ROBONIK®

CE

prietest™ ...Clinical Chemistry Reagents

CHLORIDE

In vitro diagnostic test kit, for professional use only

INTENDED USE : Quantitative in vitro determination of concentration of chloride in serum or plasma, urine on photometric systems.

ORDERING INFORMATION	**Pack Size**	**Cat No.**
	2 x 50 ml	CHL 02 50

CLINICAL SIGNIFICANCE : Chloride is the most important anion in serum besides bicarbonate. Together with sodium it is an essential osmotically active component in plasma which is involved in maintenance of water distribution and anion-cation-balance. Serum concentrations of chloride behave parallel to sodium levels and reciprocally to bicarbonate. Increased chloride values occur in dehydration, metabolic acidosis related with prolonged diarrhea and bicarbonate loss, renal insufficiencies and endocrinological disorders as reduced or increased adrenal function. Decreased values are observed in metabolic acidosis with increased production of organic acids, salt-losing nephritis and excessive sweating. Measurement of chloride concentration in urine is of clinical value with patient having persistent metabolic alkalosis who are not receiving diuretics.

METHOD :

Photometric test using Mercuric Thiocyanate, End Point.

PRINCIPLE :

In presence of ferric nitrate and mercuric thiocyanate, chloride ions lead to ferric thiocyanate formation. The coloration intensity of this brown complex is proportional to the chloride concentration.

$2\,Cl^- + Hg(SCN)_2 \longrightarrow HgCl_2 + 2\,(SCN)^-$

$3\,(SCN) + Fe^{3+} \longrightarrow Fe(SCN)_3$

REAGENTS :

COMPONENTS AND CONCENTRATIONS:

Mercury (II) Thiocyanate	:	2 mmol/l
Mercury (II) Chloride	:	0.8 mmol/l
Ferric (III) Nitrate	:	20 mmol/l
Nitric Acid	:	28 mmol/l
Preservative & Stabilizer		
Standard:	:	100 mmol/l (100 mEq/L)

STORAGE INSTRUCTIONS AND REAGENT STABILITY :

The reagent is stable up to the end of the indicated date of expiry on the vial label, if stored at 15 to 25°C, protected from light and contamination is avoided. Do not freeze the reagent! The standard is stable up to the end of the indicated date of expiry on the vial label, if stored at 15 to 25°C.

WARNINGS AND PRECAUTIONS :

1. The reagent contains mercury (II) thiocyanate and mercury (II) chloride. Do not swallow! Avoid contact with skin and mucous membranes!
2. Take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT :

Please refer to local regulation requirements.

REAGENT PREPARATION :

Reagent and standard are ready-to-use.

MATERIALS REQUIRED BUT NOT PROVIDED :

Deionised Water, General laboratory equipment, Analyser / Photometer, Pipettes etc.

SPECIMEN :

Serum or Heparinized plasma.
Stability: 7 days at 4 to 8°C
Urine collected on 24 hours.
Discard contaminated specimens.

ASSAY PROCEDURE :

Application sheets for automated systems are available on request.

Wavelength	:	Hg 510 nm, 500 nm
Optical Path	:	1 cm
Temperature	:	37°C
Mode	:	End Point

Bring all the contents of the kit to Room Temperature prior to use.
Read absorbance of sample against reagent blank
Label the test tube as blank, standard, sample, control and pipette into respective test tube the reagent, standard, sample, control sample as per the table given below :

	Blank	Standard	Sample / Control
Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	—	—
Standard	—	10 µl	—
Sample / Control	—	—	10 µl

Mix and read the absorbance (A) after a 1(One) minute incubation but within 30 minutes.

CALCULATION :

With standard or calibrator.

$$\text{Conc. of unknown Sample} = \frac{\text{Concentration of Standard}}{\text{Abs. Standard - Abs. of Reagent Blank}} \times \text{Abs. of unknown Sample} - \text{Abs. of Reagent Blank}$$

CONVERSION FACTOR :

Chloride [mmol/l] = Chloride [mEq/L]

CALIBRATION :

For the calibration of automated photometric systems use of the commercially available calibrator is recommended.

QUALITY CONTROL :

To ensure adequate quality, use of the commercially available control sera is recommended.

PERFORMANCE CHARACTERISTICS :

MEASURING RANGE :

The test has been developed to determine Chloride concentrations within a measuring range from 1 to 130 mmol/l (1 to 130 mEq/L). When values exceed higher limit of the range, such samples should be diluted 1 + 1 with Deionised Water and the result multiplied by 2.

SPECIFICITY / INTERFERENCES :

No interference was observed by Ascorbic Acid up to 10 mg/dl (567.8 µmol/L) and Hemoglobin up to 0.5 g/dl (5 g/L), Bilirubin up to 15 mg/dl (256.5 µmol/L) for normal range of chloride. triglyceride concentration of 200 mg/dl (2.26 mmol/L). For chloride determination of pathological sample Bilirubin interfers from 3.8 mg/dl (65 µmol/L) and triglycerides from 200 mg/dl (2.26 mmol/L). A list of drugs and other interfering substances with Chloride determination has been reported by Young et al.

SENSITIVITY / LIMIT OF DETECTION :

The lower limit of detection is 1 mmol/L (1 mEq/L).

PRECISION :

Intra-assay precision n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	90.3	1.47	1.63
Sample 2	108.4	2.01	1.85
Sample 3	99.50	1.38	1.39

Inter-assay precision n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	95	1.4	1.47
Sample 2	85	1.2	1.41
Sample 3	124	1.6	1.29

METHOD COMPARISON :

A comparison between Robonik Prietest Chloride (y) and a commercially available test (x) using 20 samples gave following results:

Linear Regression	:	y = 1.259x - 27.02 mmol/l
Correlation Coefficient	:	r = 0.9260

REFERENCE RANGE :

Serum plasma	:	98 to 107 mmol/l (98 to 107 mEq/L)
Urine 24 hrs	:	110 to 250 mmol/24 hrs. (110 to 250 mEq/24 hrs)

It is recommended that each laboratory should assign its own reference range.

LITERATURE :

1. Heusel, J.W., *et al., Physiology and Disorders of Water, Electrolyte, and Acid-Base Metabolism*, Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA),.
2. Tietz N.W., Clinical guide to laboratory tests, 3rd Ed., W.B. Saunders eds. Philadelphia USA,.
3. Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg.,.
4. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed. AACC Press, 1995.

INSTRUMENT APPLICATION
***prietest* TOUCH**

Name : CHLORID, Mod : END-P
Pri.: 510 , Sec.: 0
Temp: 37C , KF : 1.000
Vol : 500ul , Unit : mmol/l
Lag : 5 , Read : NA
Blk : Y, QC : Y, Norm : Y
Std : 1 , Concen :
Std.: 1 = 100
Normal HI = 107
Normal LO = 98
QCNH : *
QCNL : *
QCABH = *
QCABL = *
Rgnt. Linearity : 130
NOTE :
* Indicates user definable parameter.
NA Implies Not Applicable

PARAMETERS FOR INSTRUMENT SETTING	
TEST NAME	CHLORIDE
Reaction	End Point
Reaction Slope	Increasing
Wavelength 1	510 nm
Temperature	37°C
Zero Setting	Reagent Blank
Standard Conc.	100.0
Units	mmol/l
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation Time	1 minute
Reference Range	98 to 107
Reagent Linearity	130

ROBONIK®

An ISO 9001 : 2008 Certified Company
An ISO 13485 : 2012 Certified Company

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