Manufactured For:
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Prolactin ELISA

REF IB59110	Rx ONLY	IVD
Effective Date: November 7, 2022	Version:IVD-10.0	

1. INTENDED PURPOSE & USE

For the quantitative determination of Prolactin in human serum by an enzyme immunoassay.

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 prolactin in human serum. The kit is not calibrated for the determination of prolactin 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.
6. Some individuals may have antibodies to mouse protein that can possibly interfere in this assay. Therefore, the results from any individuals who have received a preparation of mouse antibodies for diagnosis or therapy should be interpreted with caution.
7. The measurement of prolactin may also include the measurement of its other structural forms (big prolactin, macroprolactin, etc.). As a result, individuals exhibiting elevated prolactin levels may require further investigations to make a proper diagnosis.

3. SUPPLEMENTAL INFORMATION

Prolactin is a polypeptide hormone synthesized by the lactotropic cells of the anterior pituitary gland. Structurally, it is similar to two other polypeptide hormones namely, growth hormone and placental lactogen. Prolactin is a polypeptide containing 199 amino acids, while growth hormone and placental lactogen each have 191 amino acids. There is approximately 100 µg of prolactin in the human pituitary gland, which is a very small amount when compared to growth hormone, which is present at 8–10 mg.

The target organ of prolactin is the breast (mammary gland). Its main physiological action is not only to initiate but also to sustain lactation. The hypothalamus secretes dopamine, which has a direct effect of inhibition of the secretion of prolactin.

If dopamine is not available or absent the secretion of prolactin is autonomous.

Clinical trends:

- If the pituitary gland is deficient it leads to failure of lactation.
- In Sheehan's syndrome the pituitary gland is deficient, therefore the prolactin level is reduced.
- A few conditions where increases in prolactin levels are found include hyperprolactinemia, sleep, pregnancy, hypothyroidism and stress.

4. PRINCIPLE OF THE TEST

The Prolactin ELISA is a one-step capture or 'sandwich' type immunoassay. The assay makes use of two highly specific monoclonal antibodies: A monoclonal antibody specific for prolactin is immobilized onto the microplate and another monoclonal antibody specific for a different epitope of prolactin is conjugated to horse radish peroxidase (HRP conjugate).

In the first incubation step, prolactin present in the specimen samples, calibrators and controls is simultaneously bound by the immobilized antibody and the HRP conjugate antibody, thus forming a sandwich complex. Excess and unbound materials are removed by a washing step. Next, the TMB substrate (enzyme substrate) is added which reacts with HRP to form a blue coloured product that is directly proportional to the amount of prolactin present. 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 prolactin 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. Samples values above the measuring range of the kit may be reported as >3200 µIU//mL. If further dilution and retesting is required, only calibrator A may be used to dilute serum samples. The use of any other reagent may 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.
29. When reading the microplate, the presence of bubbles in the wells will affect the optical densities (ODs). Carefully remove any bubbles before performing the reading step.

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.

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 0.1 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 2-8°C for up to 24 hours or at -10°C or lower if the analyses are to be done at a later date.

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 25 µL
2. Calibrated multi-channel pipettes to dispense 50 µL, 100 µL and 150 µL.
3. Calibrated multi-channel pipettes to dispense 300 µL (if washing manually).
4. Automatic microplate washer (recommended).
5. Microplate shaker:
   a. Orbital shaker (3 mm diameter) set to 600 rpm or
   b. Reciprocating shaker (1.5" stroke length) set to 180 oscillations/minute.
6. Disposable pipette tips.
7. Distilled or deionized water.
8. 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-prolactin monoclonal 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 | CONC — HRP Conjugate Concentrate

Contents:	One bottle containing anti-prolactin monoclonal antibody-Horse Radish Peroxidase (HRP) conjugate in a protein-based buffer with a non-mercury preservative.
Format:	Concentrated; Requires Preparation
Volume:	0.3 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.
Preparation of HRP Conjugate Working Solution:	**X51 — Dilute 1:51 Before Use** Dilute 1:51 in assay buffer before use (e.g., 40 µL of conjugate concentrate in 2 mL of assay buffer). If the whole plate is to be used dilute 240 µL of conjugate concentrate in 12 mL of assay buffer. Discard any that is left over.

