ZINC
Multi-Purpose (MPR) Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL535Z	2 x 60 ml	ZINC - 1	15-25°C
	1 x 10 ml	ZINC - Standard	
GL545Z	6 x 60 ml	ZINC - 1	15-25°C
	1 x 10 ml	ZINC - Standard	

INTENDED USE:

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

SUMMARY AND EXPLANATION[2]:

Zinc is the second most abundant trace element in humans. It is an integral part of more than two hundred enzymes. Nutritional zinc deficiency is fairly prevalent and symptoms include retardation growth and skeletal maturation, testicular atrophy and hepatosplenomegaly.

Decreased levels are found in patients with hepatic cirrhosis gastrointestinal disease, intestinal bypass and Crohns disease. Decreased levels have also been found in patients with renal disease due to protenuria.

PRINCIPLE OF THE TEST:

Zinc forms with 2-(5-Brom-2-pyridylazo)-5-(N-propyl-N-sulfopropylamino)-phenol a red chelate complex. The increase of absorbance can be measured and is proportional to the concentration of total zinc.

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: Orange 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	Bicarbonate Buffer pH 9.8	200 mmol/l
	Sodium Citrate	170 mmol/l
	Dimethylglyoxime	4 mmol/l
	5-Br-PAPS	50 µmol/l
	DETERGENTS	
Standard	Zinc	30 µmol/l

REAGENT PREPARATION AND STABILITY:

Components are ready for 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:

Use serum, heparin plasma or urine specimen. Specimen must be completely cleared before assay.

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

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
General Chemistry Control Level 1	GL922	Photometer	N/A
General Chemistry Control Level 2	GL932	General Laboratory Equipment	N/A
		Saline solution 0.9 g/l NaCl	N/A

Assay procedure:
Wavelength: 560 nm
Temperature: 25, 30, 37°C
Optical path: 1 cm light path

	Blank	**Calibrator**	**Sample**
Reagent 1	1 ml	1 ml	1 ml
Sample	----	----	50 µl
Calibrator	----	50 µl	----
Gently mix and Incubate at 37°C for 5 minutes. Read Optical Density (OD), against the reagent blank.			

Calibration:
Using standard provided or suitable calibrator with values determined for Zinc, 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:

$$\text{Concentration of Zinc} = \frac{OD_{Unknown}}{OD_{Calibrator}} \times \text{Concentration of Calibrator}$$

(Converstion Factor: Qty in µmol/L = Qty in µg/dl x 0.153).

EXPECTED VALUES:

	µg/dl	*µmol/l*
Men	72.6 - 127	11.1 – 19.5
Women	70 – 114	10.7 – 17.5

Each laboratory should establish its own expected values. The Zinc 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 up to 400µg/dl (61.2 µmol/l).
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Precision:

Within Run N = 20	Mean *(µmol/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(µmol/l)*	*SD*	*% CV*
Level 1	15.9	0.197	1.24	Level 1	22.5	0.241	1.07
Level 2	30.8	0.307	1.00	Level 2	43.3	0.358	0.83

BIBLIOGRAPHY:

1. Johnsen and R. Eliasson. Evaluation of a coercially available kit for the colorimetric determination of zinc. International Journal of Andrology. 1987, 10.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54.

SYMBOLS:

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

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard

CE Mark - Device complies with the Directives 98/79/EC

Storage temperature → Reconstitute with

Expiry Date (Last day of the month) — Manufactured By

Biological risk — Consult Instruction for Use

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