



ARCHITECT

SYSTEM

en

Prolactin

REF 7K76

48-9177/R2

B7K760


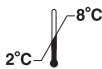



Read Highlighted Changes
Revised January, 2010

Prolactin

Customer Service: Contact your local representative or find country specific contact information on www.abbottdiagnostics.com

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

REF	List Number	REAGENT LOT	Reagent Lot
IVD	<i>In Vitro</i> Diagnostic Medical Device	SN	Serial Number
LOT	Lot Number	CAL 1	Calibrator (1, 2)
	Expiration Date	CONTROL L	Control Low, Medium, High (L, M, H)
	Store at 2-8°C	ASSAY CD-ROM	Assay CD-ROM
	Caution	REACTION VESSELS	Reaction Vessels
	Consult instructions for use	SAMPLE CUPS	Sample Cups
	Manufacturer	SEPTUM	Septum
		REPLACEMENT CAPS	Replacement Caps
		WARNING: SENSITIZER	Warning: May cause an allergic reaction

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.

NAME

ARCHITECT Prolactin

INTENDED USE

The ARCHITECT Prolactin assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of prolactin in human serum and plasma.

SUMMARY AND EXPLANATION OF TEST

Human prolactin (hPRL) is a single chain polypeptide of 199 amino acids and a molecular weight of approximately 23,000 daltons. Its existence as a distinct chemical entity, separate from growth hormone, was established through a series of studies between 1965 and 1971.^{1,2} Prolactin is produced by the anterior pituitary and its secretion is regulated physiologically by inhibitory³ and releasing⁴ factors of the hypothalamus. Prolactin appears in the blood promptly after administration of thyrotropin-releasing hormone (TRH).^{4,5} The major physiologic action of prolactin is the initiation and maintenance of lactation in women.

Hyperprolactinemia has been established as a common cause of infertility and gonadal disorders in men and women. Prolactin has been shown to inhibit the secretion of ovarian steroids^{6,7} and to interfere with follicle maturation⁷ and the secretion of LH and FSH⁸ in the human female. Measurement of elevated serum prolactin levels may provide the first quantitative evidence of pituitary dysfunction.⁹ Quantitation of prolactin levels is also of interest in the evaluation and management of patients with amenorrhea and galactorrhea.¹⁰

Various factors other than disease states have been found to influence prolactin levels. Factors which increase prolactin concentrations include: pregnancy, breast stimulation, stress, coitus, administration of estrogens, progesterone, androgens, some psychotropic and antihypertensive drugs, and TRH.^{10,11} Factors which decrease prolactin concentrations include the administration of L-dopa and bromocriptine.^{10,11}

The ARCHITECT Prolactin assay is to be used as an aid in the diagnosis of male and female infertility and pituitary dysfunction, monitoring of male and female gonadal disorders and management of amenorrhea and galactorrhea.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Prolactin assay is a two-step immunoassay to determine the presence of prolactin in human serum and plasma using Chemiluminescent Microparticle Immunoassay (CMIA) technology with flexible assay protocols, referred to as Chemiflex.

In the first step, sample and anti-prolactin (mouse, monoclonal) coated paramagnetic microparticles are combined. Prolactin present in the sample binds to the anti-prolactin (mouse, monoclonal) coated microparticles. After washing, anti-prolactin (mouse, monoclonal) acridinium labeled conjugate is added in the second step. Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of prolactin in the sample and the RLUs detected by the ARCHITECT *i* optical system.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Reagent Kit, 100 Tests/500 Tests

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT *i* Systems. Please contact your local distributor.

ARCHITECT Prolactin Reagent Kit (7K76)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL/27.0 mL) anti-prolactin (mouse, monoclonal) coated Microparticles in TRIS buffer with protein (bovine and murine) stabilizers. Preservative: antimicrobial agent.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL/26.3 mL) anti-prolactin (mouse, monoclonal) acridinium-labeled Conjugate in phosphate buffer with protein (piscine and bovine) stabilizers. Minimum concentration: 0.05 µg/mL. Preservative: antimicrobial agent.

Manual Diluent

ARCHITECT *i* Multi-Assay Manual Diluent (7D82-50)

- **MULTI-ASSAY MANUAL DILUENT** 1 Bottle (100 mL) ARCHITECT *i* Multi-Assay Manual Diluent containing phosphate buffered saline solution. Preservative: antimicrobial agent.

