



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Hormone)		
Document:	Internal Policy and Procedure		
Title:	Analysis of TSH Assay on DELFIA Fluorometer 1420		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	Index No:	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 Fluoro- Immuno Assay
2.2 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 fluoroimmunoassay 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 $\mu\text{IU/mL}$.
- 4.5 **Status:** Routine
- 4.6 **Reference ranges:** Less than 20 u/ml
- 4.7 **Limitations- interference:**
- 4.7.1 The assay is unaffected by icterus (bilirubin < 500 $\mu\text{mol/L}$ or < 30 mg/dL), haemolysis (Hb < 5g/L), lipemia (Intralipid < 5 g/L).
- 4.7.2 Patient result above 100 $\mu\text{U/ml}$ should be diluted with DELFIA diluent.
- 4.8 **Analytical sensitivity:** 0.005 $\mu\text{U/ml}$

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.

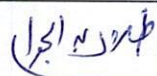


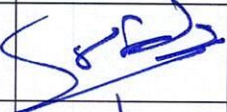


7. APPENDICES:

- 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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