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Estrone ELISA

REF	IB59105	Rx ONLY	IVD

Effective Date: January 23, 2023 | Version: USA-13.0

1. INTENDED PURPOSE & USE

For the quantitative measurement of Estrone in human serum by an ELISA (Enzyme-Linked Immunosorbent Assay).

This kit is intended for professional use only and is for laboratory use only. For *in vitro* diagnostic use only. Intended to be used manually but may be adaptable to open automated analyzers. The user is responsible for validating the performance of this kit with any automated analyzers.

2. LIMITATIONS RELATED TO INTENDED PURPOSE & USE

1. This test is not intended to be used for screening purposes.
2. This test is not intended for home testing or self-testing.
3. The kit is calibrated for the determination of estrone in human serum. The kit is not calibrated for the determination of estrone in other specimens of human or animal origin.
4. The results obtained with this kit shall never be used as the sole basis for a clinical diagnosis and for therapeutic decisions.
5. Although common interfering substances have been evaluated with this test, other substances that have not been evaluated such as drugs and the occurrence of heterophilic antibodies in individuals regularly exposed to animals or animal products have the potential of causing interferences.

3. SUPPLEMENTAL INFORMATION

Estrone is a steroid, a female sex hormone and, with estradiol and estriol, one of the three most important endogenous estrogens.
Estrogens are involved in the development of female sex organs and secondary sex characteristics. Before the ovum is fertilized the main action of the estrogens is on the growth and function of the reproductive tract in order to prepare it for the fertilized ovum.

During the follicular phase of the menstrual cycle the estrone level shows a slight increase. The production of estrone then increases markedly to peak at around day 13. The peak is of short duration and by day 16 of the cycle levels will be low. A second peak occurs at around day 21 of the cycle and if fertilization does not occur, then the production of estrone decreases.

4. PRINCIPLE OF THE TEST

The Estrone ELISA is a competitive immunoassay. Competition occurs between estrone present in calibrators, controls, specimen samples and an enzyme-labelled antigen (HRP conjugate) for a limited number of anti-estrone antibody binding sites on the microplate wells. After a washing step that removes unbound materials, the TMB substrate (enzyme substrate) is added which reacts with HRP to form a blue-coloured product that is inversely proportional to the amount of estrone present. Following an incubation, the enzymatic reaction is terminated by the addition of the stopping solution, converting the colour from blue to yellow. The absorbance is measured on a microplate reader at 450 nm. A set of calibrators is used to plot a calibrator curve from which the amount of estrone in specimen samples and controls can be directly read.

