Test Definition: ESTS

Estradiol, Rapid, Immunoassay, Serum

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 (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This test is used 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, men, and postmenopausal women is liquid chromatography tandem mass spectrometry; order EEST / Estradiol, Serum.

This test **should not be used** when monitoring estradiol concentrations in patients being treated with fulvestrant (Falodex) due to possible cross-reactivity. For these patients, estradiol concentrations should be measured using mass spectrometry; order EEST / Estradiol, Serum.

Specimen Required

Patient Preparation: For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions: Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial.

Specimen Minimum Volume

0.4 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	180 days	
	Ambient	24 hours	
	Refrigerated	5 days	

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, estradiol (E2), and estriol. 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) and albumin. Estrogen secretion is biphasic during the menstrual cycle.

The determination of E2 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.

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.

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

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 2000 to 3000 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.

Estradiol 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 and 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 is the preferred method for measurement of low serum estradiol concentrations in children, men, and postmenopausal women (EEST / Estradiol, Serum).

For assays employing antibodies, the possibility exists for interference by human anti-animal 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. 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. For these patients, estradiol concentrations should be measured using mass spectrometry (EEST / Estradiol, Serum).

Clinical Reference

1. Rifai N, Chiu RWK, Young I, Burnham CAD, Wittwer CT, eds. Tietz Textbook of Laboratory Medicine. 7th ed. Elsevier; 2023

2. Practice Committee of the American Society for Reproductive Medicine. Ovarian hyperstimulation syndrome. Fertil Steril. 2008;90(5 Suppl):S188-S193

Performance

Method Description

The Roche cobas e801 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: Elecsys Estradiol III. Roche Diagnostics; V5.0, 10/2022)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 to 2 days

Specimen Retention Time

7 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.

- Prospective clients should contact their account representative. For assistance, contact Customer Service.

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

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ESTS	Estradiol Rapid, Immunoassay, S	2243-4

Result ID	Test Result Name	Result LOINC® Value
ESTS	Estradiol Rapid, Immunoassay, S	2243-4