MAYO CLINIC LABORATORIES

Test Definition: ESTS

Estradiol Rapid, Immunoassay, S

Overview

Useful For

Rapid assessment of ovarian status, including follicle development, for assisted reproduction protocols (eg, in vitro fertilization)

Establishing time of ovulation and optimal time for conception

Method Name

Electrochemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This assay is for reproductive assessment (eg, IVF, conception). For other clinical indications, order EEST / Estradiol, Serum.

The preferred method for measurement of low serum estradiol concentrations in children, males, and postmenopausal females is liquid chromatography-tandem mass spectrometry (LC-MS/MS), order EEST / Estradiol, Serum.

Specimen Required

Patient Preparation: For 12 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Collection Instructions:

1. Serum gel tubes should be centrifuged within 2 hours of collection.
2. Red-top tubes should be centrifuged and aliquoted within 2 hours of collection.

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Minimum Volume

0.4 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	180 days	
	Refrigerated	5 days	
	Ambient		

Clinical & Interpretive

Clinical Information

Estrogens are responsible for the development and maintenance of female sex organs and female secondary sex characteristics. In conjunction with progesterone, they participate in regulation of the menstrual cycle, breast and uterine growth, and in the maintenance of pregnancy.

Estrogens affect calcium homeostasis and have a beneficial effect on bone mass. They decrease bone resorption and, in prepubertal girls, estrogen accelerates linear bone growth. Long-term estrogen depletion is associated with loss of bone mineral content, an increase in stress fractures, and postmenopausal osteoporosis.

The 3 most biologically active estrogens in order of potency are estrone (E1), estradiol (E2), and estriol (E3). Estrogens are produced primarily in the ovary (follicle, corpus luteum), but small quantities are also formed in the testes and in the adrenal cortex. During pregnancy, estrogens are mainly formed in the placenta. About 98% of estradiol is bound to transport proteins (sex hormone-binding globulin: SHBG) and albumin. Estrogen secretion is biphasic during the menstrual cycle.

The determination of estradiol is utilized clinically in the elucidation of fertility disorders in the hypothalamus-pituitary-gonad axis, gynecomastia, estrogen-producing ovarian and testicular tumors, and in hyperplasia of the adrenal cortex. Additional clinical indications are the monitoring of fertility therapy and determining the time of ovulation within the framework of in vitro fertilization (IVF).

The laboratory plays an important role in the process of ovulation induction. The principle involves administration of gonadotropins to stimulate follicular growth, followed by human chorionic gonadotropin (hCG) to stimulate ovulation follicular maturation. Clinical, laboratory, and ultrasound monitoring of the treatment cycle is necessary to identify the dose and length of therapy, determine when or whether to administer hCG, and obtain an adequate ovulatory response while avoiding hyperstimulation.

For other clinical indications, order EEST / Estradiol, Serum.

Reference Values

Males: 10-40 pg/mL

Females

Premenopausal: 15-350 pg/mL*

Postmenopausal: <10 pg/mL

*Estradiol concentrations vary widely throughout the menstrual cycle

The limit of quantitation for estradiol measured by immunoassay is 25 pg/mL. Mass spectrometry is the preferred method for measurement of low serum estradiol concentrations in children, males and postmenopausal females (EEST / Estradiol, Serum).

Interpretation

Optimal time for conception is within 48 to 72 hours following the midcycle estradiol peak. Serial specimens must be drawn over several days to evaluate baseline and peak estradiol levels. Low baseline levels and a lack of rise, as well as

persistent high levels without midcycle rise, are indicative of anovulatory cycles.
For determining the timing of initiation of ovarian stimulation in in vitro fertilization (IVF) studies, low levels before stimulation are critical, as higher values often are associated with poor stimulation cycles. Before final human chorionic gonadotropin (hCG) stimulation at mid-IVF cycle, estradiol concentrations above 2,000 to 3,000 pg/mL are considered by some IVF specialists to be indicative of an increased likelihood of ovarian hyperstimulation and it may be advisable to consider withholding further hCG stimulation.
Estradiol (E2) concentrations below 200 pg/mL following midcycle stimulation (hCG or follicle-stimulating hormone: FSH) are associated with very low pregnancy success rates.
E2 concentrations change during the menstrual cycle, as follows:
-less than 50 pg/mL before midfollicular phase
-250 to 500 pg/mL midcycle peak as the follicle matures
-Abrupt decrease after ovulation
-125 pg/mL peak during the luteal phase
Estrogen replacement in reproductive-age women should aim to mimic natural estrogen levels as closely as possible. E2 levels should be within the reference range for premenopausal women and luteinizing hormone (LH) and follicle-stimulating hormone (FSH) should be within the normal range.

Cautions

The limit of quantitation for estradiol measured by immunoassay is 25 pg/mL. Liquid chromatography-tandem mass spectrometry (LC-MS/MS) is the preferred method for measurement of low serum estradiol concentrations in children, males, and postmenopausal females (EEST / Estradiol, Serum).
For assays employing antibodies, the possibility exists for interference by human antianimal antibodies (ie, heterophile antibodies) in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies (eg, human antimouse antibodies: HAMA) that interfere with immunoassays. This may falsely elevate or falsely decrease the results.
Interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin, or ruthenium can occur.
Fulvestrant is a member of a class of drugs called "selective estrogen receptor degraders" (SERDS). Due to the risk of cross-reactivity, the Roche Elecsys Estradiol assay should not be used when monitoring estradiol concentrations in patients being treated with Fulvestrant. In these patients, estradiol concentrations should be measured using mass spectrometry (EEST / Estradiol, Serum).

Clinical Reference

1. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Fifth edition. Edited by CA Burtis, ER Ashwood, DE Bruns. St. Louis, Elsevier Saunders Company, 2013
2. Huang JYJ, Rosenwaks Z: Preventative strategies of ovarian hyperstimulation syndrome. J Exp Clin Med 2010;2:53-62
3. Practice Committee of the American Society for Reproductive Medicine. Ovarian hyperstimulation syndrome. Fertil Steril 2008 Nov;90(5 Suppl):S188-S193

Performance

Method Description

The Modular e601/602 Estradiol III method is a competitive electrochemiluminescence immunoassay that employs a

polyclonal antibody. Estradiol in the specimen reacts with an estradiol-specific biotinylated antibody forming an immunocomplex. Streptavidin-coated microparticles and an estradiol-derivative ruthenium complex are added and the mixture becomes bound to the solid phase via interaction of biotin and streptavidin. The mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of voltage to the electrode induces the chemiluminescent emission, which is then measured.(Package insert: Estradiol III. Roche Diagnostics Corporation, Indianapolis, IN)

PDF Report

No

Performing Laboratory Location

Rochester

Fees & Codes

Test Classification

This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

82670