3. CAL | A – F — Calibrator A – F

Contents:	Six bottles of calibrator containing specified prolactin concentrations. Protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of prolactin. Listed below are approximate concentrations, please refer to vial labels for exact concentrations. Concentrations: 0, 20, 100, 400, 800, 3200 µIU/mL 0, 0.77, 3.84, 15.38, 30.75, 123 ng/mL.
Format:	Ready to Use
Volume:	Calibrator A: 2.0 mL/bottle Calibrator B-F: 0.3 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 prolactin concentrations. Protein-based buffer with a non-mercury preservative. Prepared by spiking buffer with defined quantities of prolactin. Refer to the QC certificate for the target values and acceptable ranges.
Format:	Ready to Use
Volume:	0.3 mL/bottle
Storage:	2–8°C
Stability:	Unopened: Stable until the expiry date printed on the label. After Opening: Stable for four weeks.

5. ASY | BUFF Assay Buffer

Contents:	One bottle containing 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.

6. 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.

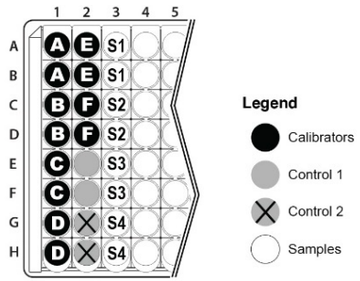
7. STOP Stopping Solution

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**

8. 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 HRP Conjugate Working Solution and Wash Buffer Working Solution (See section *9. Reagents Provided* section, *2. HRP Conjugate Concentrate* and *8. 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 25 µL** of each calibrator, control, and specimen sample into assigned wells.
5. **Pipette 100 µL** of the HRP Conjugate Working Solution into each well (the use of a multi-channel pipette is recommended).
6. **Incubate** the microplate on a microplate shaker** for **1 hour** at room temperature.
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 **300 µL/well** of Wash Buffer Working Solution (3 x 300 µL). One cycle consists of aspirating all wells then filling each well with **300 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 **300 µL/well** of Wash Buffer Working Solution (3 x 300 µL). One cycle consists of aspirating all wells by briskly emptying the contents of the wells over a waste container, then pipetting 300 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 on a microplate shaker** for **10-15 minutes** at room temperature.
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.

** See section *8. Reagents And Equipment Needed But Not Provided* for microplate shaker options.

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 3200 µIU/mL and needs to be diluted and retested, then dilute with calibrator A not more than 1:8. 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 optical density acceptable range as stated in the QC Certificate.
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

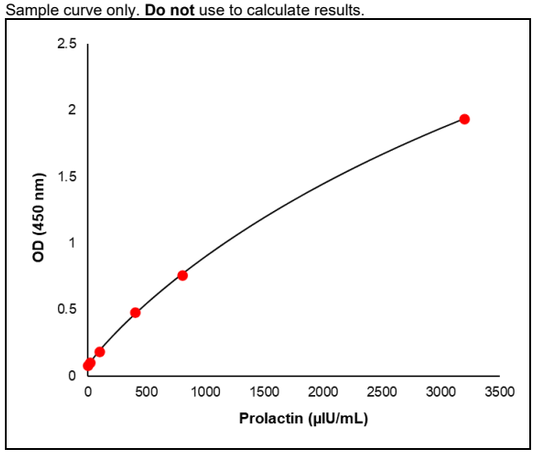
14.1 TYPICAL TABULATED DATA

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

Calibrator	Mean OD (450 nm)	% Binding	Value (µIU/mL)
A	0.078	3%	0
B	0.090	4%	20
C	0.137	6%	100
D	0.344	15%	400
E	0.624	26%	800
F	2.361	100%	3200
Unknown	0.345	-	402.9

14.2 TYPICAL CALIBRATOR CURVE

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



15. PERFORMANCE CHARACTERISTICS

15.1 SENSITIVITY

The lower detection limit is calculated from the standard curve by determining the resulting concentration of the mean OD of calibrator A (based on 10 replicate analyses) plus 2 SD. Therefore, the sensitivity of the IBL-America prolactin ELISA kit is 10 µIU/mL.