5. PROCEDURAL CAUTIONS AND WARNINGS

1. This kit is for use by trained laboratory personnel (professional use only). For laboratory *in vitro* use only.
2. Practice good laboratory practices when handling kit reagents and specimens. This includes:
   - Do not pipette by mouth.
   - Do not smoke, drink, or eat in areas where specimens or kit reagents are handled.
   - Wear protective clothing and disposable gloves.
   - Wash hands thoroughly after performing the test.
   - Avoid contact with eyes; use safety glasses; in case of contact with eyes, flush eyes with water immediately and contact a doctor.
3. Users should have a thorough understanding of this protocol for the successful use of this kit. Reliable performance will only be attained by strict and careful adherence to the instructions provided.
4. Do not use the kit beyond the expiry date stated on the label.
5. If the kit reagents are visibly damaged, do not use the test kit.
6. Do not use kit components from different kit lots within a test and do not use any component beyond the expiration date printed on the label.
7. All kit reagents and specimens must be brought to room temperature and mixed gently but thoroughly before use. Avoid repeated freezing and thawing of specimens.
8. When the use of water is specified for dilution or reconstitution, use deionized or distilled water.
9. Immediately after use, each individual component of the kit must be returned to the recommended storage temperature stated on the label.
10. A calibrator curve must be established for every run.
11. It is recommended to all customers to prepare their own control materials or serum pools which should be included in every run at a high and low level for assessing the reliability of results.
12. The controls (included in kit) must be included in every run and their results must fall within the ranges stated in the quality control certificate; a failed control result might indicate improper procedural techniques or pipetting, incomplete washing, or improper reagent storage.
13. When dispensing the substrate and stopping solutions, do not use pipettes in which these liquids will come into contact with any metal parts.
14. The TMB Substrate is sensitive to light and should remain colourless if properly stored. Instability or contamination may be indicated by the development of a blue colour, in which case it should not be used.
15. Do not use grossly hemolyzed, grossly lipemic, icteric or improperly stored serum.
16. Samples or controls containing azide or thimerosal are not compatible with this kit, they may lead to false results.
17. Serum samples with a known low estrone concentration (< 60 pg/mL) may be used to dilute serum samples with values higher than the highest calibrator. Otherwise, results may be reported as "> 2000 pg/mL". The use of any other reagent will lead to false results.
18. Avoid microbial contamination of reagents.
19. To prevent the contamination of reagents, use a new disposable pipette tip for dispensing each reagent, sample, calibrator, and control.
20. To prevent the contamination of reagents, do not pour reagents back into the original containers.
21. Kit reagents must be regarded as hazardous waste and disposed of according to local and/or national regulations.
22. Consumables used with the kit that are potentially biohazardous (e.g., pipette tips, bottles or containers containing human materials) must be handled according to biosafety practices to minimize the risk of infection and disposed of according to local and/or national regulations relating to biohazardous waste.
23. This kit contains 1 M sulfuric acid in the stopping solution component. Do not combine acid with waste material containing sodium azide or sodium hypochlorite.
24. The use of safety glasses, and disposable plastic, is strongly recommended when manipulating biohazardous or bio-contaminated solutions.
25. Proper calibration of the equipment used with the test, such as the pipettes and absorbance microplate reader, is required.
26. If a microplate shaker is required for the assay procedure, the type and speed of shaker required is stated in the REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED section. Both the type and speed of shaker used can influence the optical densities and test results. If a different type of shaker and/or speed is used, the user is responsible for validating the performance of the kit.
27. Do not reuse the microplate wells, they are for SINGLE USE only.
28. To avoid condensation within the microplate wells in humid environments, do not open the pouch containing the microplate until it has reached room temperature.

6. SAFETY CAUTIONS AND WARNINGS

6.1 BIOHAZARDS

The reagents should be considered a potential biohazard and handled with the same precautions applied to blood specimens. All human specimens should be considered a potential biohazard and handled as if capable of transmitting infections and in accordance with good laboratory practices.

The calibrators and controls provided with the kit contain processed human serum/plasma that has been tested by approved methods and found to be negative for the presence of HBsAg and antibodies to HCV, HIV 1/2 and HIV NAT. However, no test method can offer complete assurance that any viable pathogens are absent. Therefore, these components should be considered a potential biohazard and handled with the same precautions as applied to any blood specimen, following good laboratory practices.

6.2 CHEMICAL HAZARDS

Avoid direct contact with any of the kit reagents. Specifically avoid contact with the TMB Substrate (contains tetramethylbenzidine) and Stopping Solution (contains sulfuric acid). If contacted with any of these reagents, wash with plenty of water and refer to SDS for additional information.

7. SPECIMEN COLLECTION, STORAGE AND PRE-TREATMENT

7.1 Specimen Collection & Storage

Approximately 0.15 mL of serum is required per duplicate determination. Collect 4–5 mL of venous blood into an appropriately labelled tube and allow it to clot. Centrifuge at room temperature and carefully transfer the serum into a new storage tube or container. Serum samples may be stored at room temperature for up to 3 days, at 2-8°C for up to 7 days or at -20°C or lower for up to 1 month.

Consider all human specimens as possible biohazardous materials and take appropriate precautions when handling.

7.2 Specimen Pre-Treatment

Specimen pre-treatment is not required.

8. REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED

1. Calibrated single-channel pipette to dispense 50 µL.
2. Calibrated multi-channel pipettes to dispense 50 µL, 100 µL and 150 µL.
3. Calibrated multi-channel pipettes to dispense 350 µL (if washing manually).
4. Automatic microplate washer (recommended).
5. Disposable pipette tips.
6. Distilled or deionized water.
7. Calibrated absorbance microplate reader with a 450 nm filter and an upper OD limit of 3.0 or greater.

9. REAGENTS PROVIDED

1. MPL — Microplate

Contents:	One anti-estrone polyclonal antibody-coated 96-well (12x8) microplate in a resealable pouch with desiccant.
Format:	Ready to Use
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

2. HRP CONJ — HRP Conjugate

Contents:	One bottle containing Estrone-Horse Radish Peroxidase (HRP) conjugate in a protein-based buffer with a non-mercury preservative.
Format:	Ready to Use
Volume:	15 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

3. CAL A – F — Calibrator A – F

Contents:	Six bottles of calibrator containing specified estrone concentrations. Human serum-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of estrone. Listed below are approximate concentrations, please refer to vial labels for exact concentrations. Concentrations: 0, 20, 60, 200, 600, 2000 pg/mL.
Format:	Ready to Use
Volume:	1.0 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

4. CONTROL 1 – 2 — Control 1 – 2

Contents:	Two bottles of control containing different estrone concentrations. Human serum-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of estrone. Refer to the QC certificate for the target values and acceptable ranges.
Format:	Ready to Use
Volume:	1.0 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

5. TMB SUB — TMB Substrate

Contents:	One bottle containing tetramethylbenzidine and hydrogen peroxide in a non-DMF or DMSO containing buffer.
Format:	Ready to Use
Volume:	16 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

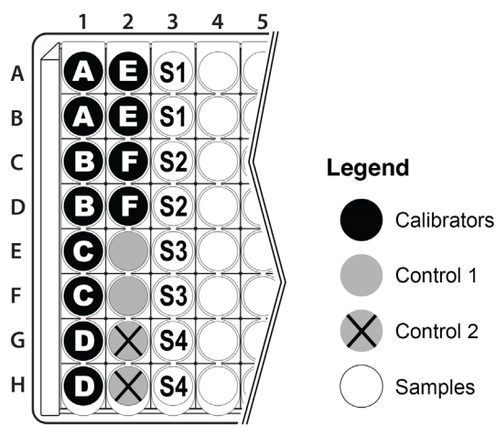
6. STOP Stopping Solution

Contents:	One bottle containing 1M sulfuric acid.
Format:	Ready to Use
Volume:	6 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.
Safety:	Refer to product SDS.  Warning

7. WASH BUFF CONC Wash Buffer Concentrate

Contents:	One bottle containing buffer with a non-ionic detergent and a non-mercury preservative.
Format:	Concentrated; Requires Preparation
Volume:	50 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks. Following Preparation: The wash buffer working solution is stable for 2 weeks following preparation, assuming Good Laboratory Practices are adhered to. To prevent microbial growth, prepare the wash buffer working solution in a clean container and store under refrigerated conditions (2-8°C) when not in use.
Preparation of Wash Buffer Working Solution:	**X10 Dilute 1:10 Before Use** Dilute 1:10 in distilled or deionized water before use. If the whole microplate is to be used dilute 50 mL of the wash buffer concentrate in 450 mL of distilled or deionized water.

10. RECOMMENDED ASSAY LAYOUT



11. ASSAY PROCEDURE

Specimen Pre-Treatment: None

All kit components, controls and specimen samples must reach room temperature prior to use. Calibrators, controls, and specimen samples should be assayed in duplicate. Once the procedure has been started, all steps should be completed without interruption.

1. After all kit components have reached room temperature, **mix** gently by inversion.
2. **Prepare** the Wash Buffer Working Solution (See section *9. Reagents Provided, 7. Wash Buffer Concentrate*).
3. **Plan** the microplate wells to be used for calibrators, controls, and samples. See section *10. Recommended Assay Layout.* Remove the strips from the microplate frame that will not be used and place them in the bag with desiccant. Reseal the bag with the unused strips and return it to the refrigerator.
4. **Pipette 50 µL** of each calibrator, control, and specimen sample into assigned wells.
5. **Pipette 100 µL** of the HRP Conjugate into each well (the use of a multi-channel pipette is recommended).
6. Gently tap the microplate frame for 10 seconds to mix the contents of the wells and **incubate** the microplate at room temperature (no shaking) for **60 minutes**.
7. **Wash** the microplate wells with an automatic microplate washer (preferred) or manually as stated below.

   Automatic: Using an automatic microplate washer, perform a **3-cycle** wash using **350 µL/well** of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells then filling each well with 350 µL of Wash Buffer Working Solution. After the final wash cycle, aspirate all wells and then tap the microplate firmly against absorbent paper to remove any residual liquid.

