BECKMAN COULTER

CE 2797

RIA Estradiol

Instruction for use in local language is available at beckmancoulter.com/techdocs.

REVISION HISTORY

Previous version: IFU-A21854-B89462-03	**Current version:** IFU-A21854-B89462-04
Standard curve *(Example of standard curve, do not use for calculation)*	*(Example of standard curve, do not use for calculation. Use the concentration of calibrators indicated on each vial label. The concentrations are lot specific, check carefully.)*
Specificity table in the chapter APPENDIX. —	Exemestane
—	Adding Ukrainian to the IFU.

REF A21854, B89462

FOR PROFESSIONAL USE ONLY

INTENDED PURPOSE

RIA Estradiol is an in vitro diagnostic manual medical device intended to be used by healthcare professionals for the quantitative measurement of estradiol in human serum and plasma. Measurement of estradiol is intended to be used for the assessment of fertility status and sexual development. In females, it is used in differential diagnosis of amenorrhea and other causes of female infertility and in monitoring of ovulation status. It is also used as an aid in diagnosis of precocious and delayed puberty in children. In males, it is used as an aid in diagnosis of feminizing syndromes, including gynecomastia. It is also used in monitoring patients on hormone replacement and antiestrogen therapy [1, 2, 3, 4, 5].

PRINCIPLE

The radioimmunoassay of estradiol is a competition assay. Samples and calibrators are incubated with ^{125}I-labeled estradiol, as tracer, in polyclonal antibody-coated tubes. After incubation, the contents of tubes are aspirated so as to remove unbound ^{125}I-labeled tracer. The bound radioactivity is then determined in a gamma counter. The estradiol concentrations in the samples are obtained by interpolation from the standard curve. The concentration of estradiol in the samples is indirectly proportional to the radioactivity.

WARNING AND PRECAUTIONS

General remarks:

- The vials with calibrators and controls should be opened as shortly as possible to avoid excessive evaporation.
- Do not mix the reagents from kits of different lots.
- A standard curve must be established with each assay.
- It is recommended to perform the assay in duplicate.
- Each tube must be used only once.

Basic rules of radiation safety

The purchase, possession, utilization, and transfer of radioactive material are subject to the regulations of the country of use. Adherence to the basic rules of radiation safety should provide adequate protection:

- No eating, drinking, smoking or application of cosmetics should be carried out in the presence of radioactive materials.
- No pipetting of radioactive solutions by mouth.
- Avoid all contact with radioactive materials by using gloves and laboratory overalls.
- All manipulation of radioactive substances should be done in an appropriate place, distant from corridors and other busy places.
- Radioactive materials should be stored in the container provided in a designated area.
- A record of receipt and storage of all radioactive products should be kept up to date.
- Laboratory equipment and glassware which are subject to contamination should be segregated to prevent cross-contamination of different radioisotopes.
- Each case of radioactive contamination or loss of radioactive material should be resolved according to established procedures.
- Radioactive waste should be handled according to the rules established in the country of use.

Sodium azide

Some reagents contain sodium azide as a preservative. Sodium azide can react with lead, copper or brass to form explosive metal azides. Sodium azide disposal must be in accordance with appropriate local regulations.

Materials of human origin

The materials of human origin, contained in this kit, were found negative for the presence of antibodies to HIV 1 and HIV 2, antibodies to HCV, as well as of Hepatitis B surface antigen (HBsAg). However, they should be handled as if capable of transmitting disease. No known test method can offer total assurance that no virus is present. Handle this kit with all necessary precautions.

All patient specimens should be handled as potentially infectious and waste should be discarded according to the country rules.

GHS HAZARD CLASSIFICATION

Not classified as hazardous

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

SPECIMEN COLLECTION, PROCESSING, STORAGE AND DILUTION

- Serum or EDTA plasma are the recommended sample types.
- Allow serum samples to clot completely before centrifugation.
- Serum and plasma samples may be stored at 2-8°C, if the assay is to be performed within 24 hours. For longer storage keep frozen (< -20°C, 1 year maximum) after aliquoting so as to avoid repeated freezing and thawing. Thawing of sample should be performed at room temperature.
- If samples have concentrations greater than the highest calibrator, they must be diluted into the Estradiol Diluent (see MATERIALS REQUIRED BUT NOT PROVIDED).

