

**INTENDED USE**

The TRUEchemie Potassium Test Kit (Colourimetry) is used for the quantitative determination of Potassium concentration in human serum.

**INTRODUCTION**

Potassium is present in all body tissues and is required for normal cell function because of its role in maintaining intracellular fluid volume and transmembrane electrochemical gradients<sup>[1,2]</sup>.

Elevated potassium levels (hyperkalemia) are often associated with renal failure, dehydration shock or adrenal insufficiency. Decreased potassium levels (hypokalemia) are associated with malnutrition, negative nitrogen balance, gastrointestinal fluid losses and hyperactivity of the adrenal cortex.<sup>[3,4]</sup>

**PRINCIPLE**

The amount of Potassium is determined by using sodium tetraphenylboron in a specifically prepared mixture to produce a colloidal suspension. The turbidity of which is proportional to potassium concentration in the range of 2-7 mEq/L.



The extent of turbidity is proportional to the potassium concentration and is measured photometrically at 620 nm (610-620)

**PACK SIZE**

<b>Kit Size</b>	<b>50 T</b>
<b>Cat. No.</b>	<b>ADX363</b>
<b>Kit Contents</b>	
1) Potassium Reagent	50 x 1 ml
2) Potassium Standard (5 mmol/L)	1 x 2 ml

**REAGENT PREPARATION**

Ready to use reagents.

**WARNINGS AND PRECAUTIONS**

- For in vitro diagnostic use.
- Specimens should be considered infectious and handled appropriately.
- Avoid ingestion. DO NOT PIPETTE BY MOUTH.
- The reagent contains sodium hydroxide that is corrosive. In case of contact with skin, flush with water. For eyes, seek medical attention.
- The disposal of the residues has to be done as per local legal regulations.

**CALIBRATION**

The procedures are calibrated with the standard solution which is included with each series of tests. The absorbance is used to calculate the results.

**REAGENT STORAGE & STABILITY**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8 °C and contaminations are prevented during their use. Do not use reagents over the expiration date.

**SPECIMEN COLLECTION AND STORAGE**

Serum is the preferred specimen.  
Do not use lipemic / turbid/ icteric samples.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Pipettes to accurately measure required volumes.
- Test tubes/rack
- Timer
- 37 °C heating block or water bath
- Photometer capable of accurately measuring absorbance at 620 nm

**TEST PROCEDURE**

Primary wavelength 620 nm  
Temperature 37°C  
Prewarm the Reagent to reaction temperature.

	Blank (µl)	Standard (µl)	Sample (µl)
Potassium Reagent	1000	1000	1000
Potassium Standard	--	50	--
Sample	--	--	50

Mix well and incubate for 5 min at room temperature. After incubation, zero the Photometer with the reagent blank. Read and record the incubated Standard and samples.

Calculation:  $\frac{\text{Sample OD}}{\text{Standard OD}} \times 5 = \text{mmol Potassium / L}$

**Note:** All glassware and cuvettes should be washed with quality distilled water before use.

**QUALITY CONTROL**

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**EXPECTED VALUE**

Serum : 3.4 - 5.3 mmol/L  
It is strongly recommended that each laboratory establish its own normal range

**PERFORMANCE CHARACTERISTICS**

Sensitivity: 0.14 mmol/L  
Linearity: 8.5 mmol/L under the described assay conditions. If the concentration is greater than linearity (8.5 mmol/L), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

**PRECISION:**

Intra-assay precision within run (n=10)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Control Level - 1	3.9	0.0	0.7
Control Level - 2	6.1	0.0	0.4

Inter-assay precision run to run (n=12)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Control Level - 1	3.9	0.0	0.6
Control Level - 2	6.0	0.0	0.4

The reagent was tested for 12 days, using two different Potassium concentrations. The coefficient of variation was <5%.

**AUTOMATED PROCEDURE**

Appropriate program sheet is available for different analyzers upon request.

**METHOD COMPARISON**

Results obtained using TRUEchemie Potassium reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r<sup>2</sup>) was 0.959 and the regression equation is y=1.059x-0.152. The results of the performance characteristics depend on the analyzer used.

**INTERFERENCES**

Turbid or icteric samples produce falsely elevated results. Bilirubin above 40 mg/dL and Urea Nitrogen above 80 mg/dL will produce elevated results. Hemolyzed sera produce elevated results. Sera containing high levels of ammonia should be avoided.

**WASTE MANAGEMENT**

Please refer to local regulation requirements.
















**SYSTEM PARAMETERS**


Mode	:	End point
Std. Conc.	:	5
Wave length	:	620 nm
Units	:	mmol/L
Flow cell Temp.	:	37 °C
Blank	:	Reagent
Reagent volume	:	1000 µL
Sample volume	:	50 µL
Incubation	:	5 min. at R.T
Low Normal	:	3.4
High Normal	:	5.3
Sensitivity	:	0.14
Linearity	:	8.5
Reaction Slope	:	Increasing

**REFERENCES**

- Institute of Medicine. Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. Washington, DC; 2005.
- Stone MS, Martyn L, Weaver CM. Potassium intake, bioavailability, hypertension, and glucose control. Nutrients 2016;8. [PubMed abstract]
- Henry, R.F. et. al., Clinical Chemistry Principles and Technics, 2nd Ed., Harper and Row, Hagerstown, M.D., (1974).
- Tietz, N.W, Fundamentals of Clinical Chemistry, W.B., Saunders Co., Philadelphia, PA, p. 874.
- ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

**Index of Symbols**

 Consult instructions for use	 Catalogue number	 Caution
 In vitro diagnostic medical device	 Batch code	 Non-sterile
 Temperature limit 2-8°C	 Do not re-use	 Use-by date
 Manufacturer	 Date of manufacture	 Keep dry
 Do not use if package is damaged	 Contains sufficient for <n> tests	 Keep away from sunlight



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