POTASSIUM LS Mono

IVD

Quantitative determination of Potassium in Serum, Plasma, Urine. Turbidimetric method (Tetraphenilborate). Endpoint.

REF CC1360 R1:2x40 mL + R2: 1x3 mL (standard)

METHOD AND PRINCIPLE

Potassium ions react with Sodium Tetraphenylborate giving rise to a stable turbidity whose optical absorbance, which can be measured photometrically at 578 nm, is proportional to the concentration of potassium in the sample under examination.

CLINICAL SIGNIFICANCE

Potassium is a cation (positively charged ion) predominantly intracellular. It helps regulate the osmotic balance of the cell membrane and therefore the cell volume. Its equilibrium with sodium, another fundamental ion, is maintained by the sodium-potassium pump, which carries sodium outside the cell and potassium inside.

Hyperkalaemia occurs in cases of acute and chronic renal failure, adrenocortical insufficiency, hypohaldosteronism, metabolic and respiratory acidosis, diabetic coma, hemolytic crisis, burns, malignant hyperthermia, use of potassium-sparing diuretics, potassium salts, ACE inhibitors, beta-blockers .

Hypopotassiemia occurs in cases of hypercortico-adrenalism, hyperaldosteronism, metabolic and respiratory alkalosis, Bartter's syndrome, renal tubular acidosis types I and II, chronic interstitial nephritis, renal failure, vomiting, diarrhea, laxative abuse, digestive fistulas, malabsorption, Westphal disease, use of thiazide diuretics, loop diuretics, cortisones, phenothiazines, insulin.

REAGENT COMPOSITION

Reagent (R1)

Tris buffer	50 mmol/L.
Tetraphenilborate	102 mmol/L

Reagent (R2)

Standard (Potassium)	value on label

REAGENT PREPARATION AND STABILITY

Liquid and ready to use reagents, stable until the expiry date shown, if stored as indicated on the label and avoid contamination, evaporation and prolonged exposure to direct light. Do not freeze the reagents.

Discard the reagent if signs of deterioration appear, such as the presence of particles and turbidity or failure to recover the values of certified control sera.

After opening the bottles, it is advisable to withdraw the necessary volume, to immediately close the bottles and store them in the fridge in order to avoid contamination, degradation from direct light and evaporation.

SPECIMEN

Serum, heparinized plasma, 24 hours-urine.

Do not use EDTA plasma. Avoid hemolysate or lipemic samples.

Collect urine without any additive, then dilute the sample 1:10 (1+9) with distilled water.

Separate the serum from the clot quickly.

Serum / Plasma stability: 6 days at 2-8° C ; 3 months at -20° C

Urine stability: 14 days at 2 – 22° C ; 3 months at -20° C

Discard contaminated samples.

PROCEDURE

Wavelength:	578 nm
Temperature:	37° C
Measurement:	against Reagent Blank

Pipette as follow:

R1 Reagent	1000 µL
Sample, Std / Cal	25 µL

Mix and incubate for 5 minutes. Read Absorbance against Reagent Blank within 30 minutes.

CALCULATION

Serum / Plasma

$$\text{Potassium} = \frac{\text{Abs Sample}}{\text{Abs Std/Cal}} \times \text{Concentration Std/Cal}$$

Urine

Calculate as for the serum/plasma and multiply the result by 10 (initial sample dilution).

Potassium [mmol/24h] = Urinary Potassium x Urine Volume 24 h (L)

Conversion factor: Potassium 1 mmol/L= Potassium 1 mEq/L

CALIBRATION

The results depend on the accuracy of the calibration, on the correct setting of the test on the instrument, on the correct volumetric ratio of reagent / sample and on the correct analysis temperature.

As an alternative to the standard included in the package, it is possible to use **MTD Diagnostics Calibrator**:

Chemistry Multicalibrator - REF CAL1010 (10 x 3 mL)

QUALITY CONTROL

Normal and abnormal control sera of known concentration should be analysed routinely with each group of unknown samples utilizing **MTD Diagnostics** Quality Control Material:

Chemistry Control N - REF CNN1010 10 x 5 mL (Level 1)
Chemistry Control P - REF CNP1020 10 x 5 mL (Level 2)

EXPECTED VALUES

Adults:

Serum	3.6 - 5.5 mmol/L
Plasma	4.0 - 4.8 mmol/L
24-hours Urine	25 – 125 mmol/L

Each laboratory should establish a range of expected values based on its patient population and, if necessary, determine its own reference interval. For diagnostic purposes, results should always be assessed together with the patient's medical history, clinical examination and other results.

PERFORMANCE

PRECISION:
Low Level: Samples= 20; Average = 3.99; S.D. = 0.11; CV = 2.75%
High Level: Samples = 20; Average = 6.10; S.D. = 0.08; CV = 1.24%

ACCURACY (CORRELATION): A comparison between this method (x) and a certified method of trade (y) gave the following correlation:

y=1.0526x-0,31 ; r=0.95

SENSITIVITY: 0.6 mmo/L

LINEARITY: 0.6 – 10.0 mmo/L

SPECIFICITY / INTERFERENCES

Bilirubin does not interfere up to concentration of 10 mg/dL.
Hemoglobin, as a consequence of haemolysis, interferes giving falsely elevated results. Triglycerides, giving a turbidity to the sample, interfere with the turbidimetric method. Other substances can interfere.

NOTES

1. This method may be used with different instruments. Any application to an instrument should be validated to demonstrate that results meet the performance characteristics of the method. It is recommended to validate periodically the instrument. Contact your distributor for any question on the application method.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.
3. Use only water without sodium, potassium and calcium ions.

PRECAUTIONS

R1 contains TETRAPHENILBORATE 102 mmol/L – CAS N. 143-66-8 - Xn R22 (H302).
R22 (H302): Harmful if swallowed.

The product does not contain any other hazardous substances or mixtures according to EC Regulation No. 1272/2008 (CLP) or their concentrations are such that they are not considered to be persistent, bioaccumulative or toxic (PBT). Therefore, it is not subject to the special labeling required by the aforementioned regulation. The product is labeled according to the directive for CE marking (98/79 / EC). Sodium Azide less than 0.1%.
However, in compliance with the normal prudential rules that everyone has to keep managing any chemical or laboratory reagent, in case of contact of reagents with the operator, you must apply the following first aid:
S26 (P305 – P351 – P338): In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 (P302 – P352): After contact with skin, wash immediately with plenty of water.
S36/37/39 (P280): Wear suitable protective clothing, gloves and eye/face protection.
S46 (P301 – P310): If swallowed, seek medical advice immediately and show container or label. If victim is conscious and alert, wash out mouth with water.
S56 (P273): Dispose of this material and its container at hazardous or special waste collection point.
S63 (P304 – P340): In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, give oxygen and get medical aid.

FOR MORE INFORMATION, REQUEST SAFETY DATA SHEET FOR REAGENT (MSDS) AT THE MANUFACTURER.

All samples, calibrators and controls should be treated as potentially infectious material capable of transmitting HIV and hepatitis.

SIMBOLOGY

CE	CE Mark (EC Directive 98/79)		
IVD	In Vitro Diagnostic		Temperature Limitation
	Consult instructions for use		Contains sufficient for <n> test
REF	Catalog Number		Use By
LOT	Batch Code		Manufacturer

BIBLIOGRAPHY

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