Serum and EDTA plasma values for 30 samples (serum values ranging from 11.38 to 163.7 pg/mL) were compared using the A21854 RIA Estradiol. Results are as follows:

[EDTA-plasma] = 0.926[serum] - 1.096
R = 0.9763

MATERIALS PROVIDED

All reagents of the kit are stable until the expiry date indicated on the kit label, if stored at 2-8°C. Expiry dates printed on vial labels apply to the long-term storage of components by the manufacturer only, prior to assembly of the kit. Do not take into account.

Kit for determination of estradiol, 100 tubes (REF. A21854)

Tubes: 2 x 50 (ready-to-use)

^{125}I-Tracer: one 55 mL vial (ready-to-use)

At the time of manufacture, the vial contains 185 kBq of ^{125}I-labeled estradiol in buffer with proteins and sodium azide (<0.1%) and a dye.

Calibrators: seven 1 mL vials (ready-to-use)

The calibrator vials contain from 0 to approximately 4,320 pg/mL of estradiol in human serum and sodium azide (<0.1%). The exact concentration is indicated on each vial label. The calibrators are traceable to a certified reference material (Cerilliant).

Control samples: two 1 mL vials (ready-to-use)

The vials contain estradiol in human serum and sodium azide (<0.1%). The concentration range is indicated on a supplement. The control samples are traceable to a certified reference material (Cerilliant).

Kit for determination of estradiol, 50 tubes (REF. B89462)

Tubes: 1 x 50 (ready-to-use)

^{125}I-Tracer: one 55 mL vial (ready-to-use)

Calibrators: seven 1 mL vials (ready-to-use)

Control samples: two 1 mL vials (ready-to-use)

MATERIALS REQUIRED, BUT NOT PROVIDED

In addition to standard laboratory equipment, the following items are required:

- Precision micropipette (100 µL).
- Repeating micropipette (500 µL).
- Vortex type mixer.
- Horizontal or orbital shaker.
- Aspiration system.
- Gamma counter set for ^{125}I.

For the dilution of serum and plasma samples

Estradiol Diluent: one 10 mL vial (ready-to-use)

Supplied upon request: REF. IM1863

- The diluent needs to be assayed first in order to determine its estradiol endogenous concentration. This concentration needs to be subtracted from the patient sample estradiol concentration before multiplication by the dilution factor. Results are meaningful if the concentration recovered is at least twice that of the concentration measured when assaying the diluent only.

PROCEDURE

Preparation of reagents

Let all the reagents come to room temperature.

Assay procedure

Step 1 Additions*	Step 2 Incubation	Step 3 Counting
To coated tubes add successively: 100 µL of calibrator, control or sample and 500 µL of tracer. Vortex gently 1-2 seconds.	Incubate for 3 hours at 18-25°C with shaking (≥ 350 rpm).	Aspirate carefully the content of tubes (except the 2 tubes «total cpm»). Count bound cpm (B) and total cpm (T) for 1 minute.

* Add 500 µL of tracer to 2 additional tubes to obtain total cpm.

RESULTS

Results are obtained from the calibrator curve by interpolation. The curve serves for the determination of analyte concentrations in samples measured at the same time as the calibrators.

Standard curve

The results in the quality control department were calculated using *spline* curve fit with logit of *B/T or B/B_0* on the vertical axis and log of analyte concentration of the calibrators on the horizontal axis.

Other calculation methods may give slightly different results.

