TECO DIAGNOSTICS
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# POTASSIUM REAGENT (COLORIMETRIC METHOD) TC MATRIX

## INTENDED USE
For the colorimetric determination of potassium in human serum and plasma on TC Matrix analyzers.

## INTRODUCTION
Potassium is the principle cation of the intracellular fluid. It is also an important constituent of the extracellular fluid due to its influence on muscle activity. Its intracellular function parallels that of its extracellular function, namely influencing acid-base balance and osmotic pressure, including water retention.[1, 2]

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.[1, 2]

In previously described colorimetric methods for determination of potassium or sodium, prior deproteinization of serum or plasma specimen was required. Our improved method is the direct spectrophotometric measurement of potassium in blood or plasma.

## PRINCIPLE
The amount of potassium is determined by using sodium tetraphenylboron in a specifically prepared mixture to produce a colloidal suspension.[3] The turbidity of which is proportional to potassium concentration in the range of 2 - 7 mEq/L.

## REAGENT CONTENTS
Each kit contains: Six Potassium Reagent (6×40 ml)

Instruction Insert.

## REAGENT PREPARATION
No preparation is required.

## REAGENT CONTENTS
Sodium Tetraphenylboron: 2.1 mM

## WARNING AND PRECAUTIONS
1. Potassium Reagent Set is for "*in vitro* diagnostic use" only.
2. Sodium Tetraphenylboron is a corrosive substance. Avoid skin contact or ingestion. DO NOT PIPET BY MOUTH. Flush with water if contact occurs.

## STORAGE AND STABILITY
Store the reagent at room temperature (15-30°C). The reagents are stable until expiration date indicated on the package label.

## REAGENT DETERIORATION
Do not use if:
1. The reagent is very cloudy.
2. The reagent fails to achieve assigned value on fresh control serum.

## SPECIMEN COLLECTION AND STORAGE[1, 2]
1. Serum is recommended.
2. Potassium in serum is stable for at least 2 weeks at 2 - 8°C.
3. Specimens for serum potassium analysis should be free from hemolysis since the high concentration of potassium released from red cells significantly increases the serum levels thereby invalidating the test results. Blood specimens should also be separated from the red cells shortly after collection to prevent any leakage of potassium from the intracellular into the extracellular fluid. Plasma from anticoagulants not containing potassium is also suitable.

## 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.

## CALIBRATION
1. Calibrator required: TECO MULTI Calibrator but is not provided in the kit.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

**Note:** Refer to the TC Matrix manual for further instructions on calibrating the instrument

## MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
TECO MULTI Calibrator
At least two levels of control material.

## PROCEDURE

| | | | |
|---|---|---|---|
| TEST NAME: | Potassium | R1: | 300 |
| TEST NO. | | R2: | 0 |
| FULL NAME: | Potassium | SAMPLE VOLUME: | 3 |
| REFERENCE NO.: | | R1 BLANK: | / |
| ANALY.TYPE: | Endpoint | MIX REAG. BLANK: | 0.1 - 1.5 |
| PRI. WAVE: | 510 nm | CONCENTRATION: | / |
| SECON. WAVE: | / | LINEARITY LIMIT: | 2 - 7 |
| TREND: | Increase | SUBSTRATE LIMIT: | / |
| REACT. TIME: | 0 - 12 | FACTOR: | / |
| INCUBATE TIME: | / | PROZONE CHECK: | / |
| UNIT: | mEq/L | Q1: / Q2: / Q3: / Q4: / | |
| PRECISION: | 0.1 | PC: / ABS.: / | |
| Calibration Type: | Calibrate+ Reag Blank | Calibration Rule: | Two-point linear |

## LIMITATIONS
Our method has been found to be linear between 2 - 7 mEq/L. It is important to note that our method may not produce accurate results when used with potassium calibrator other than that provided by us. Other products contain preservatives that interfere with this procedure and tend to produce false elevated results. Samples with values above 7 mEq/L should be diluted 1:1 with normal saline, re-assayed and results multiplied by two.

## EXPECTED VALUES[2]
3.4- 5.3 mEq/L.

It is strongly recommended that each laboratory establish its own normal range.

## PERFORMANCE

1. Linearity: 2 - 7 mEq/L.
2. Sensitivity: Based on an instrument resolution of A = 0.001, the present method has a sensitivity of 0.006 mEq/L.
3. Comparison: A comparison study performed between our method and a similar method resulted in a correlation coefficient of 0.99 with a regression equation of Y = 0.99X - 0.45.
4. Precision Study:

| | Within Run: | |
|---|---|---|
| Mean (mEq/L) | S.D. | C.V.% |
| 3.6 | 0.14 | 5.2 |
| 5.8 | 0.31 | 4.6 |

| | Run to Run: | |
|---|---|---|
| Mean (mEq/L) | S.D. | C.V.% |
| 3.6 | 0.32 | 9.2 |
| 5.8 | 0.28 | 6.1 |

## REFERENCES


1. Henry, R.F. et. al., *Clinical Chemistry Principles and Techniques*, 2nd Ed., Harper and Row, Hagerstown, M.D., (1974).
2. Tietz, N.W, *Fundamentals of Clinical Chemistry*, W.B., Saunders Co., Philadelphia, PA. p. 874.
3. Terri, A.E. and Sesin, P.G., *Am. J. Clin. Path.*, 29:86 (1958).



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Manufactured by:

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