25 °C.

Storage, stability and disposal

All the components of the kit are stable up to the date of expiration as specified on the label, when stored tightly closed, protected from light and contaminations prevented during their use. Storage temperature for this kit is 2 - 25 °C.
Handle standard very carefully to prevent contamination. The reagent should be a clear solution. If turbidity or precipitation has occurred or if blank absorbance at 510 nm ≥ 1,80, the reagent should be discarded.
Do not use the product if deterioration or contamination is suspected or beyond the expiration date or open container stability period. Dispose unused or deteriorated product and waste in compliance with local regulations.

Additional material required but not provided

- Spectrophotometer or colorimeter. Minimum analyzer specifications:
  Measuring at 510 nm (500 - 510)
  Linear measuring range: 0 - 2 AU
- Cuvettes, matching the analyzer used (1,0 cm light path)
- General laboratory equipment

Samples

Sample type: human serum, heparinized plasma or urine
- Serum or heparinized plasma: creatinine is stable 24 hours at 2 - 8 °C.
- Urine: diluted 1:50 with distilled water. Multiply the results by 50 (dilution factor). Creatinine is stable for 7 days at 2 - 8 °C.

Procedure

Make sure the reagents and samples are at room temperature.
1. Wavelength 510 nm (500 - 510); Temperature 37 °C/15 - 25 °C; Cuvette (1 cm light path).
2. Adjust the instrument to zero with distilled water.
3. Pipette into a cuvette:

For Blank	1,00 mL Working reagent
For Standard [Note 4]	100 µL Standard + 1,00 mL Working reagent
For Sample	100 µL Sample + 1,00 mL Working reagent
Mix and start stopwatch. Read A1 after 30 sec. and A2 after 90 sec. of the sample addition.	

Calculation

Calculate ΔA = (A2 - A1)
Serum and plasma:

$$Creatinine\ \left(\frac{mg}{dL}\right) = \frac{\Delta A\ Sample}{\Delta A\ Standard} \times stand.conc.\left(\frac{mg}{dL}\right)$$

Urine (24h):

$$Creatinine\ \left(\frac{\frac{mg}{kg}}{24h}\right) = \frac{\Delta A\ Sample}{\Delta A\ Standard} \times stand.conc.\left(\frac{mg}{dL}\right) \times \frac{vol\ (dL) urine 24h \times f^{*}}{weight\ of\ patient\ (kg)}$$

*f = dilution factor

Conversion Factor:
Serum and plasma: µmol/L = 88,4 x mg/dL
Urine (24h): µmol/kg/24h = 8,84 x mg/kg/24h

Quality control

Control sera are recommended for the qualification of the reagents and to monitor the performance of assay procedures. Next to legal requirements, we recommend to perform Quality Control on a daily basis and after each calibration.
Use Biochemistry Normal and Pathological Controls (HBC01, HBC02). If other controls (not manufactured by Cypress) are used, they have to be validated by the user as they can vary. Prepare and measure these controls the same as samples. Measure at least one replicate per control.
If control values are found outside the defined range, check the instrument, reagents and calibrator for problems. Do not continue testing as the results will be invalid. Each laboratory should establish its own QC scheme and corrective actions if controls do not meet the acceptable tolerances.

Reference values

Serum or plasma - Male	0,70 - 1,40 mg/dL (62 - 124 µmol/L)
Serum or plasma - Female	0,60 - 1,10 mg/dL (53 - 97 µmol/L)
Urine - Male	10 - 20 mg/kg/24h (88 - 177 µmol/kg/24h)
Urine - Female	8 - 18 mg/kg/24h (71 - 159 µmol/kg/24h)

These values are for orientation purpose. Each laboratory should establish its own reference range.

Performance characteristics

Measuring range: from 0,115 mg/dL (detection limit) to 15 mg/dL (linearity limit). If the obtained results are greater than 15 mg/dL, dilute the sample 1:2 with saline solution, repeat the determination, and multiply the result by factor 2.

Precision:

	intra-assay (n=20)		inter-assay (n=20)	
Mean (mg/dL)	1,07	3,47	1,05	3,41
SD	0,021	0,04	0,018	0,052
CV (%)	1,99	1,17	1,68	1,53

Sensitivity: 1 mg/dL = 0,0288 ΔA/min

Accuracy: Results obtained using CYPRESS DIAGNOSTICS reagents did not show systematic differences when compared with other commercial reagents.
The results of the performance characteristics depend on the analyzer used.

Interferences

No interference of hemoglobin (22 mg/dL) and ascorbic acid (34 mg/dL). A list of drugs and other interfering substances with creatinine determination has been reported by Young et al.

Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium
www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be

Notes

1. **For best use of this kit on a Cypress Diagnostics analyzer, we kindly advise to follow the application sheets of the respective analyzer. Please log in to our website (www.diagnostics.be) as a registered user to download the latest application sheets, which are located under the section of the corresponding analyzer. Compatible Cypress analyzers: CYANSmart, CYANStart, CYANExpert 130, CYANVision.**
2. **In case other instruments (not manufactured by Cypress Diagnostics) are used, the laboratory is responsible to validate the reagents in this kit on those analyzers before testing patient samples.**
3. **For this kit, application sheets for the following Mindray analyzers are available (see website): Mindray BS-120, BS-200, BS-200E.**
4. **Calibration with the aqueous standard may cause a systematic error in automatic procedures. In this case, it is recommended to use a serum based Biochemistry calibrator (HBC03).**

Bibliography

1. **Murray R.I. Creatinin. Kaplan A et al. Clin Chem The C.V. Mosby CO. St.Louis. Toronto. Princeton 1984; 1261-1266 and 418**
2. **Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press 1995**
3. **Young DS. Effects of diseases on Clinical Lab. Tests 4th ed AACC Press 2001**
4. **Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999**
5. **Tietz N W et al. Clinical Guide to Laboratory tests, 3rd ed AACC 1995**

Notice: Any serious incident that has occurred in relation to the device shall be reported to Cypress Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

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Cypress Diagnostics: Nijverheidsstraat 8 • 2235 Hulshout • Belgium
www.diagnostics.be • Tel: ++ 32 15 67 67 68 • e-mail: cypress@diagnostics.be