

Ana-Chek® CHLORIDE

METHOD – MERCURIC THIOCYANATE

PRODUCT CODE – LC03



INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Chloride in serum / plasma using Mercuric Thiocyanate method.

SUMMARY AND PRINCIPLE

Low chloride concentrations are associated with severe vomiting, diarrhoea, colitis ulcerosa, diabetic acidosis, Addison's disease. Increased levels are observed in cases of dehydration, congestive heart failure, Cushing's syndrome, hyperventilation, anaemia, nephritis and renal obstruction. Ana-Chek® Chloride is a reagent kit for quantitative determination of chloride in human serum and plasma based on Mercuric thiocyanate method.



KIT COMPONENTS

Reagent 1: Chloride Reagent
Reagent 2: Chloride Standard (100 mMol/L)

REAGENT PREPARATION, STORAGE & STABILITY

Ana-Chek® Chloride is single ready to use reagent. No preparation of working solution is required prior to use. The kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 0.200 O.D. against D/W at 510 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Chloride	Reagent Volume	1000 µl
Reaction Type	End Point	Sample Volume	10 µl
Wavelength	510 nm	Incubation Temperature	R.T.
Flow Cell Temp.	37 °C	Incubation Time	1 min.
Blank setting	Reagent	Standard Conc.	100 mMol/L
Blank abs. limit	< 0.200	Linearity	130 mMol/L

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum, heparinized or EDTA plasma can be used. Avoid haemolysis since it causes false low results. Chloride in serum/ plasma is stable for 7 days at 2 - 8 °C and 30 days at -20 °C.

COMPONENTS OF REAGENT

Component	Concentration
Mercuric Thiocyanate	2.0 mmol/l
Mercuric Chloride	1.0 mmol/l
Ferric Nitrate	20 mmol/l
Nitric Acid	45 mmol/l
Stabilizers and inactive ingredients.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 1 minutes at room temperature.			
Aspirate reaction mixture into flow cell and measure the absorbance.			
The final colour is stable for 1 hour if not directly exposed to light.			

CALCULATION

$$\text{Chloride (mMol/L)} = \frac{\text{Abs. of sample} \times 100}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

98-107 mMol/L

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 2.5 – 130 mMol/L.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL and Haemoglobin upto 300 mg/dL. A marked lipaemia will interfere in the test.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	88.1	0.92	1.0	84.65	1.04	1.2
High Value Serum	103.5	1.43	1.4	107	1.05	1.0

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Chloride. We

recommend to produce such data on daily basis for greater accuracy in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

1. The use of normal saline should be avoided as it may contaminate the reagent and lead to erroneous results.
2. Contaminated glassware is the greatest source of error, disposable plastic wares are recommended for the test.
3. Discard the working reagent if its absorbance is >0.200 against distilled water at 510 nm.
4. A marked lipemia will interfere in the test.

BIBLIOGRAPHY

1. Burtis C.A., Ashwood ER, eds. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, Pa : W.B. Saunders, 1994 : 1368.
2. Zall D., Fisher D. and Garner M., Anal. Chem. 28 : 1665, 1956.
3. Schoenfeld R.G., and Lerveller C.V., Clin. Chem., 10, 533, 1964.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE