**TECO DIAGNOSTICS**
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# ZINC REAGENT SET
**TC MATRIX-240/480**

## INTENDED USE
The test is applied for the quantitative determination of Zinc in serum, plasma or urine.

## INTRODUCTION
Zinc is the first major trace metal after Iron. It is present in Zinc metalloenzymes (e.g. carbonic anhydrase, alkaline phosphatase, RNA and DNA polymerases, thimidine kinase, carboxypeptidases and alcohol dehydrogenase). Teco Zinc reagent is a diagnostic reagent for determination of Zinc concentration. It is a liquid monoreagent. Store at 15 - 25°C. For in Vitro Diagnostic Use Only (IVD). Do not freeze.

## PRINCIPLE[1, 2, 3, 4, 5]
Nitro-PAPS reacts with Zinc in alkaline solution to form a purple colored complex, the absorbance of which is measured at 546 nm. Interference with copper and iron are virtually eliminated by pH and chelating additives.

## REAGENT COMPOSITION
1. Reagent: Bicarbonate Buffer (400 mmol/L), 5-Br-PAPS (0.08 mmol/L), Sodium Citrate (245 mmol/L), and Detergent (1%).
2. Zinc Standard

## REAGENT DETERIORATION
If turbidity has occurred, turbidity may be a sign of contamination.

## WARNING AND PRECAUTIONS
1. The reagent is for *in vitro* diagnostic use. **Caution**: Do not pipette the solution by mouth. Avoid ingestion/contact.
2. Specimens should be considered infectious and handled appropriately.

## STORAGE AND STABILITY[6]
Store reagent set at room temperature (15 - 25°C). The reagents are stable until the expiration date indicated on the label.

Once opened vials are stable for 30 days at 2 - 8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

## SPECIMEN COLLECTION
Serum, plasma heparinate, urine (Sample with EDTA cannot be used) are collected according to the standard procedures.
Sample is stable for:
7 days at 2 - 8°C
1 month at -20°C

## MATERIALS REQUIRED BUT NOT PROVIDED
1. Spectrophotometer.
2. Test tubes/rack.

## PROCEDURES

| | | | |
|---|---|---|---|
| Test Name: | Zinc | R1: | 150 |
| Full Name: | Zinc | R2: | 0 |
| Pri. Wave: | 546 nm | SAMPLE VOLUME: | 8.5 |
| Sec. Wave: | 700 nm | Calibration Type: | 2 point linear |
| Assay/ Point: | 1 point end | K Value: | / |
| Start - End: | 24 - 26 | Point: | 2 |
| Decimal place: | 1 | Blank Type: | Reagent |
| Unit: | ug/dL | Point 0 (Blank) Con.: | 0.0 |
| Linearity Range: | 3.0000 - 850.0000 | Point 1 (STD) Con.: | calibrator/ standard |
| Correlation Factor: | 1.0000 - 0.0000 | | |

## QUALITY CONTROL
It is recommended that controls be included in each set of assays. Commercially available control material with established sodium values may be used for quality control. The assigned value of the control material must be confirmed by the chosen application. Failure to obtain the proper range of values in the assay of control material may indicate reagent deterioration, instrument malfunction, or procedural errors.

## EXPECTED VALUES
Men serum: 72.6 - 127 ug/dL
Women serum: 70.0 – 114 ug/dL
Newborn (0-30 days): 49.5 – 99.7 ug/dL
Children (1 month – 18 years old): 63.8 – 110 ug/dL
(Zinc values can be low during menstruation and pregnancy)

Expected values have been verified by using CLSI EP28- A3c protocol.

## CALIBRATION STABILITY
It strongly depends on the application characteristics of in-use auto analyzer and capacity of cooling. Calibration stability is 7 days. If controls are not within acceptable limits, calibration is

required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Quality control is recommended daily. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

## PERFORMANCE CHARACTERISTICS

1. Linearity: 750 ug/dL
2. Limit of Detection (LoD): 3 ug/dL
3. Limit of Quantitation (LoQ): LoQ values are based on Coefficient of Variation Percentage (CV) 20%[8]: 4 ug/dL
4. Precision Study[9]:

| | Within Run | |
|---|---|---|
| Mean (ug/dL) | S.D. | C.V.% |
| 95.20 | 1.53 | 1.40 |
| 135.70 | 3.47 | 1.90 |

| | Run to Run | |
|---|---|---|
| Mean (ug/dL) | S.D. | C.V.% |
| 94.28 | 3.10 | 2.70 |
| 133.40 | 3.20 | 2.40 |

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

5. Method Comparison[10, 11]: Correlation with a comparative method is r= 0.98. According to Passing-Bablok Fit:
   Slope: 0.98
   Intercept: 5.0
6. Interference[3, 4, 12]: No significant interactions were observed for conjugated bilirubin, lipemia up to the interferent concentration given in the table.

| Interferant | Zinc (ug/dL) | n | Observed recovery % |
|---|---|---|---|
| Total Bilirubin: 49.5 mg/dL | 118.5 | 3 | 105 |
| Total Bilirubin: 39.15 mg/dL | 231.2 | 3 | 109 |
| Lipemia: 1190 mg/dL | 67 | 3 | 101 |
| Lipemia: 2475 mg/dL | 228.7 | 3 | 95 |

Non hemolysis serum must be used. EDTA results may interfere.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

## WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

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Manufactured by:

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