Total activity: 65,918 cpm				
Calibrators	**Estradiol (pg/mL)**	**cpm (n=3)**	**B/T (%)**	**B/B_0 (%)**
0	0	22,854	34.7	100.0
1	12.0	19,595	29.7	85.7
2	36.0	17,005	25.8	74.4
3	115	12,705	19.3	55.6
4	310	8,207	12.5	35.9
5	930	5,052	7.66	22.1
6	3,700	2,780	4.22	12.2

(Example of standard curve, do not use for calculation. Use the concentration of calibrators indicated on each vial label. The concentrations are lot specific, check carefully.)

Samples

For each sample, locate ratio B/T or B/B_0 on the vertical axis and read off the corresponding analyte concentration on the horizontal axis.

To convert pg/mL to pmol/L, multiply results by **3.671.**

EXPECTED VALUES

We recommend each laboratory to establish its own reference values. The following values obtained from healthy subjects are indicative only.

	N	Estradiol (pg/mL)				
		Median	**Min.**	**Max.**	**2.5th percentile**	**97.5th percentile**
Men	94	26.57	<10.41	64.76	<10.41	59.91
Women						
Follicular Phase	110	79.45	16.66	447.2	21.51	244.5
Luteal Phase	98	94.61	26.92	320.7	44.72	212.7
Preovulatory peak	23	199.8	97.15	497.3	100.5	431.7
Postmenopausal without ERT	32	<10.41	<10.41	41.01	<10.41	35.00
Postmenopausal with ERT	30	50.48	<10.41	284.0	<10.41	278.7

Detail information about expected values for children (sorted according to age and sex) can be found in the data sheet "APPENDIX".

QUALITY CONTROL

Good laboratory practices imply that control samples be used regularly to ensure the quality of the results obtained. These samples must be processed exactly in the same way as the assay samples, and it is recommended that their results be analyzed using appropriate statistical methods.

Failure to obtain the appropriate values for controls may indicate imprecise manipulations, improper sample handling or deterioration of reagents.

In case of packaging deterioration or if data obtained show some performance alteration, please contact your local distributor or use the following e-mail address: imunochem@beckman.com

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of EU Member State in which the user and/or patient is located.

PERFORMANCE CHARACTERISTICS

(For more details, see the data sheet "APPENDIX")

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Sensitivity

Limit of Detection (LoD): 10.41 pg/mL

The LoD of the assay is 10.41 pg/mL, determined consistent with guidelines in CLSI document EP17-A2 [6] based on the proportions of false positives (α) less than 5% and false negatives (β) less than 5%; using determinations, with 120 blank and 120 low level samples; and Limit of Blank (LoB) of 4.68 pg/mL.

Specificity

The antibody used in the immunoassay is specific for estradiol.

Precision

Repeatability and within-laboratory precision

The precision of the assay was determined consistent with guidelines in CLSI document EP05-A3 [7]. For repeatability the coefficients of variation were found below or equal to 10.0% for serum samples. For within-laboratory precision the coefficients of variation were found below or equal to 16.4% for serum samples.

Accuracy

Linearity

The assay demonstrated to be linear from 8.86 to 4,216 pg/mL using serum samples (determined consistent with guidelines in CLSI document EP06-A [8]).

Dilution test

High-concentration serum samples were serially diluted with Estradiol Diluent. The recovery percentages ranged from 92.5% to 119%.

Recovery test

Low-concentration serum samples were spiked with known quantities of estradiol. The recovery percentages obtained were between 85.4% to 105%.

Measurement range (from LoD to the highest calibrator): 10.41 to approximately 4,320 pg/mL.

LIMITATIONS

Failure to follow these instructions for use (IFU) may significantly affect results.

Results should be interpreted in the light of the total clinical presentation of the patient, including clinical history, data from additional tests and other appropriate information.

Do not use hemolyzed, lipemic or icteric samples. For more details, see Appendix, § Interference.

In immunoassays, the possibility exists for interference by 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, e.g. HAMA, that interfere with immunoassays. Immunoassays may be also affected by presence of anti-avidin or anti-streptavidin antibodies, as well as by the presence of autoantibodies directed against the determined analyte. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies [9, 10, 11].

APPENDIX

PERFORMANCE CHARACTERISTICS

Representative data are provided for illustration only. Performance obtained in individual laboratories may vary.

