respons®910

Chloride 21 FS*

Diagnostic reagent for quantitative in vitro determination of chloride in serum or plasma on DiaSys respons®910

Order Information

Cat. No. 1 1221 99 10 921
4 twin containers for 50 tests each

Method

Photometric test using Ferric (III) perchlorate

Principle

Chloride forms with ferric ions a yellow colored complex whose absorption is measured at 340 nm. A decoloring agent in reagent 2 displaces Chloride out of the complex, thereby discoloring the solution. The difference in absorbance between the colored and discolored state of the solution is proportional to the concentration of chloride in the sample.

Reagents

Components and Concentrations

R1:	Methanesulfonic acid	pH < 1,0	1 – 5 %
	Ferric (III) perchlorate		< 1 %
R2:	Inorganic salt		< 3 %

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagents.

Warnings and Precautions

1. Reagent 1: Danger. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H411 Toxic to aquatic life with long lasting effects. P260 Do not breathe vapors. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 If on skin: Wash with plenty of water/soap. P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a poison center or doctor/physician.
2. The chloride test is very susceptible to chloride contamination. The sole use of ultrapure glass ware and disposable materials is strongly recommended.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen

Serum or plasma (lithium heparin)
Separate from cellular contents immediately after blood collection.
Stability [1]:

at least one year	at	–20°C
7 days	at	4 – 8°C
7 days	at	20 – 25°C

Discard contaminated specimens. Freeze only once.

Calibrators and Controls

For calibration, DiaSys TruCal E calibrator is recommended. The assigned values of TruCal E have been made traceable to the NIST Standard Reference Material® SRM 956. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal E	1 9310 99 10 079	4 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

Performance Characteristics

Measuring range 40 – 170 mmol/L chloride	
Limit of detection**	8 mmol/L chloride
On-board stability	6 weeks
Calibration stability	7 days

Interfering substance	**Interferences < 4.5%**	**Chloride [mmol/L]**
Ascorbate	up to 30 mg/dL	91.6
	up to 30 mg/dL	113
Conjugated bilirubin	up to 30 mg/dL	89.2
	up to 42 mg/dL	111
Unconjugated bilirubin	up to 60 mg/dL	90.1
	up to 42 mg/dL	113
Lipemia (triglycerides)	up to 500 mg/dL	96.1
	up to 1000 mg/dL	110
Hemoglobin	up to 500 mg/dL	103
	up to 700 mg/dL	120
Albumin	up to 76 g/L	94.3
	up to 68 g/L	122
Bromide	up to 40 mmol/L	92.2
	up to 40 mmol/L	111
Iodide	up to 0.9 mmol/L	90.1
	up to 3 mmol/L	112
Fluoride	up to 105 µmol/L	87.5
	up to 105 µmol/L	107
For further information on interfering substances refer to Young DS [2].		

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	87.3	100	116
Coefficient of variation [%]	0.96	0.55	1.37
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	88.3	102	116
Coefficient of variation [%]	1.77	1.61	1.59

Method comparison (n=185)	
Test x	Coulometry
Test y	DiaSys Chloride 21 FS (respons®910)
Slope	1.01
Intercept	0.207 mmol/L
Coefficient of correlation	0.986

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor

Chloride [mmol/L] = Chloride [mEq/L]
Chloride [mmol/L] x 3.545 = Chloride [mg/dL]

Reference Range [3]

Adults:	95 – 105 mmol/L
Children:	
1 – 7 day(s)	96 – 111 mmol/L
7 – 30 days	96 – 110 mmol/L
1 – 6 month(s)	96 – 110 mmol/L
6 months – 1 year	96 – 108 mmol/L
> 1 year	96 – 109 mmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 22-3.
2. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
3. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 295-8.
4. Scott GS, Heusel JW, LeGrys VA, Siggard-Andersen O. Electrolytes and blood gases. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1056-94.
5. Schoenfeld RG, Lewellen CJ. A colorimetric method for determination of serum chloride. Clin Chem 1964;10:533-9.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240-1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

respons®910

Chloride 21 FS

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel

Identification	
This method is usable for analysis:	Yes
Twin reaction:	No
Name:	Cl
Shortcut:	
Reagent barcode reference:	059
Host reference:	

Technic	
Type:	End point
First reagent:[µL]	180
Blanc correction	Yes
Second reagent:[µL]	45
Blanc correction	Yes
Main wavelength:[nm]	340
Secondary wavelength:[nm]	660
Polychromatic factor:	1.000
1 st reading time [min:sec]	(04:24)
Last reading time [min:sec]	05:36
Reaction way:	Decreasing
Linear Kinetics Substrate depletion: Absorbance limit	
Linearity: Maximum deviation [%]	
Fixed Time Kinetics Substrate depletion: Absorbance limit	
Endpoint Stability: Largest remaining slope	
Prozone Limit [%]	

Sample	
Diluent	System water
Hemolysis:	
Agent [µL]	0 (no hemolysis)
Sample [µL]	0
Concentration technical limits-Lower	40
Concentration technical limits-Upper	170
SERUM	
Normal volume [µL]	8
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	8
Above normal dilution (factor)	1
URIN	
Normal volume [µL]	8
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	8
Above normal dilution (factor)	1
PLASMA	
Normal volume [µL]	8
Normal dilution (factor)	1
Below normal volume [µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	8
Above normal dilution (factor)	1
CSF	
Normal volume [µL]	8
Normal dilution (factor)	1
Below normal volume[µL]	8
Below normal dilution (factor)	1
Above normal volume [µL]	8
Above normal dilution (factor)	1

Results	
Decimals	1
Units	mmol/L
Correlation factor-Offset	0.000
Correlation factor-Slope	1.000

Range	
Gender	All
Age	
SERUM	>=95 <=105
URINE	
PLASMA	>=95 <=105
CSF	
Gender	
Age	
SERUM	
URINE	
PLASMA	
CSF	

Contaminants	
Contaminant 1	
Wash with	
Cycle	
Volume [µL]	
Contaminant 2	
Wash with	
Cycle	
Volume [µL]	
Contaminant 3	
Wash with	
Cycle	
Volume [µL]	

Calibrators details	
Calibrator list	**Concentration**
Cal. 1	*
Cal. 2	*
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	

	Max delta abs.
Cal. 1	0.05
Cal. 2	0.05
Cal. 3	
Cal. 4	
Cal. 5	
Cal. 6	
Drift limit [%]	0.8

Calculations	
Model	X
Degree	1

* Enter calibrator value