



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

| | | | |
|--------------------------|---|-------------------------|---------------|
| Department: | Laboratory and Blood Bank (Hormone) | | |
| Document: | Internal Policy and Procedure | | |
| Title: | Analysis of Thyroid Stimulating Hormone Level | | |
| Applies To: | All Laboratory Staff | | |
| Preparation Date: | January 06, 2025 | Index No: | LB-IPP-114 |
| Approval Date: | January 20, 2025 | Version : | 2 |
| Effective Date: | February 20, 2025 | Replacement No.: | LB-IPP-114(1) |
| Review Date: | February 20, 2028 | No. of Pages: | 03 |

1. PURPOSE:

- 1.1 To illustrate the necessary steps required for performing Thyroid stimulating hormone (TSH) assay on COBAS e411.

2. DEFINITONS:

- 2.1 TSH: Thyroid stimulating hormone.

3. POLICY:

- 3.1 The determination of TSH serves as the initial test in thyroid diagnostics. Even very slight changes in the concentrations of the free thyroid hormones bring about much greater opposite changes in the TSH level. Accordingly, TSH is a very sensitive and specific parameter for assessing thyroid function and is particularly suitable for early detection or exclusion of disorders in the central regulating circuit between the hypothalamus, pituitary and thyroid.
- 3.2 The Elecsys TSH assay employs monoclonal antibodies specifically directed against human TSH. The antibodies (labeled with ruthenium complex) consist of a chimeric construct from human and mouse-specific components. As a result, interfering effects due to HAMA (human anti-mouse antibodies) are largely eliminated.

4. PROCEDURE:

- 4.1 **Principle:** Sandwich principle.
- 4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes or tubes containing separating gel. Li-, Na-, NH₂-heparin, K₃-EDTA, sodium citrate and sodium fluoride/potassium oxalate plasma. Stable for 7 days at 2°-8 °C, 1 month at -20 °C.7 Freeze only once.
- 4.3 **Method:** See policy of loading sample on machine (Ref: Operative Manuals' of COBAS e411).
- 4.4 **Calculation:** The analyzer automatically calculates the analyte concentration of each sample in $\mu\text{IU/mL}$
- 4.5 **Status:** Stat and Routine
- 4.6 **Reference ranges:** 0.270-4.20 $\mu\text{IU/mL}$
 - 4.6.1 For detailed information about reference intervals in children, adolescents and pregnant women, refer to the brochure "Reference Intervals for Children and Adults", English: 04640292.
- 4.7 **Limitations- interference:**
 - 4.7.1 The assay is unaffected by icterus (bilirubin < 701 $\mu\text{mol/L}$ or < 41 mg/dL), hemolysis (Hb < 0.621 mmol/L or < 1 g/dL), lipemia (Intralipid < 1500 mg/dL), biotin (< 102 nmol/L or < 25 ng/mL), IgG < 2 g/dL and IgM < 0.5 g/dL.
 - 4.7.2 Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
 - 4.7.3 The presence of autoantibodies may induce high molecular weight complexes (macro-TSH) which may cause unexpected high values of TSH.8 In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

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

4.8 **Measuring range:** 0.005-100 μ IU/mL

4.8.1 Values below the lower detection limit are reported as < 0.005 μ IU/mL.

4.8.2 Values above the measuring range are reported as > 100 μ IU/mL.

5. **MATERIALS AND EQUIPMENT:**

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

5.1.1 **M:** Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL, preservative.

5.1.2 **R1:** Anti-TSH-Ab~biotin (gray cap), 1 bottle, 14 mL: Biotinylated monoclonal anti-TSH antibody (mouse) 2.0 mg/L; phosphate buffer 100 mmol/L, pH 7.2; preservative.

5.1.3 **R2:** Anti-TSH-Ab~Ru(bpy) (black cap), 1 bottle, 12 mL: Monoclonal anti-TSH antibody (mouse/human) labeled with ruthenium complex 1.2 mg/L; phosphate buffer 100 mmol/L, pH 7.2; preservative.

5.2 **Calibration:**

5.2.1 Every Elecsys reagent set has a barcoded label containing specific information for calibration of the reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

5.2.2 Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

5.2.3 Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

5.2.4 Renewed calibration is recommended as follows:

5.2.4.1 After 8 weeks when using the same reagent lot.

5.2.4.2 After 7 days when using the same reagent kit on the analyzer.

5.2.4.3 As required: e.g. quality control findings outside the defined limits.

5.3 **Quality control:**

5.3.1 For quality control, use PreciControl Universal or PreciControl Thyro Sensitive. In addition, other suitable control material can be used.

5.3.2 Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

6. **RESPONSIBILITIES:**

6.1 Hormone shift on charge is responsible for, running calibration and control and samples of TSH.

6.2 Hormone staff are responsible for running TSH samples every morning.

7. **APPENDICES:**

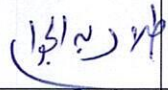


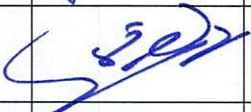


7.1 N/A

8. **REFERENCES:**

8.1 Operator's manual for the analyzer

8.2 Company Leaflets of reagents

9. APPROVALS:

| | Name | Title | Signature | Date |
|---------------------|-------------------------------|------------------------------------|---|------------------|
| Prepared by: | Dr. Talal Abdelgawad | Clinical Pathologist |  | January 06, 2025 |
| Reviewed by: | Dr. Kawther M. Abdou | Consultant & Lab. Medical Director |  | January 08, 2025 |
| Reviewed by: | Ms. Noora Melfi Alanizi | Laboratory & Blood Bank Director |  | January 09, 2025 |
| Reviewed by: | Mr. Abdulelah Ayed Al Mutairi | QM&PS Director |  | January 12, 2025 |
| Reviewed by: | Dr. Tamer Mohamed Naguib | Medical Director |  | January 12, 2025 |
| Approved by: | Mr. Fahad Hazam Alshammari | Hospital Director |  | January 20, 2025 |