   Manually: For manual washing, perform a **3-cycle** wash using **350 µL/well** of Wash Buffer Working Solution (3 x 350 µL). One cycle consists of aspirating all wells by briskly emptying the contents of the wells over a waste container, then pipetting 350 µL of Wash Buffer Working Solution into each well using a multi-channel pipette. After the final wash cycle, aspirate all wells by briskly emptying the contents over a waste container and then tap the microplate firmly against absorbent paper to remove any residual liquid.
8. **Pipette 150 µL** of TMB Substrate into each well (the use of a multi-channel pipette is recommended).
9. **Incubate** the microplate at room temperature (no shaking) for **20 minutes**. Do not tap the microplate and avoid placing in intense light or air currents.
10. **Pipette 50 µL** of Stopping Solution into each well (the use of a multi-channel pipette is recommended) in the same order and speed as was used for addition of the TMB Substrate. Gently tap the microplate frame to mix the contents of the wells.
11. **Measure** the optical density (absorbance) in the microplate wells using an absorbance microplate reader set to 450 nm, within 20 minutes after addition of the Stopping Solution.

12. CALCULATIONS

1. Calculate the mean optical density for each calibrator, control and specimen sample duplicate.
2. Use a 4-parameter or 5-parameter curve fit with immunoassay software to generate a calibrator curve.
3. The immunoassay software will calculate the concentrations of the controls and specimen samples using the mean optical density values and the calibrator curve.
4. If a sample reads more than 2000 pg/mL and needs to be diluted and retested, then dilute with a known low estrone value (<60 pg/mL) serum sample not more than 1:10. The result obtained must be multiplied by the dilution factor.

13. QUALITY CONTROL

When assessing the validity of the test results, the following criteria should be evaluated:

1. The calibrator A mean optical density meets the acceptable range as stated in the QC Certificate.
2. The calibrator with the highest concentration meets the % binding acceptable range as stated in the QC Certificate. % Binding = (OD of calibrator/OD of calibrator A) x 100.
3. The values obtained for the kit controls are within the acceptable ranges as stated in the QC certificate.
4. The results of any external controls that were used meet the acceptable ranges.

14. TYPICAL DATA

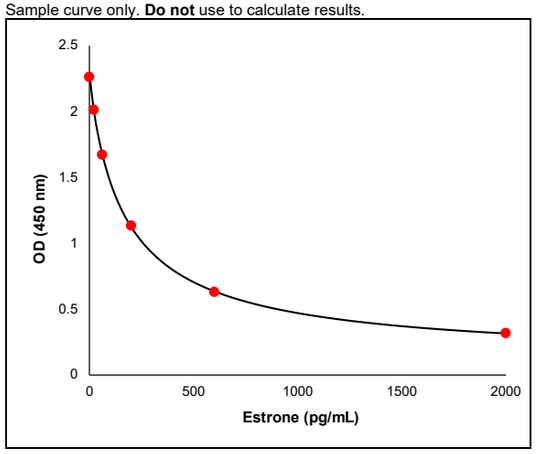
14.1 TYPICAL TABULATED DATA

Sample data only. **Do not** use to calculate results.

Calibrator	Mean OD (450 nm)	% Binding	Value (pg/mL)
A	2.261	100	0
B	2.012	89	20
C	1.671	75	60
D	1.132	50	200
E	0.632	28	600
F	0.319	14	2000
Unknown	1.481	-	96

14.2 TYPICAL CALIBRATOR CURVE

Sample curve only. **Do not** use to calculate results.



15. PERFORMANCE CHARACTERISTICS

15.1 SENSITIVITY

The analytical sensitivity study was performed according to the CLSI EP17-A2 guideline. The Limit of Background (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) are summarized in the table below:

Parameter	Estrone (pg/mL)
LoB	5.6
LoD	14.8
LoQ	17.7

15.2 SPECIFICITY (CROSS-REACTIVITY)

The following compounds were tested for cross-reactivity with estrone cross-reacting at 100%.