Other Reagents

ARCHITECT *i* Pre-Trigger Solution

- **PRE-TRIGGER SOLUTION** Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

ARCHITECT *i* Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35 N sodium hydroxide.

ARCHITECT *i* Wash Buffer

NOTE: Bottle and volume varies based on order.

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

WARNINGS AND PRECAUTIONS

- **IVD**
- For *In Vitro* Diagnostic Use
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

- **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens.¹² Biosafety Level 2¹³ or other appropriate biosafety practices^{14,15} should be used for materials that contain or are suspected of containing infectious agents.

The following warnings and precautions apply to this component:

- **Conjugate**



WARNING:
H317 Contains methylisothiazolones.
May cause an allergic skin reaction.

Prevention
P261 Avoid breathing mist / vapours / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves / protective clothing / eye protection.

Response
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice / attention.
P363 Wash contaminated clothing before use.


This material and its container must be disposed of in a safe way.

- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Handling Precautions

- Do not use reagent kits beyond the expiration date.
- **Do not mix reagents from different reagent kits.**
- Prior to loading the ARCHITECT Prolactin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
- To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
- Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts which have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions

-  The ARCHITECT Prolactin Reagent Kit must be stored at 2-8°C and may be used immediately after removal from 2-8°C storage.
- When stored and handled as directed, reagents are stable until the expiration date.
- The ARCHITECT Prolactin Reagent Kit may be stored on-board the ARCHITECT *i* System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking on-board time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored on or off the ARCHITECT *i* System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in 2-8°C storage off the system, the reagent kit must be discarded.** After reagents are removed from the system, you must initiate a scan to update the on-board stability timer.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and may require retesting. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT Prolactin assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM prior to performing the assay. For detailed instructions on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.
- The default result unit for the ARCHITECT Prolactin assay is ng/mL. An alternate result unit, mIU/L, may be selected for reporting results by editing assay parameter "Result Concentration Units", to mIU/L. The conversion factor used by the system is 21.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum (including serum collected in serum separator tubes) or plasma collected in sodium heparin, lithium heparin, or potassium EDTA may be used in the ARCHITECT Prolactin assay. Other anticoagulants have not been validated for use with the ARCHITECT Prolactin assay. Follow manufacturer's processing instructions for serum or plasma collection tubes.
- The ARCHITECT *i* System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify the correct specimen types are used in the ARCHITECT Prolactin assay.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal results, inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- For optimal results, serum and plasma specimens should be free of fibrin, red blood cells or other particulate matter.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.
- If testing will be delayed more than 24 hours, remove serum or plasma from the clot, serum separator or red blood cells. Specimens may be stored for up to 7 days at 2-8°C prior to being tested. If testing will be delayed more than 7 days, specimens should be frozen at -10°C or colder. Specimens stored frozen at -10°C or colder for 12 months showed no performance differences.

- Multiple freeze-thaw cycles of specimens should be avoided. Specimens must be mixed THOROUGHLY after thawing, by LOW speed vortexing or by gently inverting, and centrifuged prior to use to remove red blood cells or particulate matter to ensure consistency in the results.
- When shipped, specimens must be packaged and labeled in compliance with applicable state, federal and international regulations covering the transport of clinical specimens and infectious substances. Specimens must be shipped frozen (dry ice). Prior to shipment, it is recommended that specimens be removed from the clot, serum separator or red blood cells.

PROCEDURE

Materials Provided

- 7K76 ARCHITECT Prolactin Reagent Kit

Materials Required but not Provided

- ARCHITECT *i* System
- ARCHITECT *i* **ASSAY CD-ROM**
- 7K76-01 ARCHITECT Prolactin Calibrators
- 7K76-10 ARCHITECT Prolactin Controls
- 7D82-50 ARCHITECT *i* **MULTI-ASSAY MANUAL DILUENT**
- ARCHITECT *i* **PRE-TRIGGER SOLUTION**
- ARCHITECT *i* **TRIGGER SOLUTION**
- ARCHITECT *i* **WASH BUFFER**
- ARCHITECT *i* **REACTION VESSELS**
- ARCHITECT *i* **SAMPLE CUPS**
- ARCHITECT *i* **SEPTUM**
- ARCHITECT *i* **REPLACEMENT CAPS**
- For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

