BIOLABO
www.biolabo.fr
MANUFACTURER :
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

CHLORIDE Colorimetric method

Reagent for quantitative determination of chloride ions in human serum and plasma, urines or cerebrospinal fluid (CSF).

REF K1005	**R1**	4 x 17 mL
REF K2005	**R1**	4 x 30 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
support@biolabo.fr
Latest revision : www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
I It allows the quantification of chloride ions in human serum and plasma, urines or cerebrospinal fluid (CSF) to assess the electrolytes imbalance.

GENERALITIES (1)

Chloride is the major extracellular anion. Together with sodium, chloride is significantly involved in maintenance of water distribution, osmotic pressure and anion-cation balance in extracellular fluids.

PRINCIPLE (1) (4) (5)

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

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

Chloride ions react with undissociated mercuric thiocyanate to form undissociated mercuric chloride and free thiocyanate ions. Thiocyanate ions react with ferric ions to form a highly colored reddish complex of ferric thiocyanate which absorbance, proportional to the amount of chloride in the specimen, is measured at 500 nm (450-500).

REAGENTS

R1 CL Thiocyanate Reagent

Ferric nitrate	22.2	mmol/L
Chloride mercuric	0.55	mmol/L
Mercuric Thiocyanate	1.33	mmol/L
Nitric acid	30	mmol/L
Surfactant	1	mL/L

I Warning : Acute Tox. 4: H332 - Harmful if inhaled
P261: Avoid breathing mist/vapors/spray.
P271: Use only outdoors or in a well-ventilated area.
Classification due to Nitric acid < 1%. For more details, refer to Safety Data Sheet (MSDS)

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 18-25°C, reagent is stable when stored and used as described in the insert:

Unopened,
- Until the expiry date stated on the label of the Kit.

Once opened,
- Reagent is stable at least 2 years.

Discard any reagent if cloudy or if absorbance at 505 nm is > 0.100.

SPECIMEN COLLECTION AND HANDLING (2) (6)

Unhemolysed serum or heparinized plasma.

Urines or CSF.

Chloride is stable in the specimen for:
✓1 week at room temperature or 2-8°C.

LIMITS (3)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer Kenza One, Kenza 240TX/ISE or Kenza 450TX/ISE

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with

REFERENCE INTERVALS (2)

In serum or plasma	mEq/L	[mmol/L]
In cord	96-104	[96-104]
Premature	95-110	[95-110]
0 to 30 days	98-113	[98-113]
up to 90 years	98-107(108)	[98-107(108)]
> 90 years	98-111	[98-111]

In 24 h Urines	mEq/L	[mmol/L]
Newborn	2-10	[2-10]
Child < 6 years	15-40	[15-40]
6-10 years, M	36-110	[36-110]
6-10 years, F	18-74	[18-74]
10-14 years, M	64-176	[64-176]]
10-14 years, F	36-173	[36-173]
Adult	110-250	[110-250]
> 60 years	95-195	[95-195]

In CSF	mEq/L	[mmol/L]
Child	110-130	[110-130]
Adult	118-132	[118-132]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On Kenza ONE, 505 nm, 37°C with serum as specimen

Detection limit: approx. 1.8 mEq/L

Linearity Range: between 70 and 140 mEq/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mEq/L)	80,7	103,1	123,1
S.D. mEq/L	0,9	0,8	0,9
C.V. %	1,1	0,8	0,7

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mEq/L)	82,9	106,1	122,1
S.D. mEq/L	1,3	1,4	1,9
C.V. %	1,5	1,3	1,5

Analytical Sensitivity: approx. 0.042 abs for 10 mEq/L

Comparison studies with commercially available reagent:
Realized on automated analyzer with specimens (n=69) between 69 and 129 mEq/L

y =1.0391 x – 2.9153 r = 0.9944

Interferences:

Turbidity	Positive interference from 0.067 OD
Total bilirubin	Positive interference from 558 µmol/L
Direct bilirubin	No interference up to 24 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 1044 mg/dL
Hemoglobin	Positive interference from 76 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 14 days

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations

Performances and stability data on Kenza 240TX/ISE and Kenza 450TX/ISE are available on request.

CALIBRATION (7)

- REF 95015 Multicalibrator *traceable to SRM 909*

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N level I
- REF 95011 EXATROL-P level II
- REF 95012 Urinary controls
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to specific application for specimen assayed on Kenza Analyzer.

Contact support@biolabo.fr for more details

CALCULATION

The analyzer provides directly final result.
Refer to the user's manual of Kenza analyzer.

REFERENCES

(1) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1063-1064, 1104.*
(2) *Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 234-239*
(3) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-137 à 3-141*
(4) *Zall D.M., Fisher D., Garner D.O., Anal. Chem. 28, 1665 (1956).*
(5) *Florence T.M. and Y.J. FARRAR: Spectrophotometric determination of Chloride at the parts per-billion level by the mercury (II) thiocyanate method, Anal. Chim. Acta., 54: 373-377 (1971).*
(6) *HENRY R. J. (Ed), Clinical chemistry: Principles and technics (2nd éd.), Harper and Row, p.718-719 (1974)*
(7) *SRM: Standard Reference Material ®*