

CHLORIDE Multi-Purpose (MPR) Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL554CL	4 x 250 ml 1 x 10 ml	CHLORIDE CHLORIDE - Standard	15 - 25°C
GL564CL	6 x 60 ml 1 x 10 ml	CHLORIDE CHLORIDE - Standard	15 - 25°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Chloride in serum and plasma on automated and semi-automated analysers.

PRINCIPLE OF THE TEST: 1

Chloride ions form a coloured complex when reacting with mercury II thiocyanate solution. The intensity of the colour is proportional to the chloride concentration in the sample.

Cl⁻ + Mercury II Thiocyanate → Coloured complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only

Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:

Reagent 1: Very pale yellow liquid.

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:

CAUTION: Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

Handling precautions:

- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request.

COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	Mercury II Thiocyanate Iron III Nitrate Nitric Acid	2 mmol/L 20 mmol/L 45 mmol/L
Standard	Chloride	100mmol/L (355mg/dL)

REAGENT PREPARATION AND STABILITY:

Reagent 1 and standard are ready to use.

Before use, mix reagent by gently inverting each bottle.

If stored and handled properly, components are stable until expiry date stated on label.

TYPE OF SPECIMEN: 2

Use serum or heparin plasma as specimen.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sample container, with proper specimen identification.

Stability: If not analysed immediately, specimen may be stored at 2 - 4°C or frozen

TEST PROCEDURE:

Materials required but not supplied:

Description	Catalog No.	Description	Catalog No.
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932	Photometer	N/A

Assay procedure:

Wavelength: 480 nm

Temperature: 20°C, 25°C or Room Temperature.

Optical path: 1 cm light path

	Blank	Calibrator	Sample
Reagent 1	1 ml	1 ml	1 ml
Sample	---	---	10 µl
Calibrator	---	10 µl	---
Gently mix and incubate for 5 minutes. Read Optical Density (OD), against the reagent blank.			

Calibration:

Using standard provided, calibrate the assay:

- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Control results are out of range.

Quality Control:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed:

- Prior reporting** patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory QC Programme.

CALCULATION:

$$\text{Concentration of Chloride} = \frac{\text{OD}_{\text{Sample}}}{\text{OD}_{\text{Calibrator}}} \times \text{Concentration of Calibrator}$$

EXPECTED VALUES: 1

In serum or plasma	98 - 107 mmol/L
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Each laboratory should establish its own reference range. Chloride results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:

This assay is linear between 75 – 130 mmol/l.

For samples with a higher concentration, dilute 1:1 with DDH₂O and reassay. Multiply result obtained by 2.

Precision:

















Within Run N = 20	Mean (UI)	SD	% CV
Level 1	85.5	0.242	0.28
Level 2	104.3	0.245	0.23

BIBLIOGRAPHY:

- Abe A., Yamashita S., Noma A., Clin Chem., 552-554, 35 (1989)
- C. A. Burtis, E.R. Ashwood. Tietz Fund. Of Clin. Chem. 5th ed. 30:54 and 496-500,

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

	In Vitro Diagnostics		Catalogue No
	Batch Code		Content
	Reagent		Antibody
	Calibrator		Substrate
	Buffer		Aqueous Standard
	Storage temperature		Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use



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