respons®920

Chloride 21 FS*

Diagnostic reagent for quantitative in vitro determination of chloride in serum or plasma on DiaSys respons®920

Order Information

Cat. No. 1 1221 99 10 921
4 twin containers for 50 determinations 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. H290 May be corrosive to metals. H314 Causes severe skin burns and eye damage. H411 Toxic to aquatic life with long lasting effects. P234 Keep only in original container. P260 Do not breathe vapors. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P303+P361+P353 If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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. P390 Absorb spillage to prevent material damage.
2. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
3. The chloride test is very susceptible to chloride contamination. The sole use of ultrapure glass ware and disposable materials is strongly recommended.
4. In very rare cases, samples of patients with gammopathy might give falsified results [6].
5. 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.
6. 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

DiaSys TruCal E calibrator is recommended for calibration. 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**	7 mmol/L chloride
On-board stability	6 weeks
Calibration stability	10 days

Interfering substance	**Interferences < 4.5%**	**Chloride [mmol/L]**
Ascorbate	up to 30 mg/dL	89.5
	up to 30 mg/dL	109
Conjugated bilirubin	up to 60 mg/dL	89.8
	up to 60 mg/dL	108
Unconjugated bilirubin	up to 54 mg/dL	88.4
	up to 60 mg/dL	108
Lipemia (triglycerides)	up to 800 mg/dL	91.3
	up to 1000 mg/dL	105
Hemoglobin	up to 800 mg/dL	98.6
	up to 700 mg/dL	114
Albumin	up to 76 g/L	90.2
	up to 84 g/L	115
Bromide	up to 40 mmol/L	88.7
	up to 40 mmol/L	109
Iodide	up to 3 mmol/L	94.3
	up to 3 mmol/L	113
Fluoride	up to 105 µmol/L	88.6
	up to 105 µmol/L	109
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]	89.3	101	115
Coefficient of variation [%]	1.08	0.72	0.90
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	88.7	103	116
Coefficient of variation [%]	0.91	1.02	1.37

Method comparison (n=187)	
Test x	Coulometry
Test y	DiaSys Chloride 21 FS (respons®920)
Slope	0.986
Intercept	3.14 mmol/L
Coefficient of correlation	0.989

** 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]

* fluid stable

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

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respons®920

Chloride 21 FS

Application for serum and plasma

Test Details			Test Volumes			Reference Ranges		
Test	:	CL21				Auto Rerun		☐
Report Name	:	Chloride				Online Calibration		☐
Unit	:	mmol/L	Decimal Places	:	1	Cuvette Wash		☐
Wavelength-Primary	:	340	Secondary	:	660	Total Reagents	:	2
Assay Type	:	2-Point	Curve Type	:	Linear	Reagent R1	:	CL21 R1
M1 Start	:	16	M1 End	:	16	Reagent R2	:	CL21 R2
M2 Start	:	20	M2 End	:	20	**Consumables/Calibrators:**		
Sample Replicates	:	1	Standard Replicates	:	3	TruCal E L1 or L2*		*
Control Replicates	:	1	Control Interval	:	0	TruCal E L3 or L4		*
Reaction Direction	:	Decreasing	React. Abs. Limit	:	0.0000	*to be set as “Blank” in consumables		
Prozone Limit %	:	0	Prozone Check	:	Upper			
Linearity Limit %	:	0	Delta Abs./Min.	:	0.0000			
Technical Minimum	:	40.0	Technical Maximum	:	170.0			
Y = aX + b a =	:	1.0000	b=	:	0.0000			

* Please enter calibrator value

Test Details			Test Volumes			Reference Ranges
Test	:	CL21				
Sample Type	:	Serum				

Sample Volumes

Normal	:	8.00	µL	Dilution Ratio	:	1	X
Increase	:	8.00	µL	Dilution Ratio	:	1	X
Decrease	:	8.00	µL	Dilution Ratio	:	1	X
Standard Volume	:	8.00	µL				

Reagent Volumes and Stirrer Speed

RGT-1 Volume	:	180	µL	R1 Stirrer Speed	:	Medium	
RGT-2 Volume	:	45	µL	R2 Stirrer Speed	:	Medium	

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other

Test Details			Test Volumes	Reference Ranges
Test	:	CL21		
Sample Type	:	Serum		
Reference Range	:	DEFAULT		
Category	:	Male		

Reference Range

		Lower Limit (mmol/L)	Upper Limit (mmol/L)
Normal	:	95.00	105.00
Panic	:	0.00	0.00

Sample Types

- ☑ Serum
- ☐ Urine
- ☐ CSF
- ☑ Plasma
- ☐ Whole Blood
- ☐ Other