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 80005 **R1** 2 x 125 mL **R2** 1 x 5 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 (manual or 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 coloured reddish complex of ferric thiocyanate which absorbance, proportional to the amount of chloride in the specimen, is measured at 500 nm.

REAGENTS

R1 CHLORIDE 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)

R2 CHLORIDE Standard

Chloride 100 mmol/L

According to 1272/2008/EC Regulation, this reagent is not classified as dangerous.

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

Reagents are 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:
- Transfer requested quantity, well recap vial and store at 18-25°C.
- Reagent is stable at least 2 years
- Discard any reagent if cloudy or if absorbance at 500 nm is > 0.100.

SPECIMEN COLLECTION AND HANDLING (2) (6)

Unhemolysed serum or heparinised 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. Spectrophotometer (1 cm path length) or Biochemistry Clinical Analyzer

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)

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]

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]

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 240TX, 505 nm, 37°C

Linearity Range: between 70 and 140 mEq/L

Detection limit: approx. 3.3 mEq/L

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*
Mean (mEq/L)	83.3	1072	120.8
S.D. mEq/L	0.7	0.7	1.3
C.V. %	0.8	0.7	1.1

Between run N = 20	*Low level*	*Normal level*	*High level*
Mean (mEq/L)	85.7	108.2	121.3
S.D. mEq/L	1.2	1.3	1.9
C.V. %	1.4	1.2	1.6

Analytical Sensitivity: approx. 0.040 abs for 10 mEq/L

Comparison studies with commercially available reagent:
Realised 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 0.076 OD
Total bilirubin	Positive interference from 486.7 µmol/L
Direct bilirubin	No interference up to 237.5 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 1048 mg/dL
Haemoglobin	Positive interference from 81 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: 1month

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

CALIBRATION (7)

- REF 95015 Multicalibrator traçable sur SRM 909
- REF 80005 (vial R2) for urines or CSF and manual method only

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 calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

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

PROCEDURE

Manual method

Reagent	1000 µL
Blank, Standard, control or specimen	10 µL

Mix well. Let stand for 5 minutes at room temperature.
Record absorbance at 500 nm (450-500) against reagent blank.
Color is stable for 30 minutes away from light.

1- Urines:

- Dilute specimen 1+1 in demineralized water
- Use standard of the kit to calibrate (do not dilute)
- Control with REF 95012 (diluted as patient's urines)

2. Performances with manual procedure should be validated by user.
3. Kenza applications and other applications proposal are available on request.

1- Specimen blanking: for cloudy or icteric serum (replace reagent by water and read absorbance against water).

CALCULATION

Serum or plasma:

$$\text{Result} = \frac{\text{Abs1 (assay)}}{\text{Abs1 (Standard)}} \times \text{Standard concentration}$$

Serum or plasma (with specimen blank):

$$\text{Result} = \frac{\text{Abs1 (assay) - Abs2 (Specimen blank)}}{\text{Abs1 (Standard)}} \times \text{Standard concentration}$$

Abs 1= Absorbance against reagent blank
Abs2= Absorbance against water

Urines:

Multiply the result by 2 (dilution factor)

REFERENCES

(1) *TIETZ N.W. Text book 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 PARTSPER-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 ®*