Chloride Electrode

Catalog number: 781611393

CE IVD Rx Only
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1. Intended use

The chloride electrode is an ion selective electrode that is intended for use on the ion selective electrode (ISE) unit of the Yumizen C1200 analyzer.
The chloride electrode is used to quantify the concentrations of chloride ions in serum, plasma, and urine. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

2. Clinical interest [1) 2)]

Electrolytes are involved in many metabolic functions. Sodium, potassium, and chloride are the most important physiological ions. They are absorbed through the digestive tract, and excreted by kidneys.
Chloride is the main extracellular anion and its function is to regulate the extracellular electrolyte balance. The decrease of plasma or serum chloride levels is sometimes due to prolonged vomiting or diarrhea, a decrease in the renal reabsorption, or an excessive retention of liquid. The main causes of increased chloride are excessive loss of liquid, renal insufficiency, a high chloride supply, and intoxication by salicylic products. Urine-chloride levels are measured in order to evaluate the hydroelectrolytic acid-base balance.

3. Method

- Ion selective electrolyte assay
- Dilution measurement method (indirect)
- The variance in potential is measured between the reference electrode and corresponding ion selective electrode reaction to the sample.

4. Sample type

- Serum
- Plasma lithium heparin
  - ✓ Anticoagulants other than lithium heparin have not been validated and are therefore not recommended for use with this assay.
- Urine

5. Characteristics

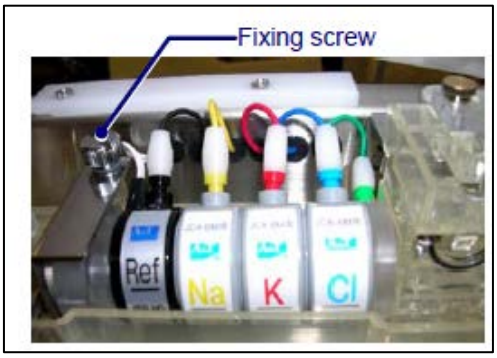
- Chloride Electrode is packaged individually.
- Chloride Electrode should be used according to this notice. The manufacturer cannot guarantee its performance if used otherwise.

6. Handling

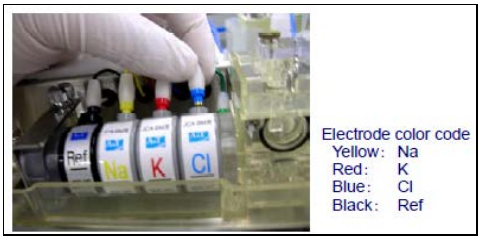
6.1 Replace the electrode

An aging electrode can result in measurement instability. Replace the electrode as required. For detail, refer to “7.8 Maintenance Performed as Required” in the user manual.

1. Prepare a new electrode.
2. Remove the fixing screw that holds the electrode in place.



3. Detach the connector from the electrode.
4. Replace the electrode in the indicated position.
   - ✓ Make sure that the new electrode has the O-ring in place to prevent leaks.
5. Tighten the fixing screw by hand while pressing the fixing plate onto the electrode assembly.
6. Insert the electrode connector.



7. Perform calibration.

❖ Be sure to perform calibration after electrode replacement.

7. Calibrator

For calibration use:

■ For serum and plasma:

- ISE Serum Standard Set (NA)
  Catalog number: 781611351
  Pack size:
  ISE Serum High Standard 100 mL × 1
  ISE Serum Low Standard 100 mL × 1

■ For urine:

- ISE Urine Standard Set
  Catalog number: 781611369
  Pack size:
  ISE Urine High Standard 100 mL × 1
  ISE Urine Low Standard 100 mL × 1

8. Control

For internal quality control, use:

■ For serum and plasma:

- Yumizen C1200 N Multi Control
  Catalog number: 1300023938
  Pack size: 5 mL × 6, lyophilisate
  Catalog number: 1300023939
  Pack size: 5 mL × 20, lyophilisate

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- Yumizen C1200 P Multi Control
  Catalog number: 1300023940
  Pack size: 5 mL × 6, lyophilisate
  Catalog number: 1300023941
  Pack size: 5 mL × 20, lyophilisate

■ For urine:

- Yumizen C1200 Urine Level 1 Control
  Catalog number: 1300023946
  Pack size: 5 mL × 6
- Yumizen C1200 Urine Level 2 Control
  Catalog number: 1300023947
  Pack size: 5 mL × 6

9. Materials required but not provided

Automated clinical chemistry analyzer: Yumizen C1200 equipped with ISE module.

