SBio ZINC KIT

(Colorimetric Method)

(For invitro diagnostic use only)

REF	90900025
Pack Size	25 ml

CE

8°C 2°C Store at 2-8°C	Manufacturer	IVD *In vitro* Diagnostic Medical Device	L1 Buffer Reagent	Colorimetric Colorimetric Method
Use by (Last day of stated month)	Consult Instructions for use	LOT Batch Number	L2 Colour Reagent	
Date of Manufacture	REF Catalogue Number	EC REP Authorised Representative in the European Community	S Zinc Standard (200 µg/dl)	This way up

INTENDED USE

Zinc Kit is used for the determination of Zinc in serum and urine.

PRINCIPLE OF THE TEST

Zinc in an alkaline medium reacts with Nitro - PAPS to form a purple coloured complex. Intensity of the complex formed is directly proportional to the amount of Zinc present in the sample.

Zinc +Nitro - PAPS —(Alkaline Medium)→ Purple Coloured Complex

CLINICAL SIGNIFICANCE

Zinc is important in human for growth and sexual development. It is present in various organs and is a component of many enzymes. Zinc found in serum is totally bound to protein with over 60% being bound to albumin. Increased levels are found in patients associated with gastrointestinal disorders accompanied with nausea, vomiting, high fever and a metallic taste. Decreased levels are found in cirrhosis, lung carcinomas, sickle cell anemia, acute myocardial infarction, renal failure, corticosteroid and oral contraceptive therapy.

PRESENTATION	25 ml
L1 : Buffer Reagent	20 ml
L2 : Colour Reagent	5 ml
S : Zinc Standard (200 µg/dl)	2 ml

COMPOSITION

Borate Buffer 290 mM; pH 8.2; Salicilaldoxime 10 mM; Dimethylglyoxime 1.0 mM; NITRO-PAPS 0.08 mM; Surfactants and Preservatives.

STORAGE / STABILITY

Contents are stable at 2-8°C till the expiry mentioned on the labels.

SAMPLE REQUIRED

Serum (Free from hemolysis) or urine. Zinc is reported to be stable in serum for 7 days at 2-8°C.

REAGENT PREPARATION

Reagents are ready to use.

Working reagent: Pour the contents of 1 bottle of L2 (Colour Reagent) into 1 bottle of L1 (Buffer Reagent). This working reagent is stable for at least 2 weeks when stored at 2-8°C.
Alternatively for flexibility as much of working reagent may be made as and when desired by mixing together 4 parts of L1 (Buffer Reagent) and 1 part of L2 (Colour Reagent). Alternatively 0.8 ml of L1 and 0.2 ml of L2 may also be used instead of 1 ml of the working reagent directly during the assay.

SAMPLE WASTE AND DISPOSAL

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance.
This product requires the handling of human specimens. It is recommended that all human sourced material are considered potentially hazardous and are handled in accordance with the OSHA standard on blood borne pathogens.
Appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
Handle specimens, solid and liquid waste and test components in accordance with local regulations and NCCLS guidelines M29, or other published biohazard safety guidelines.

PROCEDURE

Wavelength / filter : 570 nm (Hg 578 nm) / Yellow
Temperature : R.T.
Light path : 1 cm

MATERIALS REQUIRED BUT NOT PROVIDED

Photometer analyzer with standard thermostatic cuvette holder, micropipette and appropriate laboratory equipment.

Pipette into clean dry test tubes labelled as Blank (B), Standard (S), and Test (T):

Addition Sequence	B (ml)	S (ml)	T (ml)
Working Reagent	1.0	1.0	1.0
Distilled Water	0.05	--	--
Zinc Standard (S)	--	0.05	--
Sample	--	--	0.05

Mix well and incubate at R.T. (25° C) for 5 mins. Measure the absorbance of the Standard (Abs. S), and Test Sample (Abs. T) against the Blank, within 20 mins.

CALCULATIONS

$$\text{Zinc in µg/dl} = \frac{\text{Abs.T}}{\text{Abs.S}} \times 200$$

QUALITY CONTROL

The following process is recommended for QC during the assay of Zinc.
*Define and establish acceptable range for your laboratory.

1. Two levels of control (Normal and Abnormal) are to be run on a daily basis.
2. If QC results fall outside acceptance criteria, recalibration may be necessary.
3. Review QC results and run acceptance criteria following a change of reagent lot.

SPECIFIC PERFORMANCE CHARACTERISTICS

Linearity:
This procedure is linear upto 700 µg/dl. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Limit of detection:
The limit of detection for Zinc is 5 µg/dl.

Interferences:
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Precision:
Precision studies were performed with two controls using NCCLS protocol EP5-A. The results of the precision studies are shown below:

Sample	Within-run		Between-run		Total	
	Mean	CV%	Mean	CV%	Mean	CV%
Control 1	145.54	1.86	145.51	1.90	291.05	3.76
Control 2	176.00	5.37	184.72	1.65	360.72	7.02

Method comparison:
Comparative studies were done to compare our reagent with another commercial Zinc Assay. No significant differences were observed. Details of the comparative studies are available on request.

REFERENCE RANGE

Serum : 60-120 µg/dl
Urine : 100-1000 µg/24 hrs.

It is recommended that each laboratory establish its own normal range representing its patient population.

NOTE

In vitro diagnostic reagent for laboratory and professional use only Not for medicinal use. The reagent contain sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water. Only clean and dry glassware must be used. Chelating agents such as EDTA, Oxalate and Citrate, present even in traces, prevent the formation of the colour complex, hence necessary care should be taken during the assay. Highly lipemic samples could interfere and should be cleared by centrifugation / filtration before use. For a Seminal fluid assay, centrifuge the sample for 10 min. at 3000 RPM. Dilute the supernatant 1+ 99 normal saline before use. The reagent may be used in several automated analyzers. Instructions are available on request. Do not use turbid, deteriorated or leaking reagents.

REFERENCES

1. Akita Abe, Yiamashita, S., (1989) Clin. Chem. 35/4: 552 - 554.
2. Tetsuo Makino, (1991) Clin. Chem. Acta. 197:209-220.

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EC REP

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