Compound	% Cross-Reactivity
Estrone	100
11-Deoxycorticosterone	< 0.1
17-Hydroxyprogesterone	< 0.1
17α-Estradiol	3.6
17β-Estradiol	7.9
Aldosterone	< 0.1
Androstenedione	< 0.1
Androsterone	< 0.1
Cholesterol	< 0.01
Corticosterone	< 0.1
Cortisol	0.2
Danazol	< 0.1
DHEA	0.1
DHEAS	< 0.1
DHT	< 0.1
Equilin	19.1
Estradiol sulfate	≤ 2.9
Estriol	2.6
Estrone sulfate	2.5
Ethisterone	< 0.1
Prednisone	< 0.1
Pregnenolone	< 0.1
Pregnenolone sulfate	< 0.1
Progesterone	< 0.1
Testosterone	< 0.1

15.3 INTERFERENCES

Potential interferents were spiked into human serum samples to determine the effect on the measured estrone values. Haemoglobin up to 10 g/L, Bilirubin conjugated up to 20 mg/dL, Bilirubin unconjugated up to 10 mg/dL, Triglycerides up to 1500 mg/dL, Biotin up to 2.4 µg/mL, HAMAS up to 1.2 µg/mL, Rheumatoid Factor (RF) up to 1688 IU/mL, Fulvestrant up to 100 ng/mL, and Mifepristone up to 4.6 µg/mL did not interfere with the assay. Interferences were observed for bilirubin unconjugated at levels of 20 mg/dL or higher.

15.4 PRECISION

The precision study was performed according to the CLSI EP05-A3 guideline.

Repeatability

The experimental protocol used a nested components-of-variance design with 8 serum samples, 10 testing days, two lots and two scientists per day. Each scientist ran two tests with two lots per day and two replicate measurements per run (a 10 x 2 x 2 x 2 design) for each sample. The results were analyzed with a two-way nested ANOVA and are summarized in the table below.

Sample	Mean (pg/mL)	Within Run		Between Run		Total	
		SD (pg/mL)	CV%	SD (pg/mL)	CV%	SD (pg/mL)	CV%
1	91.5	8.5	9.2%	11.7	12.8%	14.4	15.8%
2	40.7	5.1	12.4%	6.2	15.1%	8.0	19.6%
3	144.8	11.9	8.2%	15.2	10.5%	20.1	13.9%
4	744.4	33.4	4.5%	31.7	4.3%	46.7	6.3%
5	632.8	26.3	4.2%	41.9	6.6%	56.2	8.9%
6	1027.0	55.1	5.4%	26.1	2.5%	73.5	7.2%
7	381.0	18.2	4.8%	25.5	6.7%	34.1	8.9%
8	1211.7	53.0	4.4%	71.2	5.9%	106.2	8.8%

Reproducibility

The reproducibility study evaluated the precision performance of the device following EP05-A3 experimental design model 3 x 5 x 5 (3 locations x five testing days x five replicates per day) across laboratories located in Italy, the USA and Canada. The results were analyzed with a two-way nested ANOVA and are summarized in the table below.

Sample	Mean (pg/mL)	Repeatability		Within Location		Reproducibility	
		SD (pg/mL)	CV%	SD (pg/mL)	CV%	SD (pg/mL)	CV%
Control 1	88.3	6.7	7.5%	9.2	10.5%	10.8	12.2%
Control 2	515.5	25.9	5.0%	33.6	6.5%	46.1	8.9%
1	43.0	6.6	15.4%	7.0	16.3%	7.1	16.6%
2	75.1	6.8	9.1%	8.8	11.8%	9.8	13.0%
3	122.6	9.7	7.9%	13.0	10.6%	14.4	11.7%
4	129.4	8.7	6.7%	9.7	7.5%	11.9	9.2%
5	447.4	24.5	5.5%	31.3	7.0%	38.0	8.5%
6	912.3	51.3	5.6%	64.8	7.1%	66.9	7.3%

15.5 LINEARITY

The linearity study was performed according to the CLSI EP06-Ed2 guideline using six human serum samples covering the range of the assay. The samples were diluted in low estrone value (<60 pg/mL) serum samples up to ten percent (1:10), tested in duplicate, and the regression equation of the results (y) compared to the concentration (x) predicted from the dilution factor was y = 1.001x + 10.2, r = 0.999.

The relative non-linearity ranged between -10.6% and 10.5% across all samples and measurement dilution points. The statistical analysis shows that the assay is sufficiently linear up to a 1:10 dilution when using low estrone value (<60 pg/mL) serum samples as the diluent.

15.6 RECOVERY

Three low value samples and three high value samples were mixed in three groups at different ratios. The original samples and each set of mixed samples were tested in duplicate with calibrators and controls also in duplicate. The expected concentration values were determined by the fraction contribution of each sample to the final mix. The recovery% was calculated as the ratio percent between the sample's measured result and expected value. The results are summarized in the table below.

