

LiquiMAX Zinc-SLR

5-Br-PAPS Method

ORDER INFORMATION:

Ref. No	Pack Size	Presentation
AVZNC - 25	25 ml	Mono Reagent

INTENDED USE:

LiquiMAX Zinc is an in-vitro diagnostic kit for the quantitative determination of Zinc in human Serum, Urine and Seminal Fluid.

PRODUCT FEATURES:

1. Liquid Stable Mono Reagent
2. Linearity : 1000 µg /dL
3. Measuring wavelength : 546 nm
4. End Point Method
5. Calibrator Provided

CLINICAL SIGNIFICANCE:

Zinc is an essential element in the nutrition of human beings, zinc is required in the genetic make-up of every cell and is an absolute requirement for all biologic reproduction. Zinc is needed in all DNA and RNA syntheses and is required at every step of the cell cycle. About 2 grams of zinc is Distributed throughout the body human. Hypozincemia is a condition where insufficient zinc is available for metabolic needs. The deficiency may lead to Anorexia, Diarrhia and Pneumonia or cognitive and motor function impairment in children. Zinc deficiency during pregnancy can negatively affect both the mother and fetus.

In some cases Hyperzincemia is reported and is attributed to the intake of Zinc containing foods which elevate zinc concentration in blood.

PRINCIPLE:

Zinc reacts with 2-(5-bromo-2-pyridylazo)-5-(N-propyl-N sulfopropylamino) - phenol (5-Br-PAPS) to form a red chelate complex in pH = 9.8 . The increase of absorbance measure at 546/600 nm is proportional to the concentration of total zinc in the sample.

STORAGE AND STABILITY

All the reagents are stable up to the expiry date mentioned on the labels when the proper storage conditions are maintained.

KIT COMPONENTS

1. Zinc Reagent
2. Zinc Standard : Concentration as stated on the label

COMPOSITION

Bicarbonate buffer, pH = 9.8	500 mmol/L
5-Br-PAPS	0.03 mmol/L
Sodium citrate	68 mmol/L
Dimethyl glyoxime	4 mmol/L
Detergent	

Standard: The concentration as indicated on vial. (Lot Specific)

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance exceeds 1.2 at 546 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION AND STORAGE

1. Non-hemolyzed serum is the specimen of choice
2. Collect the blood in a Serum vacutainer tube
3. Remove serum from clot as soon as possible.
5. Stability in serum: 7 days at 2 – 8 °C.
6. 24/ hr. Urine: Collect in clean, plastic urine container with no metal cap. Refrigerate after completion of collection.
7. Seminal fluid: Centrifuge the sample at 3000 rpm for 10-15 min. Stability of the sample 7 days at 2 – 8 °C. Dilute supernatant (1+99) with sodium chloride solution (0.9%) and multiply the result by 100

SYSTEM PARAMETERS:

Reaction type	:	End Point
Reaction Slope	:	Increasing
Wave length	:	546 nm
Flow cell Temp.	:	37°C
Sample volume	:	50 µl
Reagent volume	:	1000 µl
Calibrator concentration	:	Printed on the Label
Units	:	µg/dl
Blanking with	:	Reagent
Low normal	:	45
High normal	:	150
Linearity	:	1000

TEST PROCEDURE:

Reagent	Blank	Calibrator	Sample
Reagent	1000 µL	1000 µL	1000 µL
Calibrator	–	50 µL	–
Sample	–	–	50 µL

Mix, incubate for 10 min. at 37 °C. Read the absorbance of Standard and Sample against the reagent blank.

CALCULATIONS:

$$\text{Conc. Zinc (µg/dl)} = \frac{\text{Abs of sample}}{\text{Abs of Calibrator}} \times \text{Conc. Calibrator (µg/dl)} \quad \text{(Lot Specific)}$$

EXPECTED VALUE

Serum:		µg/dl
< 4 Months.		65 - 137
4 – 12 Months		65 - 130
1 – 5 Years		65 - 118
6 – 9 Years		78 - 105
10 – 13 Years	Men	78 - 98
	Women	78 - 118
14 – 19 Years	Men	65 - 118
	Women	59 - 98
Adults		45 - 150
Urine:		300 – 800 µg/24hr
		15 – 120 µg/dL (Spot Urine)
Seminal Fluid		2000 – 10000 µg/dL

Note:

Serum zinc levels are generally 5 -15 % higher than plasma levels due to zinc released from platelets and erythrocytes during clotting.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

- When using a new reagent or lot.
- When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 1000 µg /dL

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 5 µg /dL

3. Interferences

No significant interference was observed from Bilirubin up to 20 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl, Lipemia as Triglycerides up to 2000 mg/dl, Ascorbic acid up to 50 mg/dl.

4. Precision:

Intra-Assay

N=20	Mean (µg /dL)	SD (µg /dL)	CV%
Control serum 1	48.2	0.13	1.59
Control serum 2	122.3	0.32	2.15
Control serum 3	248.6	0.58	1.95

Inter-Assay

N=20	Mean (µg /dL)	SD (µg /dL)	CV%
Control serum 1	48.3	0.033	1.49
Control serum 2	122.6	0.035	1.32
Control serum 3	249.3	0.031	0.80

5. Method Comparison:

A comparison of the LiquiMAX Zinc - SLR (y) with a commercial obtainable assay (x) gave the following result : $y = 1.113x - 0.278$; $r = 0.990$

LIMITATIONS

Measuring range: 5-1000 µg /dL. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.














NOTES

- Use only disposable plastic containers or iron free tubes and cuvettes. Avoid any contamination by the use of clean laboratory material.
- Reagent contains sodium azide. Don't swallow. Avoid any contact with skin and mucous membranes. Sodium azide may react with lead and copper plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.

REFERENCES:

- Johansen and R.Eliasson. Evaluation of a commercially available kit for colorimetric determination of zinc. International Journal of andrology, 1987, April 10 (2): 435 - 440.
- Young, DS., Effects of Drugs on Clinical Laboratory Tests, fifth edition 2000, AACC Press, Washington, D.C.

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		



AVECON™ Healthcare Pvt. Ltd.
Manufactured in India by :
Transforming Research into Innovations