



HEALTH HOLDING

HAFER ALBATIN HEALTH  
CLUSTER  
MATERNITY AND  
CHILDREN HOSPITAL

<b>Department:</b>	Laboratory and Blood Bank ( Hormone)		
<b>Document:</b>	Internal Policy and Procedure		
<b>Title:</b>	Analysis of TSH Assay on DELFIA Fluorometer 1420		
<b>Applies To:</b>	All Laboratory Staff		
<b>Preparation Date:</b>	January 06, 2025	<b>Index No:</b>	LB-IPP-113
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## 1. PURPOSE:

1.1 To elucidate the necessary steps required for Performing TSH Assay on DELFIA Fluorometer 1420.

## 2. DEFINITONS:

2.1 DELFIA: Double Europium Layer Flouro- Immuno Assay 5.2. TSH: Thyroid Stimulating hormone.

2.2 RT: Room temperature.

## 3. POLICY:

3.1 The determination of TSH serves as the initial test in thyroid diagnostics.

## 4. PROCEDURE:

4.1 **Principle:** The DELFIA hTSH assay is a solid phase, two site fluoroimmunometric assay based on direct sandwich technique.

4.2 **Specimen collection and preparation:** serum can be used. Samples can be stored 2 days at 2° - 8°C. For longer periods store samples at —20°C. Repeated freezing and thawing should be avoided.

4.3 **Method:** See policy of loading sample on machine (Ref: Operative Manuals' of DELFIA machine).

4.4 **Calculation:** The analyzer automatically calculates the analyte concentration of each sample in  $\mu$ IU/mL.

4.5 **Status:** Routine

4.6 **Reference ranges:** Less than 20  $\mu$ U/ml

4.7 **Limitations- interference:**

4.7.1 The assay is unaffected by icterus (bilirubin < 500  $\mu$ mol/L or < 30 mg/dL), haemolysis (Hb < 5g/L), lipemia (Intralipid < 5 g/L).

4.7.2 Patient result above 100 $\mu$ U/ml should be diluted with DELFIA diluent.

4.8 **Analytical sensitivity:** 0.005  $\mu$ U/ml

## 5. MATERIALS AND EQUIPMENT:

5.1 **Reagent:** For preparation see package insert

5.1.1 Anti-TSH microtitration strips

5.1.2 TSH standards A-F

5.1.3 Anti-TSH-EU

5.1.4 TSH Ultra Assay Buffer

5.1.5 Wash concentrate

5.1.6 Enhancement solution

5.2 **Calibration:**

5.2.1 6 calibrators (A-F) Each putted into 2 wells of strip A.

5.3 **Quality control:**

5.3.1 Quality control run with every batch

## 6. RESPONSIBILITIES:

- 6.1 Hormone shift on charge is responsible for, running calibration and control and samples of TSH of new-born.
- 6.2 Hormone staff are responsible for running TSH samples of new-born every morning.

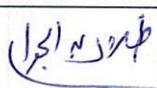
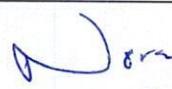
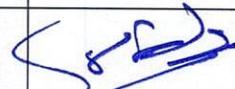
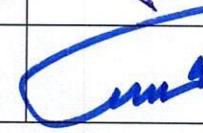
## 7. APPENDICES:

- 7.1 N/A

## 8. REFERENCES:

- 8.1 Operator's manual for the analyzer
- 8.2 Company Leaflets of reagents

## 9. APPROVALS:

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