Chloride Kit

CliniQuant - FSR

Ferric Thiocyanate Method, End Point

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

REF	Pack Size	R1 Chloride Reagent	R2 Chloride Standard
CHDFSR-01	2 x 25ml	2 x 25ml	1 x 5ml

INTENDED USE

This reagent is intended for quantitative determination of chloride concentration in human serum or plasma.

CLINICAL SIGNIFICANCE

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. Hyperchloremia occurs with dehydration, renal tubular acidosis, acute renal failure, metabolic acidosis associated with prolonged diarrhea , and loss of sodium bicarbonate, in diabetes insipidus, in adrenocortical hyperfunction, and in salicylate intoxication. Extremely high dietary intake of salt and overtreatment with saline solutions are also causes of hyperchloremia. Hypochloremia is observed in salt-losing nephritis as associated with chronic pyelonephritis.

PRINCIPLE OF THE METHOD

Chloride ions react with mercuric ions, forming an equal quantity of thiocyanate ions. Thiocyanate ions react with trivalent ferric ions present in solution to form colored complex with an absorbance at 505 nm.

KIT COMPONENTS

Composition

R1 - Chloride Reagent : Mercuric thiocynate 1.01 mmol/l, Ferric Nitrate 62.01 mmol/l, Nitric acid 89.5 mmol/l, Mercuric Nitrate 0.099 mmol/l, Methanol 1.847 Mol/l

R2 - Chloride Standard : 100 mEq/l, HCL 8.3 ml/l

MATERIALS REQUIRED BUT NOT PROVIDED

Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath, controls, saline.

REAGENT PREPARATION, STORAGE & STABILITY

Reagent is ready to use. Keep away from direct light sources.

Stability: up to expiration date on labels at 2 - 8°C.
Stability since first opening of vials: preferable within 60 days at 2 - 8°C.

REAGENT DETERIORATION

Keep the Standard vial plugged after use, in order to avoid deterioration.

WARNINGS AND PRECAUTIONS

1. Reagent may contain some non-reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
2. Specimens should be considered infectious and handled appropriately.
3. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Serum or plasma heparinate should be separated from the cells promptly. Serum / plasma are stable for 7 days at 2-8 °C and 30 days at -20 °C. Sweat is a suitable sample.
Use 24 hours urine.
Dilute sample urine 1:2 with redistilled water and multiply results by two.

Programme Parameter for MERILYZER CliniQuant

Reading Mode	End Point
Standard Conc.	100 (mEq/l)
Filter – 1 (nm)	505
Filter – 2 (nm)	670
Temperature	37 °C
Volume (µl)	500
Delay Time (sec)	5
Reaction Direction	Increase
Reference Low	96
Reference High	108
Linearity Limit	130

CE
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TEST PROCEDURE

Dispense	Blank	Standard	Sample
Reagent 1	1ml	1ml	1ml
Distilled water	10 µl	-	-
Standard	-	10 µl	-
Sample	-	-	10 µl
Mix, incubate for 1 min at 37°C. Read absorbance of standard (As) and samples (Ax) against reagent blank.			

RESULT CALCULATION

Serum/plasma:

Chloride mEq/l = Ax/Ac x Concentration of Standard

Random urine sample: Chloride mEq/l = Ax/As x Concentration of Standard x 2

24 hours urine sample: Chloride mEq/24h = Ax/As x Concentration of Standard x 2 x urine volume

SI conversion factor: 1 mEq/l x 1.0 = 1 mmol/l

EXPECTED VALUES

Serum/plasma: 96 - 108 mEq/l

Urine: 110 – 250 mEq/24h (diet variations are possible)

Sweat: up to 30 mEq/l

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and to assure the accuracy of patient result.

Using the recommended Calibrator (BioCal) or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range

PERFORMANCE CHARACTERISTICS

1. Linearity

The linearity is up to 130 mEq/l.

2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.8 mEq/l.

The limit of quantification is 2.5 mEq/l.

3. Interferences

Gross hemolysed, lipaemic and icteric specimen causes falsely elevated results. Do not use normal saline for diluting the specimen.

4. Precision

Intra-assay precision

	Mean	SD	CV
n = 20	mEq/l	mEq/l	%
sample 1	99.5	0.209	0.210
sample 2	100.5	0.399	0.397

Inter-assay precision

	Mean	SD	CV
n = 20	mEq/l	mEq/l	%
sample 1	98.61	2.91	2.95
sample 2	122.23	2.63	2.15

5. Methods Comparison

Comparison was done between reference Chloride Reagent and CliniQuant - FSR Chloride Reagent (test).

N = 24 $y = 0.938x - 1.448$

$r^2 = 0.979$

LIMITATIONS

Samples with values above 130 mEq/l should be diluted with DI water, re-run and results multiplied by dilution factor.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

REFERENCES

1. Burtis, C.A., Ashwood, E.R., editors. Tietz Textbook of Clinical Chemistry. 2nd ed. Philadelphia, W.B. Saunders Company, 1994, p. 1366 – 1370.

2. Data on file: Meril Diagnostics.

IFU/CHDFSR01/00

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Symbols used on Meril Diagnostics labels:

REF	Catalogue No.		Attention See Instruction for Use
LOT	Batch No.	IVD	*In vitro* Diagnostics
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage Temperature
	Keep Dry		Keep Away from Sunlight
	Manufacturing Date		Do not use if package is damaged

EC REP Authorized European Representative in the European Community