TECO DIAGNOSTICS
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POTASSIUM
TC MATRIX-160

INTENDED USE
The test is applied for the in-vitro quantitative determination of potassium in serum, plasma, and urine

TEST SUMMARY AND PROCEDURE [1,2,3,4,5]
Potassium is determined enzymatically via potassium dependent pyruvate kinase activity using phosphoenol- pyruvate as substrate. The formed pyruvate reacts with NADH in the presence of LDH to form Lactate and NAD. The corresponding decrease in absorbance at 340 nm is proportional to the potassium concentration.

$$PEP + ADP \xrightarrow{K+/(PK)} Pyruvate + ATP + PK + LDH$$

$$Pyruvate + NADH + H^+ \xrightarrow{LDH} Lactate + NAD^+$$

TEST PARAMETERS
Method : Enzymatic Colorimetric
Wavelength : 340 nm
Linearity : 10 mmol/L

REAGENT COMPOSITION
Reagent 1. Buffer/Enzymes

Tris buffer	≤ 280 mmol/L pH 8.2
Cryptand	≤ 14 mmol/L
PET	≥ 3.3 mmol/L
ADP	≥ 3.15 mmol/L
α - oxoglutarrte	≥ 1.2 mmol/L
NADH	≥ 0.35 mmol/L
GLDH	≥ 11 U/mL
PK	≥ 1.2 U/Ml

Reagent 2. Enzymes

LDH	≥ 65 U/mL

Low Standard	3 mmol/L
High Standard	7 mmol/L

Reagent Preparation
Reagents are ready to use.

REAGENT STORAGE AND STABILITY[6]
Reagents are stable at 2-8º C until the expiration date stated on the label which is only for the closed vials.

Once opened vials are stable for 30 days at 2-8º C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A Protocol.

SAMPLE
Serum and plasma treated with lithium heparinate are collected according to the standard procedures. Potassium in serum is stable for:
1 week at 2-8°C,
1 year at -20°C.

Potassium in urine is stable for:
1 week at +20/+25°C,
2 weeks at 2-8°C,
30 days at -20°C

Unit Conversion:
mmol/L x 3.9682 = mg/dL

REFERENCE INTERVAL (NORMAL VALUES) [7]
3.5-5.1 mmol/L
It is recommended that each laboratory establish its own normal range. Reference interval has been verified by using CLSI EP28- A3c protocol.

QUALITY CONTROL AND CALIBRATION
Commercially available control material with established values determined by this method may be used.

The assay requires the use of an Auto Calibrator / Potassium Calibrator. Two levels of controls should be assayed at least once a day. Obtained values should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be followed:
1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

Calibration Stability
It strongly depends on the application characteristics of in-use auto analyzer and capacity of cooling. Calibration stability is 15 days.

If controls are not within acceptable limits, calibration is required, and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PROCEDURES

Test Name:	K	R1:	116
Full Name:	Potassium	R2:	34
Pri. Wave:	340 nm	Sample Volume:	3
Sec. wave:	405 nm	Calibration Type:	2 point linear
Assay/Point:	Fixed Time	K value:	/
Start-End:	14 - 23	Reference Interval:	3.5 - 5.1
Decimal Place:	2	Point:	2
Unit:	mmol/L	Blank Type-	Water
Linearity Range:	2.000– 10.000	Point (0) Blank Con.:	0.0
Correlation Factor:	1.0000-0.0000	Point (1) STD. Con.:	Standard/ Calibrator

PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD): The limit of the test detection is 0.8 mmol/L.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ≤ 20%]:[8] 2 mmol/L
LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 10 mmol/L.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.
Linearity may vary considerably depending on the instrument used.

Precision Studies [9]

Repeatability (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
4.04	0.04	0.93	20
6.14	0.04	0.59	20

Repeatability (Day to Day) (Inter-Assay)

Mean Concentration	SD*	CV%	n
3.98	0.046	1.16	20
6.14	0.106	1.76	20

**SD: Standard Deviation*

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Method Comparison:[10, 11]

Correlation with a comparative method is: r= 1.0
According to Passing-Bablok Fit:
Slope: 0.94 , Intercept: 0.20

Interference: [3, 4, 12]

No significant interactions were observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given.
Bilirubin ≤ 665 µmol/L
Hemoglobin ≤ 1.0 g/L
Lipemia ≤ 24.2 mmol/L

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.
Interferences may affect the results due to medication or endogenous substances.
These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

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