Interference

Serum samples containing estradiol concentrations (low and high) were spiked with multiple concentrations of the substances listed below and assayed using RIA Estradiol. Values were calculated as described in CLSI EP07-A2 [12]. Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). No interference (defined as a shift in dose > 15 %) was found for addition of interferent up to concentration stated in the table below.

Interferent	Test concentration
Hemoglobin	2,019 µg/mL
Conjugated bilirubin	207.9 µg/mL
Unconjugated bilirubin	188.8 µg/mL
Biotin	1,517 ng/mL
Ascorbic acid	44.36 µg/mL
Acetylsalicylic acid	47.89 µg/mL
Ibuprofen	143.0 µg/mL
Cholesterol	3.00 mg/mL
Heparin	30.87 µg/mL
Prednisone	282.6 ng/mL
Prednisolone	2,926 ng/mL
Protein (γ-globulin)	49.06 mg/mL
Rheumatoid factor	15.01 IU/mL
Triglycerides	8.69 mg/mL

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In spite of hemoglobin, bilirubin (conjugated, unconjugated) and triglyceride interference data in the table, we advise to avoid using hemolyzed, lipemic or icteric samples.

Specificity

The cross-reactivity has been measured against various compounds in this assay. The percent cross-reactivity is expressed as the ratio of the estradiol concentration to the concentration of the reacting compound at 50% binding of the estradiol zero calibrator.

Compound	Cross reaction (%)
Estradiol	100.0
Estrone	13.72
Estradiol-glucuronide	3.72
Equilenin	1.45
Estriol	0.89
Equilin	0.56
Estrone-3-sulfate	0.49
Estradiol-3-sulfate	0.33
Estrone-glucuronide	0.28
17α-OH progesterone	ND
17α-estradiol	ND
Androstenedione	ND
Corticosterone	ND
Cortisol	ND
Cortisone	ND
Danazol	ND
Dexamethasone	ND
DHEA	ND
DHEAS	ND
Ethinyl stradiol	ND
Exemestane	ND
Fulvestrant	ND
Mifepristone	ND
Norethisterone	ND
Norgestrel	ND
Progesterone	ND
Tamoxifene	ND
Testosterone	ND

· ND - not detectable (< 0.1%)

Repeatability and within-laboratory precision

Samples were assayed for 20 days, 2 runs per day, in triplicates per run. Assays were performed by two lab technicians, by two reagent lots. There were 120 individual measurements per sample with no invalid results.

Serum	Mean (pg/mL)	Repeatability		Within laboratory precision	
		SD (pg/mL)	C.V. (%)	SD (pg/mL)	C.V. (%)
S1	2,009	165.7	8.25	214.0	10.66
S2	725.6	51.69	7.12	87.32	12.03
S3	206.6	11.68	5.65	19.25	9.32
S4	88.21	8.04	9.11	13.87	15.72
S5	59.23	5.92	9.99	9.69	16.35

EDTA plasma	Mean (pg/mL)	Repeatability		Within laboratory precision	
		SD (pg/mL)	C.V. (%)	SD (pg/mL)	C.V. (%)
P1	1,563	161.4	10.33	204.0	13.05
P2	695.9	43.76	6.29	57.37	8.24
P3	203.5	12.16	5.98	18.96	9.32
P4	70.18	6.17	8.79	10.81	15.41
P5	43.61	5.62	12.89	8.39	19.23

Accuracy

Linearity

The assay demonstrated to be linear from 8.90 to 4,315 pg/mL using EDTA-plasma samples (determined consistent with guidelines in CLSI document EP06-A [8]).

Dilution test

Samples were diluted into the Estradiol Diluent and assayed according to the assay procedure of the kit.

