

# CHLORIDE

## Diagnostic reagent for determination of Chloride concentration.

Liquid. Monoreagent. Store at +2/+8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Ambalaj
MD121	90 mL
CL202N	120 mL
CL201N	100 mL
CL200N	500 mL
PL2065	240 mL
MCL20	250 mL

*Changes made in the instructions for use are marked as grey*

### INTENDED USE

The test is applied for the quantitative determination of chloride in serum, plasma and urine.

### TEST SUMMARY AND PROCEDURE <sup>1, 2, 3, 4, 5</sup>

Chloride ions react with mercury of thiocyanate ions. Thiocyanate ions react with trivalent ferric ions present in solution to form a red colored complex with an absorbance peak at 480 nm.

### TEST PARAMETERS

Method : Endpoint  
 Wavelength : 480 nm (460-500)  
 Linearity : 200 mEq/L

### REAGENT COMPONENTS

Mercury (II) thiocyanate : ≤ 2.5 mM,  
 Mercury (II) chloride : ≤ 1.2 mM,  
 Iron (III) nitrate : ≤ 22 mM.

### REAGENT PREPARATION

Reagent is ready for use.

### REAGENT STABILITY AND STORAGE <sup>6</sup>

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

### SAMPLE

Serum, plasma lithium heparinate are collected according to the standard procedures.

Separation of cells from plasma should be prompt. Sweat is a sample suitable for use. Use urine in 24 hours. Dilute

sample urine 1:2 with redistilled water and multiply the results by 2.

Chloride in serum is stable for:  
 7 days at +20/+25°C,  
 7 days at +2/+8°C,  
 1 year at -20°C.

Chloride in urine is stable for:  
 7 days at +20/+25°C,  
 7 days at +2/+8°C  
 7 days at -20°C.

### Unit Conversion:

mmol/L x 3.5460 = mg/dL  
 mEq/L = mmol/L

### REFERENCE INTERVAL (NORMAL VALUES) <sup>7</sup>

Serum/plasma : 98 - 110 mEq/L  
 Urine : 110 - 250 mEq/24h  
 (Dietary variations are possible)  
 Sweat : Up to 30 mEq/L

It is recommended that each laboratory establish its own reference range.

Reference interval has been verified by using CLSI EP28-A3c protocol.

### CALIBRATION and QUALITY CONTROL

**Calibration:** The assay requires the use of Arcal Auto Calibrator.

Arcal Auto Calibrator-Lyophilized

**Ref.No: A39052**

**Ref.No: A39054**

**Ref.No: A39055 (Olympus AU serisi içindir.)**

Reagents must not be kept on the instrument. After the study, the reagent must be tightly closed and stored at +2/+8°C. Make sure that the cover to be used during storage does not carry the risk of contamination. Calibration stability is 15 days for products stored at +2/+8°C in a closed with a cap after the study. Calibration period is 1 day for reagents that remain on the device

during the onboard period. Calibration stability depends on the application characteristics and cooling capacity of the autoanalyzer used.

**Control:** Commercially available control material with established values determined by this method can be used. We recommend:

Arcon N Level 1 Control- Lyophilized  
**Ref.No: A3910**  
**Ref.No: A3912 (For Olympus AU series.)**  
**Ref.No: A3913 (For BS series.)**  
**Ref.No: A3914 (For Erba.)**

Arcon P Level 2 Control- Lyophilized  
**Ref.No: A3920**  
**Ref.No: A3922 (For Olympus AU series.)**  
**Ref.No: A3923 (For BS series.)**  
**Ref.No: A3924 (For Erba.)**

At least two level controls must be run once in every 24 hours. Each laboratory should determine its own quality control scheme and procedures. If quality control results are not within acceptable limits, calibration is required.

## PERFORMANCE CHARACTERISTICS

**Limit of Detection (LoD):** The limit of detection is 1 mEq/L.

**Limit of Quantitation (LoQ)** [LoQ values are based on Coefficient of Variation Percentage (CV) % $\leq$ 20]:<sup>8</sup> 5 mEq/L.