- ISE Buffer (IS)
  Catalog number: 781611334
- Internal Standard
  Catalog number: 781611342
- Reference Electrode
  Catalog number: 781611407
- ISE Detergent Solution
  Catalog number: 781611415

10. Reference range

Each laboratory should establish its own reference ranges. The values given here are used as guidelines only.

- Serum and plasma
  98 mmol/L to 107 mmol/L[3)]
- Urine-24 hour
  110 mmol/day to 250 mmol/day[3)]

11. Storage and stability

■ Storage

- Unopened
  - ✓ Avoid direct sunlight.
  - ✓ Store at 2 °C to 32 °C.
- If removing a used electrode from the unit for more than 30 minutes then:
  - ✓ Cover the electrode with the ISE Buffer.

❖ Activity will be lost if the electrode membrane dries out. The inner membrane exposed to the flow pass is invisible from the outside. Immerse it in the ISE Buffer when not in use.

❖ Rinse the connector with water before use. Maintain the electrode at room temperature.

■ Stability

The unopened electrodes may be installed up to the expiration date on the label if stored at 2 °C to 32 °C. Once installed on the ISE module, Chloride Electrode can be used for 3 months or 30000 measurements.

12. Packaging damage

In case of damage, do not use the electrode. The damage may have an effect on the product performance.

13. Waste management

Refer to local legal requirements.

14. General precautions

- This electrode is for professional in vitro diagnostic use only.
- Observe the standard laboratory precautions for use.
- Operate the instrument according to the user manual under appropriate conditions.
- Wear gloves during a replacement of electrodes.
- Do not use the product if there is visible evidence of biological, chemical or physical deterioration.
- Before the first analysis of the day, perform calibration and Quality Control.
- Be sure to perform calibration and Quality Control after maintenance, when replacing ISE Buffer, replacing Internal Standard, replacing the electrode, or replacing the consumable items.
- It is the user's responsibility to verify that this document is applicable to the electrode in use.

15. Performance on Yumizen C1200

15.1 Sample volume

Serum, Plasma, Urine: 22 µL/test

15.2 Precision

■ Repeatability (within-run precision)

The repeatability was determined according to the Valtec guideline.
2 level controls, 3 samples of low, middle, and high level concentrations, and the spiked samples were tested 20 times by 3 reagent lots.

		Serum	
		Mean value (mmol/L)	CV (%)
Yumizen C1200 N Multi Control	Lot1	114.04	0.2
	Lot2	115.47	0.3
	Lot3	114.24	0.4
Yumizen C1200 P Multi Control	Lot1	112.75	0.3
	Lot2	114.50	0.2
	Lot3	113.45	0.3
External control N	Lot1	91.21	0.2
	Lot2	91.70	0.3
	Lot3	91.64	0.3
External control P	Lot1	112.01	0.3
	Lot2	112.17	0.3
	Lot3	111.72	0.3
Low sample	Lot1	90.61	0.2
	Lot2	90.89	0.3
	Lot3	90.46	0.2
Middle sample	Lot1	101.81	0.2
	Lot2	102.29	0.4
	Lot3	101.71	0.3
High sample	Lot1	112.79	0.4
	Lot2	113.09	0.4
	Lot3	112.46	0.3
Spiked sample	Lot1	130.18	0.3
	Lot2	130.35	0.3
	Lot3	129.65	0.3

