SyRe

TBA-120FR

AGAPPE

ZINC

1 x 92/1 x 26 mL
12011068

Intended Use
This reagent is intended for *in vitro* quantitative determination of Zinc in serum, plasma & urine.
- Nitro PAPS methodology

Clinical Significance
Zinc is needed for the body's defensive (immune) system to properly work. It plays a role in cell division, cell growth, wound healing, and the breakdown of carbohydrates. Zinc is also needed for the senses of smell and taste. Zinc supplements in large amounts may cause diarrohea, abdominal cramps, and vomiting. Decreased levels are found in cirrhosis, lung carcinomas, sickle cell anemia, acute myocardial infarction, renal failure, corticosteroid and oral contraceptive therapy.
Although zinc is an essential requirement for good health, excess zinc can be harmful.

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

Kit Components

Reagent/ Component	Product Code 12011068	Description
Zinc R1	1 x 92 mL	Borate Buffer (p^H 8.2) 0.3 M Salicilaldoxime 12.5 mM Dimethylglioxime 1.25 mM
Zinc R2	1 x 26 mL	Nitro PAPS 0.4 mM Preservatives

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Zinc R1 & R2 Reagents are ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8^{o}C.

Open Vial Stability
Once opened the reagents are stable up to 30 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 7 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Serum/Plasma (Do not use lipemic or hemolysed sample). Use Heparin as anticoagulant.

Interferences
No interference for
Bilirubin up to 20 mg/dL

Materials provided
Zinc R1 & R2 Reagent

Reagents required but not provided
Zinc Calibrator (Product Code: 11640001)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
µg/dL	µmol/L	x 0.153

Calibration
Zinc Calibrator (Product Code: 11640001) is recommended for calibration of the assay.

Quality Control
It is recommended to use Control to verify the performance of the measurement procedure.
Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values.
The following value may be used as guide line.
Serum/Plasma : 70 - 115 µg/dL
Urine (24 hours) : 100 - 1000 µg/dL
Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 1000 µg/dL. If the concentration is greater than linearity (1000 µg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.998 and a regression equation of y = 0.985x.
3. Precision

	Intra Run		Inter Run	
Control	Level 2	Level 3	Level 2	Level 3
n	20	20	20	20
Mean (µg/dL)	147.97	215.41	142.81	219.16
SD	2.4	3.9	4.1	1.7
CV(%)	1.6	1.8	2.9	0.8

Accuracy (µg/dL)		
Control	Expected Value	Measured Value
Control Level 2	127 ± 25	139.0
Control Level 3	219 ± 43	219.0

4. Sensitivity
Lower detection Limit is 29 µg/dL

Bibliography

1 Pasquinelli, F.; Diagnostica e Tecniche di Laboratorio, (pag.:1103-1104) Rossini Editrice.(1984)
2. Testsuo Makino; Chimica Clinica Acta 197, 209-220(1991)
3. Maringonia, A., Illuzi, R, ATB 1991 Abstract.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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CE ISO 9001:2015
EN ISO 13485:2016