Serum	Dilution factor	Measured (pg/mL)	Expected (pg/mL)	Ratio (%) Measured/ Expected
S1	-	577.7	-	-
	1:2	314.3	302.9	103.8
	1:4	181.1	165.5	109.4
	1:8	112.5	96.84	116.1
	1:16	58.57	62.49	93.73
S2	-	2,366	-	-
	1:2	1,400	1,197	117.0
	1:4	642.4	612.5	104.9
	1:8	350.8	320.3	109.5
	1:16	207.7	174.2	119.2
S3	-	2,283	-	-
	1:2	1,202	1,156	104.0
	1:4	547.7	591.8	92.54
	1:8	301.9	310.0	97.40
	1:16	186.3	169.1	110.2

EDTA plasma	Dilution factor	Measured (pg/mL)	Expected (pg/mL)	Ratio (%) Measured/ Expected
P1	-	869.8	-	-
	1:2	372.6	453.0	82.25
	1:4	219.3	244.6	89.65
	1:8	138.5	140.4	98.62
	1:16	78.69	88.33	89.09
P2	-	1,082	-	-
	1:2	547.2	559.1	97.87
	1:4	317.9	297.7	106.8
	1:8	194.4	167.0	116.4
	1:16	121.5	101.6	119.6
P3	-	1,608	-	-
	1:2	701.5	821.9	85.34
	1:4	426.5	429.1	99.41
	1:8	247.9	232.7	106.5
	1:16	146.0	134.4	108.6

Recovery test

Samples were spiked with known quantities of estradiol and assayed according to the assay procedure of the kit.

Serum	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
S1	43.00	24.16	67.16	70.16	104.5
	41.91	47.09	89.00	76.69	86.17
	43.00	96.10	139.1	119.3	85.78
S2	30.82	15.25	46.06	43.60	94.65
	30.32	30.00	60.32	53.61	88.88
	29.37	58.13	87.50	80.13	91.58
S3	15.45	15.25	30.70	27.30	88.93
	15.20	30.00	45.20	39.28	86.90
	14.96	44.29	59.25	50.62	85.44

EDTA plasma	Endogen. conc.	Added conc.	Expected conc.	Measured conc.	Ratio (%) Measured/ Expected
	(pg/mL)				
P1	65.92	30.00	95.92	102.6	106.9
	63.86	58.13	122.0	115.7	94.85
	66.14	107.8	173.9	185.3	106.6
P2	78.34	38.63	117.0	127.5	109.0
	76.15	63.54	139.7	148.4	106.2
	78.59	142.3	220.9	215.4	97.53
P3	57.46	15.25	72.71	72.37	99.53
	56.35	32.89	89.25	100.5	112.6
	54.26	66.22	120.5	128.1	106.4

Expected values for children

Results are sorted according to the age and sex.

Boys	N	Estradiol (pg/mL)				
		Median	Min.	Max.	2.5th percentile	97.5th percentile
6 months - 9 years	36	<10.41	<10.41	18.40	<10.41	16.74
10 - 13 years	30	<10.41	<10.41	52.59	<10.41	35.41
≥ 14 years	30	30.25	11.65	82.13	12.01	67.90

Girls	N	Estradiol (pg/mL)				
		Median	Min.	Max.	2.5th percentile	97.5th percentile
0 - 2 months	35	54.07	15.52	394.4	17.64	229.4
3 - 6 months	33	15.33	<10.41	33.8	<10.41	30.07
7 months - 2 years	36	<10.41	<10.41	23.25	<10.41	18.11
3 - 9 years	34	12.22	<10.41	26.14	<10.41	23.14
10 - 12 years	35	14.47	<10.41	188.6	<10.41	175.1
≥ 13 years	61	62.36	11.62	434.3	17.63	358.5

^{125}I Characteristics

$T_{1/2}$ (^{125}I) = 1443 h = 60.14 d

^{125}I	E (MeV)	%
γ	0.035	6.5
K_α X-ray	0.027	112.5
K_β X-ray	0.031	25.4

Symbols Key

REF — Product Reference / Référence du produit / Produktreferenz / Riferimento prodotto / Número de referencia del producto / Referência do produto / Produktreferens / Κωδικός αναφοράς προϊόντος / 产品参考 / Gaminio nuoroda / Termékszám / Dane referencyjne produktu / Reference k produktu / Referenčné označenie výrobku / 제품 참조 자료 / Ürün Referansı / Ссылка на продукт / Референца за производ / 產品參考