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		Urine	
		Mean value (mmol/L)	CV (%)
Yumizen C1200 Urine Level 1 Control	Lot1	62.04	0.4
	Lot2	62.48	0.3
	Lot3	66.09	0.4
Yumizen C1200 Urine Level 2 Control	Lot1	163.60	0.2
	Lot2	162.67	0.2
	Lot3	171.54	0.3
Low sample	Lot1	24.13	1.1
	Lot2	25.79	0.8
	Lot3	30.78	2.2
Middle sample	Lot1	102.07	0.2
	Lot2	104.55	0.4
	Lot3	106.76	0.8
High sample	Lot1	199.91	0.3
	Lot2	199.77	0.3
	Lot3	190.33	0.6
Spiked sample	Lot1	322.88	0.4
	Lot2	318.66	0.3
	Lot3	292.00	0.3

■ Reproducibility

The reproducibility was determined according to the CLSI guideline EP05-A3. 2 level controls, 3 samples of low, middle, and high level concentrations, and the spiked samples were tested in duplicate for more 20 days (2 series per day).

	Serum	
	Mean value (mmol/L)	CV (%)
Yumizen C1200 N Multi Control	113.49	0.4
Yumizen C1200 P Multi Control	111.34	0.4
External control N	90.77	0.4
External control P	111.51	0.4
Low sample	90.25	0.3
Middle sample	101.59	0.3
High sample	112.36	0.3
Spiked sample	129.46	0.4

	Urine	
	Mean value (mmol/L)	CV (%)
Yumizen C1200 Urine Level 1 Control	60.40	1.8
Yumizen C1200 Urine Level 2 Control	162.60	1.2
Low sample	24.29	3.1
Middle sample	100.79	0.7
High sample	199.13	0.4
Spiked sample	323.05	0.6

15.3 Linearity and measuring range

The Limit of Quantitation was determined according to the CLSI guideline EP17-A2.
The Linearity was determined according to CLSI guideline EP06-A.
The Measuring range of the chloride electrode on the Yumizen C1200 was validated by the Limit of Quantitation and Linearity studies.

Parameters	Limit of Quantitation	Linearity	Measuring range
Serum (mmol/L)	22.59	51.7 to 238.9	52 to 200.0
Urine (mmol/L)	7.00	6.9 to 456.4	15 to 400.0

15.4 Correlation

The Yumizen C1200 was compared to the Olympus AU400 Clinical Chemistry Analyzer. The patient samples were correlated with a commercial ISE module taken as the reference method according to the CLSI guideline EP09-A3. The equation for the regression line using Passing Bablok was obtained.

Passing Bablok	N	Intercept	Slope	Correlation - r
Serum	172	0.818	0.992	0.998
Plasma	173	-1.568	1.019	0.998
Urine	194	0.525	0.991	1.000

15.5 Interferences

The Interferences were determined according to the CLSI EP07-A2. The calculated bias was within the 10 % acceptance criteria on serum and urine samples at the following concentrations.

Serum	
Hemoglobin	0.5 g/dL
Triglycerides	52.1 mmol/L
Total bilirubin	396 µmol/L
Total protein	121.13 g/L
Urea	71.9 mmol/L
Salicylic acid	0.53 mmol/L
Imipramine	2.50 µmol/L
Procainamide	102 µmol/L
Chlorpromazine	6.30 µmol/L
Erythromycin	81.6 µmol/L
Ampicillin	150 µmol/L

Urine	
Hemoglobin	1.25 g/dL
Total bilirubin	256 µmol/L
Protein	3.31 g/L
Urea	988.3 mmol/L
Ascorbic acid	3.40 mmol/L

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16. Sample stability[4)]

- Serum and plasma
  - ✓ At 20 °C to 25 °C: 7 days
  - ✓ At 4 °C to 8 °C: 7 days

17. Reference

1) Scott MG, LeGrys VA, Klutts JS. Electrolytes and Blood Gases. In: Burtis CA, Ashwood ER, Bruns DE, eds. Tietz Textbook of Clinical Chemistry and Molecular Diagnosis. 4th ed. St Louis, Missouri: Elsevier Saunders (2006): 983-990.
2) David S. Jacobs et al. Laboratory Test Handbook, Lexi-comp inc, 4th Edition (1996): 109.
3) Tietz NW, Clinical Guide for Laboratory Tests 3rd edition. WB Saunders Company, Philadelphia, PA, pp. 610-611 (1995)
4) WHO/DIL/LAB/99.1 Rev.2, 2002