



# CHLORIDE LR liquid reagent

REF C2100620 518 Test

CE C2100620A 518 Test

IVD For in vitro medical device

## Use

Kit for measurement of chlorides in serum, plasma and urine. Colorimetric method mercurious thiocyanate.

## Summary

Chloride measurements are used in the diagnosis and treatment of disorders characterized by chlorides plasmatic variation like metabolic acidosis, hypercorticalsurrenialism and renal insufficiency .

## Principle

Chlorides determination method is based on the formation of a coloured compound between trivalent iron and thiocyanate ions released by reaction of chloride with mercurious thiocyanate. The resulting colour intensity is proportional to chlorine concentration in the sample.

## Reagents

R1	Mercurious thiocyanate	1.0 mmol/l
	iron nitrate	12.0 mmol/l
	nitric acid	70.0 mmol/l
	nitrate mercurious	0.20 mmol/l

## Reagent Preparation

Reagents are liquid and ready to use.

## Storage and stability

- Store the kit at 15-25°C.
- After opening, the R1 vial is stable up to 30 days if recapped immediately and protected from contamination, evaporation, direct light, and stored at the correct temperature.

## Precaution in Use

The product is not classified as dangerous (DLg. N. 285 art. 28 l. n. 128/1998). However the reagent should be handled with caution, according to good laboratory practice.

## Waste Management

Please refer to the local legal requirements.

## Specimen Collection and Preparation

- Serum or plasma.
- Diluted urine 1:2.
- Do not use samples with haemolysis.
- Samples strongly jaundiced, lipoemic or with haemolysis, require the use of a blank sample against distilled water.
- The chlorides are stable in the samples up to 7 days at 2-8°C.

## Note

- The kit, according to this method, must be used in manual procedures. About automatic use follow specific applications.
- Avoid direct light, contamination and evaporation.
- In case of complaint or quality control request, refer to the lot number on the package or to the lot number on the single vials.

## Procedure

Wavelength	λ: 480 (460-500) nm
Working Temperature	37°C
Optical path	1 cm
Reaction	"end point"

## -- Monoreagent Procedure "sample starter"

	BLANK	STD	SAMPLE
Working Reagent	1000 µl	1000 µl	1000 µl
Distilled Water	10 µl	--	--
Sample	--	--	10 µl
Standard	--	10 µl	--

Mix, then incubate for 5' at 37°C.

Measure the absorbance of the sample (EC) and standard (ES) against the reagent blank.

## Calculation

Chlorides [mEq/l] = EC/ES x Conc. STD

The reagent performances are related to 37°C, 1 cm and 480 nm.

## Reference Values

Sierum or plasma	90-110 mmol/l	98-110 mEq/l
Urine	150-250 mmol/l	170-250 mEq/l

Diluted urines: multiply the result for diluting factor.

Reference values are considered indicative since each laboratory should establish reference ranges for its own patient population. The analytical results should be evaluated with other information coming from patient's clinical history.

## ANALYTICAL PERFORMANCES

### Linearity

Reaction is linear up to a concentration of 150 mEq/l. Samples with values exceeding 150 mEq/l must be diluted with saline solution. Then, multiply, the result for diluting factor.

### "Intra-Assay" precision (within-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mmol/l)	N = 87.15	H = 125.15
S.D.	N = 2.26	H = 1.93
C.V.%	N = 2.60	H = 1.54

### "Inter-Assay" precision (between-Run)

Determined on 20 samples for each control (N-H) (Normal- High). Results:

MEAN (mmol/l)	N = 90.77	H = 123.70
S.D.	N = 2.27	H = 2.49
C.V.%	N = 2.50	H = 2.01

### Analytical sensitivity

The test sensitivity in terms of detection limit is: 22.0 mEq/l.

### Correlation

A study made in comparison of this method with a similar one, on 20 samples, has given a correlating factor  $r = 0.9116$

$$y = 0.8234x + 16.764$$

## Interferences

No interference was observed by the presence of:

Bilirubin	≤ 8 mg/dl.
Hemoglobin	≤ 10 mg/dl.

Do not use lipemic sample.

For a comprehensive review of interfering substances, refer to the publication by Young.

## Quality controls

It's necessary, each time the kit is used, to perform quality controls and to check that values obtained are within the acceptance range provided in the insert. Each laboratory should establish its own mean and standard deviation and adopt a quality control program to monitor laboratory testing.

## Bibliography

Kaplan, L.A., Pesce, A.J.: "Clinical Chemistry", Mosby Ed. (1996).

Young D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, DC 5<sup>th</sup> ed.2000.

Schoenfeld R.G., loewellw C.S.: Clinical Chemistry (1964), 10, 533.

## Simbols

CE CE Mark (requirement of 98/79 regulation)

IVD in vitro medical device

LOT Batch Code

Hourglass icon Use by

Open book icon Storage temperature limits  
Open book icon Read instruction for use

Factory icon Gesam Production srl