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Expiration Date / Date D'expiration / Verfallsdatum, Verw. bis: / Data Di Scadenza / Fecha De Caducidad / Data de validade / Utgångsdatum / Ημερομηνία λήξης / 失效日期 / Galiojimo data / Lejárati idő / Data ważności / Datum exspirace / Dátum exspirácie / 만료 날짜 / Son Kullanma Tarihi / Срок годности / Срок на годност / 到期日

LOT — Lot Number / Numéro de lot / Chargennummer / Numero di lotto / Lote número / Número de lote / Satsnummer / Αριθ. παρτίδας / 批次号 / partijos numeris / Tételszám / Numer serii / Číslo šarže / 로트 번호 / Lot Numarası / Номер партии / Номер на партида / 批號

Date of Manufacture / Date de Fabrication / Herstellungsdatum / Data di Fabbricazione / Fecha de Fabricación / Data de Fabrico / Produktionsdatum / Ημερομηνία Παραγωγής / 生产日期 / Pagaminimo Data / Gyártás Dátuma / Data Produkcji / Datum Výroby / Dátum Výroby / 제조 일자 / Üretim Tarihi / Дата Производства / Дата на Производство / 製造日期

Biohazard / Risque biologique / Biogefährdung / Rischio biologico / Riesgo biológico / Risco biológico / Biologisk fara / Βιολογικός κίνδυνος / 生物危害 / Biologisk fara / Veszélyes biológiai anyag / Zagrożenie biologiczne / Biologické riziko / Biologické riziko / 생물학적 위험 / Biyolojik tehlike / Биологическая опасность / Биологична опасност / 生物危害

Radioactive / Radioactif / Radioaktiv / Radioattivo / Radiactivo / Radioactivo / Radioaktivt / Ραδιενεργό / 放射性 / Radioaktyvioji medžiaga / Radioaktív / Radioaktywny / Radioaktivní / Rádioaktívny / 방사성 / Radyoaktif / Радиоактивный / Радиоактивен / 具放射性

Ag 125I / Ab 125I — Tracer / Traceur / Tracer / Marcato / Trazador / Marcador / Tracer / Ανιχνευτής / 追踪剂 / Atsekamoji medžiaga / Nyomjelző / Znacznik / Radioindikátor / Indikátor (tracer) / 트레이서 / Tracer´lar / метка / Индикатор / 追蹤劑

CAL / CAL 0 — Calibrator / Calibrateur / Kalibrator / Calibratore / Calibrador / Calibrador / Kalibrator / Βαθμονομητής / 校准品 / Kalibravimo medžiaga / Kalibrátor / Kalibrator / kalibrátor / Kalibrátor / 보정 물질 / Kalibratör / Калибратор / Калибратор / 校正液

CTRL — Control / Contrôle / Kontrolle / Controllo / Control / Controlo / Kontrolle / Μάρτυρας / 质控品 / Kontrolinė / Kontroll / Kontrola / Kontrola / Kontrola / 정도관리 / Kontrol / Контроль / Контролна / 質控品

TUBE — Tubes / tubes / Röhrchen / provette / tubos / Tubos de amostra / Provrör / σωληνάρια / 试管 / Mėgintuvėliai / Csövek / Probówki / Zkumavky / Skúmavky / 튜브 / Tüpler / пробирки / Епруветки / 試管

IFU — Instruction for Use / Mode d'emploi / Gebrauchsanweisung / Istruzioni per l'uso / Instrucciones de uso / Instruções de utilização / Bruksanvisning / Οδηγίες χρήσης / 使用说明 / Naudojimo instrukcija / Használati utasítás / Instrukcja użycia / Návod k použití / Návod na použitie / 사용 안내 / Kullanma Talimatı / Инструкции / Инструкции за употреба / 使用說明

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