HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Hormone)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Progesterone Level		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-107
Approval Date:	January 20, 2025	**Version :**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-107(1)
Review Date:	February 20, 2028	**No. of Pages:**	03

1. PURPOSE:

1.1 To illustrate the necessary steps required for performing Progesterone assay on COBAS e411.

2. DEFINITONS:

2.1 Progesterone is a steroid hormone which is mainly formed in the cells of the corpus luteum and during pregnancy in the placenta.

3. POLICY:

3.1 The progesterone concentration correlates with the development and regression of the corpus luteum. Whereas progesterone is barely detectable in the follicular phase of the female cycle, a rise in the progesterone level is observed one day prior to ovulation. Increased progesterone synthesis occurs during the luteal phase. In the second half of the cycle pregnanediol is excreted in urine as the main degradation product of progesterone.

3.2 Progesterone brings about the conversion of the uterine mucosa into some tissue rich in glands (secretion phase), to prepare for the intrauterine implantation of the fertilized ovum. During pregnancy, progesterone inhibits the contraction of the myometrium. In the mammary gland, progesterone (together with oestrogens) promotes the proliferation, secretion and disposition of the alveoli.

3.3 The determination of progesterone is utilized in fertility diagnosis for the detection of ovulation and assessment of the luteal phase.

4. PROCEDURE:

4.1 **Principle:** Competition principle (For details refer to Company Leaflets of reagent).

4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes or tubes containing separating gel. Li-heparin, K2-EDTA and K3-EDTA plasma. Li-heparin plasma tubes containing separating gel can be used. Stable for 1 day at 20°-25°C, 5 days at 2°-8°C, and 6 months at -20 ° C. 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 µIU/mL.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:** 0.270-4.20 µIU/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 µmol/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 µIU/mL

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

4.8.2 Values above the measuring range are reported as > 100 µIU/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 analyser.

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. 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 Progesterone.

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

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Operator's manual for the analyser

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