15.2 SPECIFICITY (CROSS-REACTIVITY)

The specificity of the IBL-America prolactin ELISA kit was determined by measuring the apparent prolactin values of the following compounds:

Substance	Concentration Range	Apparent PRL Value (µIU/mL)
hCG (WHO 75/537)	100–2500 IU/L	Not Detected
FSH (WHO 1st 83/575)	25–4000 IU/L	Not Detected
hGH (WHO 80/505)	10–1000 mg/L	Not Detected
PL	0.1–50 mg/L	Not Detected
TSH (WHO 80/558)	25–1000 mIU/L	Not Detected

The specificity towards other structural forms of prolactin, including macroprolactin has not been determined.

15.3 PRECISION

INTRA-ASSAY PRECISION

Three serum samples were assayed ten times each on the same calibrator curve. The results (in µIU/mL) are tabulated below:

Sample	Mean	SD	CV%
1	202	14	6.9
2	586	68	11.6
3	1320	136	10.3

INTER-ASSAY PRECISION

Three serum samples were assayed ten times over a period of four weeks. The results (in µIU/mL) are tabulated below:

Sample	Mean	SD	CV%
1	237	18	7.6
2	589	85	14.4
3	1725	277	13.2

15.4 LINEARITY

Three serum samples were diluted with calibrator A. The results (in µIU/mL) are tabulated below:

Sample	Observed Result	Expected Result	Recovery %
1	292	-	-
1:2	124	146	84.9
1:4	87	73	119.2
1:8	41	37	110.8
2	444	-	-
1:2	202	222	91.0
1:4	116	111	104.5
1:8	69	56	123.2
3	1965	-	-
1:2	1014	983	103.2
1:4	427	491	87.0
1:8	209	246	85.0

15.5 RECOVERY

Spiked samples were prepared by adding defined amounts of prolactin to three serum samples. The results (in µIU/mL) are tabulated below:

Sample	Observed Result	Expected Result	Recovery %
1 Unspiked	55	-	-
+ 62	95	117	81.2
+ 130	172	185	93.0
+ 542	508	597	85.1
2 Unspiked	59	-	-
+ 49	127	108	117.6
+ 145	258	204	126.5
+ 775	792	834	95.0
3 Unspiked	707	-	-
+ 145	807	852	94.7
+ 385	1356	1092	124.2
+ 775	1868	1482	126.0

16. REFERENCE RANGES

As for all clinical assays each laboratory should collect data and establish their own range of expected normal values.

Group	Absolute Range (µIU/mL)
Males	67 – 360
Females Postmenopausal	55 – 2500 < 400

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		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:	9.0 (Combined)	**New Version:**	IVD-10.0
Changes:	New IFU format with numbered headings. **HEADING** Removal of country-specific regulatory information. Addition of Rx ONLY symbol. **1. INTENDED PURPOSE & USE** Addition: 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 and 2 added. **5. PROCEDURAL CAUTIONS AND WARNINGS** **Additional cautings and warnings added.** Some previous limitations added to this section. **8. REAGENTS AND EQUIPMENT NEEDED BUT NOT PROVIDED** Addition of microplate shaker options. **9. REAGENTS PROVIDED** Addition of symbols for all components and safety informaiton if applicable. In-use stability statement added for all components. Control low and high now called control 1 and 2, respectively. **10. RECOMMENDED ASSAY LAYOUT** New section added. **11. ASSAY PROCEDURE** Component names revised to match symbol definitions. **12. CALCULATIONS** Removed instructions for manually plotting calibrator curve. **13. QUALITY CONTROL** New section added. **14.1 TYPICAL TABULATED DATA** Table data updated. **18. SYMBOLS GLOSSARY** Addition of symbols and definitions. **19. CHANGE HISTORY** New section added. **20. GENERAL INFORMATION** Addition of product complaints, warranty and limitation of liability sections. Build: *v1.3D*		

20. GENERAL INFORMATION

CONTACT INFORMATION
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Web: www.ibl-america.com

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.