	Sample	Measured (pg/mL)	Expected (pg/mL)	Recovery %
Low value: Sample A High value: Sample B	100% Sample A	45.5	-	-
	100% Sample B	878.2	-	-
	90% Sample A /10% Sample B	135.7	128.8	105.4
	70% Sample A /30% Sample B	285.7	295.3	96.8
	50% Sample A /50% Sample B	397.3	461.9	86.0
	30% Sample A /70% Sample B	616.9	628.4	98.2
	10% Sample A /90% Sample B	838.3	795.0	105.5
Low value: Sample C High value: Sample D	100% Sample C	56.8	-	-
	100% Sample D	768.5	-	-
	90% Sample C /10% Sample D	152.2	127.9	119.0
	70% Sample C /30% Sample D	318.4	270.3	117.8
	50% Sample C /50% Sample D	482.8	412.6	117.0
	30% Sample C /70% Sample D	553.7	555.0	99.8
	10% Sample C /90% Sample D	641.3	697.4	92.0
Low value: Sample E High value: Sample F	100% Sample E	45.2	-	-
	100% Sample F	1113.2	-	-
	90% Sample E /10% Sample F	146.0	152.0	96.1
	70% Sample E /30% Sample F	373.4	365.6	102.1
	50% Sample E /50% Sample F	676.3	579.2	116.8
	30% Sample E /70% Sample F	928.4	792.8	117.1
	10% Sample E /90% Sample F	994.7	1006.4	98.8

15.7 COMPARATIVE STUDIES

This IBL-America Estrone ELISA kit (y) was compared against a Liquid Chromatography-Mass Spectrometry (LC-MS/MS) method (x) and yielded the following linear regression results:
y = 0.80x + 25.82, 105 samples, r = 0.92, Slope =0.80.

16. REFERENCE RANGES

Reference ranges (95%) were estimated using samples obtained from individuals of diverse races (all values are reported in pg/mL). Each laboratory shall establish their own range of reference values.

Cohort	N	Mean	Median	95% Range	
				2.5%	97.5%
Adult Female Premenopausal*	140	93.9	83.3	19.5	231.9
Adult Female, Menstrual Cycle					
1 – 10 days	40	84.4	81.5	29.8	146.7
11 – 20 days	40	87.7	79.6	20.9	232.0
21 – 30 days	40	82.2	73.2	27.2	173.8
Adult Female Postmenopausal*	205	31.9	42.5	ND	166.4
Adult Male	202	59.1	52.1	ND	187.2

*The menopausal status was classified according to age.
ND = Non-Detectable; results below the LoD (14.8 pg/mL).

17. LITERATURE

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18. SYMBOLS GLOSSARY

Symbol	Definition	Symbol	Definition
REF	Catalogue number		Manufacturer
LOT	Batch code		Date of manufacture
IVD	In vitro diagnostic medical device		Biological risks
UDI	Unique Device Identifier		Consult instructions for use
X #	Dilute 1:# Before Use	Rx ONLY	Prescription only: Device restricted to use by or on the order of a physician
QTY	Quantity		Keep away from sunlight
	Use-by date	EC REP	Authorized representative in the European Community/ European Union
	Do not re-use		Temperature limit
	Caution	Σ	Contains sufficient for <n> tests
LYO	Lyophilized	RUO	For Research Use Only. Not for use in diagnostic procedures.

The definitions of symbols used for kit component names are described in the *Reagents Provided* section.

19. CHANGE HISTORY

Previous Version:	IVD-13.0	**New Version:**	USA-13.0
Changes:	Change in version prefix from IVD to USA. Build: *v1.2D*		

20. GENERAL INFORMATION

Distributed and Manufactured for:

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Product Complaints

In the case of product complaints, the user shall submit in writing to the distributor or manufacturer a description of the complaint and provide accompanying data and/or information.

Warranty

IBL-America guarantees that the product is free of defects and will perform within the product specifications when the product is used prior to the expiration date, according to the intended purpose and use, and according to the instructions for use provided with the product. Any deviations from the intended purpose and use, instructions for use, modifications to kit components or use beyond the expiration date will invalidate any warranty claims.

Limitation of Liability

IBL-America liability in all circumstances whether in tort (including negligence) or at common law, and for any damage or loss, including but not limited to loss of profit and loss of sales, suffered whether direct, indirect, consequential, incidental, or special is limited to the purchase price of the product(s) in question.