CHLORIDE

Diagnostic reagent for determination of Chloride concentration.
Liquid. Monoreagent. Store at +15/+25°C. For in Vitro Diagnostic Use. Do not freeze.

Ref No	Package	Ref No	Package	Ref No	Package	Ref No	Package
BB045	160 mL	DMCL20	222 mL	LM464	160 mL	PL2065	240 mL
BY200	450 mL	HN325	300 mL	MCL20	250 mL	PL2066	150 mL
CL200N	500 mL	LB065	160 mL	MCL21	200 mL	S2081	100 mL
CL201N	100 mL	LCL20	160 mL	MD121	90 mL	TCL20	225 mL
				M4L25	300 mL	8A200	450 mL

Chagnes 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 [1, 2, 3, 4, 5]

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) tiocyanate : ≤ 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 [6]

Reagents are stable at +15/+25˚C till the expiration date stated on the label which is only for closed vials.

Reagents must not be stored on the instrument. Upon completion of the analysis, promptly cap the reagent vial.Ensure that the vial cap is free from any cross-contamination with other reagents prior to use. When stored at +15°C to +25°C under the specified handling and usage conditions, the reagent maintains stability for up to 20 days.

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

SAMPLE

Serum, plasma 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/+8ºC,
1 year at -20°C.

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

Unit Conversion:
mmol/L x 3.5460 = mg/dL

REFERENCE INTERVAL (NORMAL VALUES) [7]

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.

QUALITY CONTROL AND CALIBRATION

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

Arcal Auto Calibrator-Lyophilized
Ref.No: A39052
Ref.No: A39054
Ref.No: A39055 (For Olympus AU series.)

When reagents are properly stored (tightly capped) at +15°C to +25°C after analysis, calibration stability is

maintained for up to 2 days. For reagents kept onboard the instrument, calibration stability is limited to 1 day.

Any change in the reagent lot number requires recalibration.If quality control results fall outside the acceptable range, recalibration must be performed.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) %≤20]**:**[8] 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:[9]

Repeatability (Within Run) (Intra-Assay)

Mean Concentration	SD*	CV%	n
114.8 mEq/L	1.48	1.30	40
111.0 mEq/L	1.41	1.30	40

Reproducibility (Run to Run) (Inter-Assay)

Mean Concentration	SD	CV%	n
117.03 mEq/L	2.95	2.50	40
134.4 mEq/L	3.26	2.90	40

*SD: Standard Deviation

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

Method Comparison:[10, 11]
Correlation with a comparative method is: r= 0.927
According to Passing-Bablok Fit:
Slope: 0.869
Intercept: 14.402

Interference:[3, 4, 5, 12]
No significant interference was observed for hemoglobin, bilirubin, lipemia, up to the interferent concentration given.

Hemoglobin	: ≤ 500 mg/dL
Bilirubin	: ≤ 32 mg/dL
Lipemia	: ≤ 500 mg/dL

The acceptable interference limit is set 10% below the highest interference concentration within ± 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: AACC Press (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

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests



Archem Sağlık Sanayi ve Tic. A.Ş.
Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
Bağcılar/İstanbul/Turkey
Tel: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr **www.archem.com.tr**

CE