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

**High Linearity:** The method is linear up to 200 mEq/L.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

### Precision Studies:<sup>9</sup>

#### Repeatability (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
114.8 mEq/L	1.48	1.29	40
111.0 mEq/L	1.41	1.28	40

#### Reproducibility (Run to Run) (Inter-Assay)

Mean Concentration	SD	CV%	n
117.03 mEq/L	2.95	2.52	40
134.4 mEq/L	3.26	2.43	40

\*SD: Standard Deviation

Precision studies data have been verified by using CLSI EP05-A3 protocol.

### Method Comparison:<sup>10, 11</sup>

Correlation with a comparative method is:  $r = 0.927$   
 According to Passing-Bablok Fit:  
 Slope: 0.869  
 Intercept: 14.402

### Interference:<sup>3, 4, 5, 12</sup>

No significant interference was observed for hemoglobin, bilirubin, lipemia, up to the interferent concentration given.

Hemoglobin	: $\leq$ 500 mg/dL
Bilirubin	: $\leq$ 32 mg/dL
Lipemia	: $\leq$ 500 mg/dL

The acceptable interference limit is set 10% below the highest interference concentration within  $\pm$  10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

## WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.

Do not use expired reagents.

Reagents with two different lot numbers should not be interchanged.

For professional use.

Follow Good Laboratory Practice (GLP) guidelines.

**CAUTION:** Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

### Danger

EUH032	: Releases a very toxic gas if contacts with acid.
H317	: May cause allergic skin reaction.

### Precaution

P280	: Use protective gloves / clothes / glasses / mask.
P264	: Wash your hands properly after using.
P272	: Contaminated work clothes should not be allowed to be used outside of the workplace.

### Intervention

P302+P352	: Wash with plenty of water and soap if it contacts with skin.
P333+P313	: Seek medical help if it irritates your skin or develops rash.
P362+P364	: Remove contaminated clothes and wash properly before using.

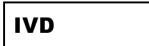

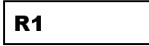


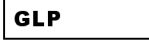








**Disposal**

P501 :Dispose the vials and contents according to the local regulations.

**REFERENCES**

1. Tietz, N.W., Fundamentals of Clinical Chemistry, p. 940, W.B. Saunders Co., Philadelphia, 1987.
2. Tietz NW. Clinical Guide to Laboratory Test. 2nd ed. Philadelphia, PA: WB Saunders Company; 1995,52.
3. Tietz NW. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Company; 1995:88-91.
4. Tietz NW, ed. Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia: WB Saunders 1995:919.
5. Tietz Fundamentals of Clinical Chemistry. 5th ed. Burtis CA, Ashwood ER, eds. Philadelphia, PA: WB Saunders Company; 2001:605.
6. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI Document EP25-A. Wayne, PA: CLSI; 2009.
7. Clinical and Laboratory Standards Institute (CLSI). Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition. CLSI Document EP28-A3c. Wayne, PA: CLSI; 2010.
8. Clinical and Laboratory Standards Institute (CLSI). Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline. CLSI Document EP17-A. Wayne, PA: CLSI; Vol. 24 No. 34.
9. Clinical and Laboratory Standards Institute (CLSI). Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014
10. Passing-Bablok W et al. A General Regression Procedure for Method Transformation. J Clin Chem Clin Biochem 1988;26:783-79.
11. Clinical and Laboratory Standards Institute (CLSI). Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition; Approved Guideline. CLSI Document EP09-A2. Wayne, PA: CLSI; Vol. 22 No. 19.
12. Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline. CLSI Document EP07. Wayne, PA: CLSI; 3rd Edition. CHERIAN G., SOLDIN ST. Clin. Chem. 27/5:748-752 (1981)
13. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
14. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACCPress (1990).
15. Levinson S.S., Direct determination of serum chloride with a semiautomated discrete analyzer, Clin.Chem. 22:273-274, 1976
16. Wu, Alan H.B. Tietz Clinical Guide to Laboratory Tests. 4th ed. Saunders Elsevier, St. Louis, MO: 2006, 234-241.

17. Eisenman G. Glass Electrodes for Hydrogen and Other Cations, Principles and Practice. New York: Marcel Dekker Inc.; 1967:2.
18. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.

SYMBOLS	
	In Vitro Diagnostic Medical Device
	Lot Number
	Reagent 1
	Global Trade Item Number
	Reference Number
	Good Laboratory Practices
	Identifies Products to Be Used Together
	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests



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