Assay Procedure

- Before loading the ARCHITECT Prolactin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment:
 - Invert the microparticle bottle 30 times.
 - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
 - Once the microparticles have been resuspended, remove and discard the cap. Wearing clean gloves, remove a septum from the bag. Carefully snap the septum onto the top of the bottle.
 - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
- Order tests.
- Load the ARCHITECT Prolactin Reagent Kit on the ARCHITECT *i* System. Verify that all necessary assay reagents are present. Ensure that septums are present on all reagent bottles.
- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation verify adequate sample cup volume is present prior to running the test.
 - Priority: 80 µL for the first Prolactin test plus 30 µL for each additional Prolactin test from the same sample cup
 - ≤ 3 hours onboard: 150 µL for the first Prolactin test plus 30 µL for each additional Prolactin test from the same sample cup
 - > 3 hours onboard: additional sample volume is required. Refer to the ARCHITECT System Operations Manual, Section 5 for information on sample evaporation and volumes.
- If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- ARCHITECT Prolactin Calibrators and Controls should be mixed by gentle inversion prior to use.
 - To obtain the recommended volume requirements for the ARCHITECT Prolactin Calibrators and Controls, hold the bottles **vertically** and dispense 4 drops of each calibrator or 3 drops of each control into each respective sample cup.

- Load samples.
 - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN. The ARCHITECT *i* System performs the following function:
 - Moves the sample to the aspiration point
 - Loads a reaction vessel (RV) into the process path
 - Aspirates and transfers sample into the RV
 - Advances the RV one position and transfers microparticles into the RV
 - Mixes, incubates and washes the reaction mixture
 - Adds conjugate to the RV
 - Mixes, incubates and washes the reaction mixture
 - Adds Pre-Trigger and Trigger Solutions
 - Measures chemiluminescent emission to determine the quantity of prolactin in the sample
 - Aspirates contents of RV to liquid waste and unloads RV to solid waste
 - Calculates the result
- For information on ordering patient specimens, calibrators and controls, and general operating procedures refer to the ARCHITECT System Operations Manual, Section 5.
- For optimal performance, it is important to follow the routine maintenance procedures defined in the ARCHITECT System Operations Manual, Section 9. If your laboratory requires more frequent maintenance, follow those procedures.

Specimen Dilution Procedures

Specimens with a prolactin value exceeding 200 ng/mL are flagged with the code "> 200" and may be diluted with the Automated Dilution Protocol.

- If using the Automated Dilution Protocol, the system performs a 1:10 dilution of the specimen and automatically calculates the concentration of the undiluted specimen and reports the result.
- If a sample run using the Automated Dilution Protocol is flagged with the code "< 6.0", it needs to be retested at a lower dilution or undiluted. The result and interpretation should not be reported.
- For samples run with the 1:10 Automated Dilution Protocol which are flagged with the code "> 2000", manual dilutions should be performed as follows:
 - The suggested dilution for Prolactin is 1:40.
 - For a 1:40 dilution, add 25 μ L of the patient specimen to 975 μ L of ARCHITECT Multi-Assay Manual Diluent (7D82-50).
 - The operator must enter the dilution factor in the patient or control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution. This will be the reported result.
 - If the operator does not enter the dilution factor, the reported result will be that of the diluted sample. This result (before dilution factor is applied) should be greater than 5 ng/mL. **The reported result must be multiplied by the dilution factor to obtain the concentration of the undiluted sample.**
- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- To perform an ARCHITECT Prolactin calibration, test Calibrators 1 and 2 in duplicate. A single sample of all levels of prolactin controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrators should be priority loaded.
- Calibration Range: 0 - 200 ng/mL.
- Once an ARCHITECT Prolactin calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
 - A reagent kit with a new lot number is used.
 - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT Prolactin assay is a single sample of all control levels tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures. Ensure that assay control values are within the concentration ranges specified in the control package insert.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B. The ARCHITECT Prolactin assay belongs to method group 1.

RESULTS

The ARCHITECT Prolactin assay utilizes a 4 Parameter Logistic Curve Fit data reduction method (4PLC, X weighted) to generate a calibration curve.

Alternate Result Units

- The default result unit for the ARCHITECT Prolactin assay is ng/mL. When the alternate result unit, mIU/L, is selected, the conversion factor used by the system is 21.
- Conversion Formula: (Concentration in ng/mL) x (21) = mIU/L.

