CHLOROIDE

INTENDED USE

Vitro Chloride reagent is intended for the determination of chloride in human serum, plasma and urine on both automated and manual systems

METHOD

Thiocyanate method

CLINICAL SIGNIFICANCE

Chloride is the most abundant extracellular anion. Together with natrium-chloride is responsible for the maintenance of osmotic pressure, the anion-cation balance and therefore of the water distribution in the extracellular fluid compartment. Decreased plasma chloride concentrations (hypochloremia) can result from salt-losing nephritis, persistent gastric secretion, prolonged vomiting and metabolic acidosis that are caused by increased production or reduced secretion of organic acids. Increased plasma Cl--concentrations (hyperchloremia) occur with dehydration, renal tubular acidosis, acute renal failure, in adrenocortical hyperfunction, salicylate intoxication and metabolic acidosis associated with prolonged diarrhea and loss of sodium bicarbonate. Chloride is often analyzed in combination with natrium and kalium to determine the anion gap in serum and/or urine. The urinary anion gap is useful in the initial evaluation of hyperchloremic metabolic acidosis. Due to the different reactivity equivalents of chloride and bromide the thiocyanate method is less disturbed by the presence of bromide than measurement with an ion selective electrode.

ASSAY PRINCIPLE

Chloride ions and Hg II-thiocyanate form thiocyanate ions in acidic medium. These ions react with HNO3 and FE III-ions and effect a red color. The increasing extinction is directly proportional to the concentration of chloride ions.

EXPECTED VALUES

Serum	95 – 115	mmol/l
Urine 24 h urine	110 – 250	mmol/24h
CSF	95 – 110	mmol/l

REAGENTS

R_1 Standard	Chloride	100	mmol/l
R_2 Color Reagent	Hg – II - thiocyanate	2	mmol/l
	Fe – III - nitrate	30	mmol/l
	HNO3	40	mmol/l

- **Reagent Preparation & Stability**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at room temperature protected from light and contaminations prevented during their use. Do not use reagents over the expiration date.

SPECIMEN

Serum, Plasma and CSF : Free of hemolysis

Serum

Separate serum from the clot and cells within 45 min.

Urine

Collect 24-hour urine specimen in chloride free containers.
Urine has to be diluted 1+2 with distilled water. Multiply result by 3.
Centrifuge samples containing precipitate before performing the assay.

- Stability of the sample: Chloride is stable in serum for one day at room temperature and for three months frozen when stored tightly capped.

PROCEDURE

- **Manual Procedure**

Wavelength	460 - 500 nm
Cuvette	1 cm light path
Temperature	RT
Zero adjustment	against reagent blank
Specimen	Serum or plasma or urine

	Blank	Standard	Specimen
R2	1.0 ml	1.0 ml	1.0 ml
Standard	……	10 µl	……
Specimen	……	……	10 µl

Mix, and Incubate for 5 minutes at room temperature Measure the absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank.
The color is stable for 60 minutes.

- **Automated Procedure**

User defined parameters for different auto analyzers are available upon request.

CALCULATION

Calculate the Chloride concentration in serum or CSF by using the following formulae:

Chloride Concentration=

$$\frac{\text{Absorbance of Specimen}}{\text{Absorbance of Standard}} \text{ X Standard value}$$

Calculate the Chloride concentration in Urine 24 h by using the following formulae:

$$\frac{\text{Absorbance of Specimen}}{\text{Absorbance of Standard}} \text{ X Standard value x 3 x Volume urine / 24 h (dL)}$$

Conversion between conventional and SI units: 1 mEq/l = 1 mmol/l
Conversion between mmol/l and mg/dl: mmol/l = 0.282 x mg/dl

QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established Chloride values may be routinely used for quality control.
Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

WARNING & PRECAUTION

For in vitro diagnostic use.
Exercise the normal precautions required for all laboratory reagents.
Contains mercuric thiocyanate. Toxic, harmful if inhaled or absorbed through skin. Consider local disposal regulations.

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INTERFERING SUBSTANCES

Icterus: No significant interference up to a bilirubin concentration of 30 mg/dl.
Hemolysis: No significant interference up to a haemoglobin concentration of 1000 mg/dl.
Lipemia (Intralipid): No significant interference up to a triglyceride concentration of 400 mg/dl.

PERFORMANCE

Imprecision
Reproducibility was determined using in an internal protocol. The following results were obtained.

	Within Run		Between Day	
Control	Level I	Level II	Level I	Level II
Number of samples	20	20	20	20
Mean (mmol/l)	84.2	114	82.5	111
SD (mmol/l)	0.81	0.62	1.07	1.87
CV (%)	0.96	0.55	1.30	1.68

Method Comparison
Comparison studies were carried out using another similar commercially available Chloride reagent as a reference. Serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained:
Number of sample pairs 50
Correlation coefficient 0.96731
Regression equation: y= 0.990x + 0.100

Sensitivity

The sensitivity is defined as the lower detection limit represents the lowest measurable chloride concentration that can be distinguished from zero.

When run as recommended the sensitivity of this assay is 0.454 mmol/l.

Linearity
When run as recommended, the assay is linear Up to 140 mmol/l
Dilute samples having higher concentrations 1+1 with distilled water. Multiply the result by factor 2

BIBLIOGRAPHY

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SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
14901	2 X 25 ml
14902	2 x 50 ml
14903	2 X 100 ml

Article # :149 -EN
Date of Revision : 03/2021

ISO 13485:2016 CE

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