TRUEchemie Chloride Test Kit (Thiocyanate)

for the quantitative determination of Chloride in serum or CSF or urine

INTENDED USE

The TRUEchemie Chloride Test Kit (Thiocyanate) is used for the quantitative determination of Chloride in serum or CSF or urine.

INTRODUCTION

Chloride and bicarbonate are the principal serum anions whereas sodium and potassium are the principal serum cations. These ions are involved in maintaining proper water distribution, osmotic pressure and normal anion cation balance between intra and extra cellular fluids. Hyperchloridemia is observed in dehydration and in conditions causing decreased renal blood flow such as congestive heart failure. Hypochloridemia may be seen in salt-losing nephritis, metabolic acidosis and vomiting. In a normal person, urinary chlorideexcretion ceases when plasma chloride level falls below the lower limit of normal range. However, in Addison's disease due to adrenal cortical insufficiency, excretion of chloride continues in spite of its low plasma level. Lower CSF chloride values may be seen in Meningitis especially untreated Tuberculous Meningitis.

There are number of methods for chloride quantification like Titrimetric, Amperometric, Colorimetric and use of Chloride meter. However, due to its simplicity and rapidity, the Colorimetric Method is a better choice. The Chloride kit is based on the modified Schoenfeld & Lewellen Colorimetric Method.

PRINCIPLE

The Chloride ions react with Mercuric thiocyanate to release thiocyanate ions, which in turn react with ferric ions to form a red coloured complex of Ferric thiocyanate. The absorbance of the red coloured complex at 510 nm is proportional to the Chloride concentration.

$$Hg(SCN)_2 + 2\,Cl^- \longrightarrow HgCl_2 + 2\,SCN$$

$$3\,SCN + Fe^{3+} \longrightarrow Fe(SCN)_3 \text{ (red coloured complex)}$$

PACK SIZE

Kit Size	1 x 50 ml	50 T
Cat. No.	ADX301	ADX304
Kit contents		
1) Chloride Reagent	1 x 50 ml	50 x 1 ml
2) Chloride Standard (100 mmol/L)	1 x 2 ml	1 x 2 ml

REAGENT COMPOSITION

1) Chloride Reagent
Buffer : 50 mmol/L
Mercuric thiocyanate : 1.8 mmol/L
Ferric nitrate : 20 mmol/L
Surfactants and anti-oxidants
2) Chloride Standard : 100 mmol/L

REAGENT PREPARATION

Ready to use reagents.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use.
2. Specimens should be considered infectious and handled appropriately.
3. Avoid ingestion. DO NOT PIPETTE BY MOUTH.
4. Essential precautions must be taken against accidental contamination. Use only disposable material (test tubes, micro tips etc.).
5. Contamination of glassware will adversely affect the chloride test results.
6. Contamination free disposable plastic tubes are only recommended to perform the chloride assay.
7. The disposal of the residues has to be done as per local legal regulations.

CALIBRATION

The procedures are calibrated with the standard solution which is included with each series of tests. Its absorbance is used to calculate the results.

REAGENT STORAGE & STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 15-30ºC and contaminations are prevented during their use. Do not use reagents over the expiration date.

SPECIMEN COLLECTION AND STORAGE

Serum/ urine /CSF
Urine specimen should be diluted 1:1 with distilled water (multiply result with 2).

MATERIALS REQUIRED BUT NOT PROVIDED

1. Pipettes to accurately measure required volumes.
2. Disposable test tubes
3. Timer
4. Photometer capable of accurately measuring absorbance at 510 nm.

TEST PROCEDURE

Wavelength : 510 nm

	Blank (µl)	Standard (µl)	Sample (µl)
Chloride Reagent	1000	1000	1000
Chloride Standard	--	10	--
Sample	--	--	10

Incubate all tubes at Room Temperature for 5 minutes. After incubation, zero the photometer with the reagent blank at 510 nm. Read and record the incubated standards and samples.

QUALITY CONTROL

Quality Controls are recommended to monitor the performance of automated assay procedures. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

EXPECTED VALUE

Serum Chloride : 98 - 109 mmol / L
Urine Chloride : 170 - 250 mmol / 24 hours
CSF Chloride : 118 - 132 mmol / L
It is strongly recommended that each laboratory establish its own normal range.

PERFORMANCE CHARACTERISTICS

Sensitivity: 2.10 mmol/L
Linearity: upto 150 mmol/L under the described assay conditions. If the concentration is greater than linearity (150 mmol/L), dilute the sample with distilled water and repeat the assay. Multiply the result with dilution factor. The linearity limit depends on the sample / reagent ratio, as well as the analyzers used.

PRECISION:

Intra-assay precision within run (n=10)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Control Level - 1	74.5	0.3	0.5
Control Level - 2	68.5	0.3	0.5

Inter-assay precision run to run (n=12)	Mean (mmol/L)	SD (mmol/L)	CV (%)
Control Level - 1	78.1	0.5	0.6
Control Level - 2	65.2	0.8	1.2

The reagent was tested for 12 days, using two different Chloride concentrations. The coefficient of variation was <5%.

AUTOMATED PROCEDURE

Appropriate Program sheet is available for different analyzers upon request.

METHOD COMPARISON

Results obtained using TRUEchemie Chloride reagent (y) did not show systematic differences when compared with another commercial reagent (x) with similar characteristics. The results obtained is below: The correlation coefficient (r^2) was 0.985 and the regression equation is y=1.010x-1.364. The results of the performance characteristics depend on the analyzer used.

INTERFERENCES

1. No interference from Hemoglobin up to 1000 mg/dl.
2. No interference from Bilirubin up to 20 mg/dl and Lipemia 1000 mg/dl.

WASTE MANAGEMENT

Please refer to local regulation requirements.

SYSTEM PARAMETERS

Mode	:	End point
Std. Conc.	:	100
Wave length	:	510 nm
Units	:	mmol/L
Flow cell Temp.	:	37 °C
Blank	:	Reagent
Reagent volume	:	1000 µl
Sample volume	:	10 µl
Incubation	:	5 min. at R.T.
Low Normal	:	98
High Normal	:	109
Sensitivity	:	2.1
Linearity	:	150
Reaction Slope	:	Increasing

REFERENCES

1. Levinson, S.S. (1976) Clin.Chem, 22, 273.
2. Schoenfeld, R.G.(1964) Clin.Chem 10,533.
3. ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

Index of Symbols

Consult instructions for use	REF Catalogue number	Caution
IVD *In vitro* diagnostic medical device	LOT Batch code	Non-sterile
15°C 30°C Temperature limit 15-30°C	Do not re-use	Use-by date
Manufacturer	Date of manufacture	Keep dry
		Keep away from sunlight

Do not use if package is damaged — Contains sufficient for <n> tests

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