Flags

- Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- If the prolactin results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies.^{16,17} Additional information may be required for diagnosis.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.¹⁸ Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.
- Prolactin may exist in alternate structural forms (e.g., macroprolactin)¹⁹⁻²² which may exhibit variable levels of physiological activity.²³ In patients with elevated prolactin results, additional information may be required for diagnosis.

EXPECTED VALUES

The expected ranges for this assay were established by testing serum specimens from 100 apparently healthy males and 100 apparently healthy, nonpregnant females. The expected range for males includes the entire range of values. For the female expected range, the central 90 percent interval of all values is reported in the following table.

Population	n	Prolactin Values (ng/mL)	
		Median	Range
Males	100	6.99	3.46 - 19.40
Females	100	10.29	5.18 - 26.53

It is recommended that each laboratory establish its own expected ranges, which may be unique to the population it serves, depending on its demographics.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

Precision was determined as described in [Clinical and Laboratory Standards Institute \(CLSI, formerly NCCLS\) Protocol EP5-T2.24](#). A three member buffered protein based panel was assayed, using a single lot of reagents, in replicates of two at two separate times per day for 20 days on two instruments. Data from this study are summarized in the following table.

Panel Member	Reagent Lot	Instrument	n	Mean			Total	
				Conc. Value (ng/mL)	Within Run SD	%CV	SD	%CV
1	1	1	80	6.93	0.266	3.8	0.323	4.7
1	1	2	80	7.05	0.223	3.2	0.310	4.4
2	1	1	80	18.24	0.537	2.9	0.748	4.1
2	1	2	80	17.92	0.477	2.7	0.655	3.7
3	1	1	80	35.86	1.098	3.1	1.302	3.6
3	1	2	80	35.25	0.793	2.3	1.165	3.3

Recovery

Known concentrations of prolactin were added to five aliquots of human serum. The concentration of prolactin was determined using the ARCHITECT Prolactin assay and the resulting percent recovery was calculated. The percent recovery of the ARCHITECT Prolactin assay ranged from 92.4% to 101.1% with an average of 95.8%.

Analytical Sensitivity

The analytical sensitivity of the ARCHITECT Prolactin assay was calculated to be better than 0.6 ng/mL (n = 24 runs). Analytical sensitivity is defined as the concentration at two standard deviations from the mean RLU value of the ARCHITECT Prolactin MasterCheck Level 0 (0.0 ng/mL), and represents the lowest measurable concentration of prolactin that can be distinguished from zero.

Specificity

Human serum specimens containing 13-16 ng/mL of prolactin were supplemented with follicle stimulating hormone (FSH), human chorionic gonadotropin (hCG), human growth hormone (hGH), human placental lactogen (hPL), luteinizing hormone (LH), or thyroid stimulating hormone (TSH) at specific levels. The results are stated in the following table.

Potential Cross Reactant	Concentration Tested	Cross Reactivity(%)
FSH	1,000 mIU/mL	0
hCG	100,000 mIU/mL	0
hGH	1,000 ng/mL	0.03
hPL	100,000 ng/mL	0
LH	5,000 mIU/mL	0.001
TSH	20,000 μ IU/mL	0

Interference

Potential interference from hemoglobin, bilirubin, triglycerides, and protein was studied in the ARCHITECT Prolactin assay. The ARCHITECT Prolactin assay demonstrated the following interferences.

- Hemoglobin < 10% at 500 mg/dL
- Bilirubin < 10% at 20 mg/dL
- Triglycerides < 10% at 3000 mg/dL
- Protein < 10% at 2.0 g/dL and 12.0 g/dL

Accuracy by Correlation

The ARCHITECT Prolactin assay was compared to a commercially available diagnostic kit. The results of the specimen testing are shown in the following table.

Abbott ARCHITECT Prolactin vs. Abbott AxSYM Prolactin				
Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares				
Linear Regression	597	0.55	0.98	0.995
Passing-Bablok				
Linear Regression*	597	0.49	0.99	0.995

In this evaluation, serum specimens tested ranged from 0.65 ng/mL to 185.74 ng/mL with the ARCHITECT Prolactin assay.

* A linear regression method with no special assumptions regarding the distribution of the samples and the measurement errors.²⁵

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