SPECTRUM

The Creative Approach to Bioscience

Chloride
Single Reagent

REF: 233 001 (2 x 25ml) 50 test
REF: 233 002 (4 x 25ml) 100 test
REF: 233 003 (4 x 50ml) 200 test

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum-Diagnostics Chloride reagent is intended for the in-vitro quantitative diagnostic estimation of Chloride in human serum, plasma and urine.

Background

Chloride is the most abundant extracellular anion. Together with sodium , chloride is responsible for the maintenance of osmotic pressure, the anion-cation balance and therefore of the water distribution in the extracellular fluid compartment.
Decreased plasma Cl^- concentrations (hypochloremia) can result from salt-losing nephritis, persistent gastric secretion, prolonged vomiting and metabolic acidosis that are caused by increased production or reduced secretion of organic acids.
Increased plasma Cl^--concentrations (hyperchloremia) occur with dehydration, renal tubular acidosis, acute renal failure, in adrenocortical hyperfunction , salicylate intoxication and metabolic acidosis associated with prolonged diarrhoea and loss of sodium bicarbonate. Chloride is often analyzed in combination with Sodium and Potassium to determine the anion gap in serum and/or urine. The urinary anion gap is useful in the initial evaluation of hyperchloremic metabolic acidosis.
Due to the different reactivity equivalents of chloride and bromide the thiocyanate method is less disturbed by the presence of bromide than measurement with an ion- selective electrode.

Method

Colorimetric method.

Assay Principle

The chloride ion displaces thiocyanate from non-ionized mercuric thiocyanate to form Mercuric chloride and thiocyanate ions. The released thiocyanate ions react with ferric ions to form a color complex that absorbs light at 480 nm. The intensity of the color produced is directly proportional to the chloride concentration.

Reagents

Reagent **(R)**

Hg II - thiocyanate	2 mmol/l
Fe III - nitrate	30 mmol/l
HNO_3	40 mmol/l

Standard **(S)**

Chloride	100 mmol/l (354.6 mg/dl)

Precautions and Warnings

The reagent contains mercuric thiocyanate which is toxic and harmful if inhaled or absorbed through skin.
Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Storage and Stability

Reagents and standard are ready-to-use. When stored at 2 – 8 °C; they are stable up to the expiry date stated on the label.Once opened, the reagent and the standard are stable for 3 months at 2 - 8 °C.

Sample

Serum
Freshly drawn non hemolysed serum is the specimen of choice. Chloride in serum is stable for 7 days at 2-8°C.

Urine
Urine has to be diluted 1+2 with distilled water. Multiply result by 3.

System Parameters

Wavelength	492 nm (460 - 500 nm)
Optical path	1 cm
Assay type	colorimetric end-point
Direction	Increase
Sample: Reagent Ratio	1:100
e.g.: Reagent volume	1 ml
Sample volume	10 µl
Temperature	25 °C, 30 °C, 37 °C
Zero adjustment	Against reagent blank
Linearity	130 mmol/l (462 mg/dl)
Incubation	5 min.

Procedure

Pipette into clean test tubes:

	Blank	Standard	Sample
Reagent (**R**)	1 ml	1 ml	1 ml
Standard	.....	10 µl	.....
Sample	.....	.....	10 µl

Mix well, let stand for 5 minutes, then read absorbances ,A standard and A sample against Reagent Blank at 492 nm.

Calculation

$$\text{Serum Chloride Conc.(mmol/l)} = \frac{\Delta A_{\text{Sample}}}{\Delta A_{\text{Standard}}} \times 100$$

Expected Values

Serum		97 – 108 mmol/l.
Urine	24 h urine	95 – 240 mmol/24h
	morning urine	54 – 158 mmol/l

Conversion between conventional and SI units: 1 mEq/l = 1 mmol/l

Conversion between mmol/l and mg/dl: mmol/l = 0.282 x mg/dl

Note:
It is recommended for each laboratory to establish and maintain its own reference values. The given data are only an indication.

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Sensitivity

When run as recommended, the minimum detection limit of the assay 5 mmol/L

Performance Characteristics

A study using 20 human specimens between this chloride reagent and a reference method yielded a correlation coefficient of 0.993 and a linear regression equation of y = 1.021x + 0.072

Precision
Within run (Repeatibility)

	Level 1	Level 2
n	20	20
Mean (µg/dL)	1.8	3.5
SD	0.04	0.06
CV%	2.3	1.3

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (µg/dL)	1.8	3.5
SD	0.07	0.14
CV%	3.4	4.1

Linearity

The assay is linear up to 130 mmol/l (462 mg/dl)

Interfering substances

Bromide and Fluoride
They can cause falsely elevated chloride values.

Lipemia
Lipemic specimens do not interfere with the test.

Icterus
Icteric serums do not interfere with the reaction.

Waste Disposal

This product is made to be used in professional laboratories.
Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Bablok W. et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-790.
2. Batlle DC. et al. The use of the urinary anion gap in the diagnosis of hyperchloremic metabolic acidosis. N Engl J Med 1988, 318:594-599.
3. Krieg M. et al. Comparative quantitative clinico-chemical analysis of the characteristics of 24-hour urine and morning urine (in German). J Clin Chem Clin Biochem 1986, 24:863.
4. Passing H., Bablok W. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods. J Clin Chem Clin Biochem 1983;21:709-720.
5. Schönfeld, RG. Lewellen, CJ. A colorimetric method for determination of serum chloride. Clin Chem., 10, 533 (1964)
6. Tietz N.W. Clinical Guide to Laboratory Tests, 3rd Philadelphia: W.B. Saunders Company, 1995:516-519.

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
233 001	2 x 25 ml
233 002	4 x 25 ml
233 003	4 x 50 ml

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CE

ISO 13485:2016