Quantitative determination of Chloride in serum / plasma / Urine /CSF / Sweat
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
CHLO 100	2 X 50 mL
CHLOM 50	50 X 1 mL

CLINICAL SIGNIFICANCE

It is important clinically the determination of chloride due regulation of osmotic pressure of extra cellular fluid and to its significant role in acid-base balance. Increases in chloride ion concentration may be found in severe dehydration, excessive intake of chloride, severe renal tubular damage and in patients with cystic fibrosis. Decrease in chloride ion concentration may be found in metabolic acidosis, loss from prolonged vomiting and chronic pyelonephritis. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

Method

Photometric test using Mercurous (II) thiocyanate.

PRINCIPLE

Chloride ions react with mercurous thiocyanate to form mercury per chlorate and thiocyanate. Thiocyanate forms a red complex with ferric ions in the presence of nitric acid.

REAGENT

Reagent I : Chloride reagent
Chloride standard : 100 mEq/L

REAGENT PREPARATION

All Reagents are ready to use

REAGENT STORAGE AND STABILITY

When stored at recommended storage temperature stated on label, reagent is stable until the expiration date stated on the bottle and kit box label

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.
- Proceed carefully with this product because due to its nature it can get contaminated easily.
- Most of the detergents and water softening products used in the laboratories contain chelating agents. A defective rinsing will invalidate the procedure.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum or plasma (lithium heparin)
Separate from cellular contents immediately after blood collection.
Stability: at least one year at –20°C in case of immediate freezing.
7 days at 4 – 8°C
Freeze only once! Discard contaminated specimens!
Urine: Collect 24-hour urine specimen in chloride free containers. Dilute a sample 1/2 in distilled water. Mix. Multiply results by 2 (dilution factor).
Stability of the sample:
1 week at refrigerator (2-8ºC) or frozen (-20ºC) temperatures.

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28 ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	505 nm
Cuvette	1 cm
Measurement	Against Reagent Blank
Reaction Temperature	RT (22-30ºC)
Reaction Type	End Point
Reaction Direction	Increasing
Incubation	5 Min.
Sample Volume	10 µL
Reagent I Volume	1000 µL
Blank Absorbance Limit	< 0.30
Units	mEq/L

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	Blank	Standard	Test
Reagent 1	1000µL	1000µL	1000µL
Standard	--	10µL	--
Sample	--	--	10µL

- Mix Well & Incubate it for 5 minutes at RT (22-30ºC)
- Read and record absorbance of the reagent blank, standard, Control and each unknown sample immediately.
- CHLOM 50 are specially treated monovials with 1ml pre-dispensed reagent. Just add 10 µl sample / std., Incubate at R. T. for 5 min. & aspirate. Use the same programme as above.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 130 mEq/L.
- Dilute samples above this concentration 1:1 with DI Water
- Repeat assay. Multiply the result by 2.

CALCULATION

$$\text{Chloride Conc. in Serum / Plasma (mEq/L)} = \frac{\text{Abs Sample}}{\text{Abs Standard}} \times \text{Concentration of Standard}$$

$$\text{Chloride Conc. in Urine (mEq/L)} = \frac{\text{Abs Sample}}{\text{Abs Standard}} \times \text{Conc. of Standard} \times 2$$

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Chloride standard** have been made traceable to the NIST Standard Reference Material SRM 956.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	99.64	3.38	3.39%
Path	128.56	4.21	3.27%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	99.62	2.34	2.35%
Path	128.83	3.14	2.44%

LINEARITY

This method is linear upto a concentration of 130 mEq/L.
Dilute samples above this concentration 1:1 with DI Water and Repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Chloride is 30mEq/L.

METHOD COMPARISON

A comparison of Accucare Chloride with a commercially available assay (x) using 20 samples gave following results: R2 = 0.9590

REFERENCE VALUES

Serum:	**95 – 115 mEql/L**
Urine :	**110 – 250 mEq/L / 24Hr**
CSF :	**95 – 110 mEq/L**
Sweat :	**Upto 60 mEq/L**

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 32mg/dl.
- Hemoglobin: No interference found upto 500mg/dl.
- Lipemia: No interference found upto 500mg/dl.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

Tietz N.W., White, W.L.Mosby, CO St.Louis, P.Young.D.S, Henry, R,J., Chem. (1964), 10, 533.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
Email: accucarediagnostics.com; Website: www.labcarediagnostics.com

CE

Art No.: IFU/BC/CHL
Effective Date: 20/09/2019
Revision No.: 01