

CHLORIDE

CL 0100 CH	2 x 50 ml
CL 0500 CH	4 x 125 ml

INTENDED USE

Reagent for quantitative in vitro determination of chloride in biological fluids.

SUMMARY OF TEST

Chloride is the major extracellular anion. Sodium and chloride together represent the majority of the osmotically active constituents of plasma. Chloride is therefore significantly involved in maintenance of water distribution, osmotic pressure and anion-cation balance in the extracellular fluid compartment.

PRINCIPLE OF THE METHOD

Chloride ions react with mercuric ions, giving available an equal quantity of thiocyanate ions. Thiocyanate ions react with trivalent ferric ions present in solution to form a red colored complex with an absorbance peak at 480 nm.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

CL R1	0100:	2 x 50 ml (liquid) blue cap
	0500:	4 x 125 ml (liquid) blue cap

Composition: mercury(II) thiocyanate 2.2 mM, mercury(II) chloride 0.7 mM, iron (III) nitrate 19 mM.

Standard: chloride solution 100 meq/l - 5 ml

Store all components at 15-25°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Deionized water.

REAGENT PREPARATION

Use reagent ready to use.

Stability: up to expiration date on labels at 15-25°C.

Stability since first opening of vials: preferably within 60 days at 15-25°C.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum, plasma heparinate. Separation of cells from plasma should be prompt. Sweat is a suitable sample.

Use 24 hours urine.

Dilute sample urine 1:2 with redistilled water and multiply results by two.

TEST PROCEDURE

Wavelength:	480 nm (allowed 460 ÷ 500 nm)		
Lightpath:	1 cm		
Temperature:	25, 30 or 37°C		
dispense:	blank	standard	sample
reagent	1 ml	1 ml	1 ml
water	5 µl	-	-
standard	-	5 µl	-
sample	-	-	5 µl
Mix, incubate at 25, 30 or 37°C for 5 minutes. Read absorbances of standard (As) and samples (Ax) against reagent blank.			

RESULTS CALCULATION

Serum/plasma sample:

chloride meq/l = $Ax/As \times 100$ (standard value)

Random urine sample:

chloride meq/l = $Ax/As \times 100 \times 2$ (standard value and dilution factor)

24 hours urine sample:

chloride meq/24h = $Ax/As \times 100 \times 2 \times$ urine volume (standard value, dilution factor and diuresis in decilitres)

EXPECTED VALUES

serum/plasma:	98 - 110 meq/l
urine:	110 - 250 meq/24h (dietary variations are possible)
sweat:	up to 30 meq/l

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

QUANTINORM CHEMA

with normal or close to normal control values

QUANTIPATH CHEMA

with pathological control values.

If required, a multiparametric, human based calibrator is available:

AUTOCAL H

Please contact Customer Care for further information.

TEST PERFORMANCE

Linearity

the method is linear up to 200 meq/l.

If the limit value is exceeded, it is suggested to dilute sample 1+9 with distilled water and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD)

the limit of detection is 1.5 meq/l.

Interferences

no interference was observed by the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 32 mg/dl
lipids	≤ 500 mg/dl

Precision

intra-assay (n=10)	mean (meq/l)	SD (meq/l)	CV%
sample 1	114.80	1.48	1.30
sample 2	111.00	1.41	1.30

inter-assay (n=20)	mean (meq/l)	SD (meq/l)	CV%
sample 1	117.03	2.95	2.50
sample 2	113.44	3.26	2.90

Methods comparison

a comparison between Chema and a commercially available product gave the following results:

$$\begin{aligned} \text{Chloride Chema} &= x \\ \text{Chloride competitor} &= y \\ n &= 83 \end{aligned}$$

$$y = 0.869x + 14.402 \text{ meq/l} \quad r^2 = 0.927$$

WASTE DISPOSAL

This product is made to be used in professional laboratories.

P501: Dispose of contents according to national/international regulations.

REFERENCES

Levinson S.S., Direct determination of serum chloride with a semiautomated discrete analyzer, Clin.Chem. 22:273-274, 1976

Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).

MANUFACTURER

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SYMBOLS

	in vitro diagnostic medical device
	batch code
	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use