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

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 +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/+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
mEq/L = mmol/L

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.

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 instument. 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) %≤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	1.29	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:[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.

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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

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