ARCHITECT Progesterone

REF 7K77-20
REF 7K77-25
REF 7K77-35

en
Progesterone
7K77
G6-5477/R08
B7K770

Read Highlighted Changes: Revised February 2016.

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.

NAME

ARCHITECT Progesterone

INTENDED USE

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

SUMMARY AND EXPLANATION OF THE TEST

Progesterone is produced primarily by the corpus luteum of the ovary in normally menstruating women and to a lesser extent by the adrenal cortex.[1] At approximately the 6th week of pregnancy, the placenta becomes the major producer of progesterone.[2-5] The major functions of progesterone are in the preparation of the uterus for implantation and maintenance of pregnancy.

During the follicular phase of the cycle, progesterone levels remain low (0.2-1.5 ng/mL).[1, 6, 7] Following the LH surge and ovulation, luteal cells in the ruptured follicle produce progesterone in response to LH. During this luteal phase, progesterone rises rapidly to a maximum of 10-20 ng/mL at 5 to 7 days following ovulation. If conception does not occur, progesterone levels decrease during the last four days of the cycle due to the regression of the corpus luteum.[1, 6-11] If conception occurs, the levels of progesterone are maintained at mid-luteal levels by the corpus luteum until about week six. At that time, the placenta becomes the main source of progesterone and levels rise from approximately 10-50 ng/mL in the first trimester to 50-280 ng/mL in the third trimester.[1, 12, 13]

Serum progesterone is a reliable indicator of either natural or induced ovulation because of its rapid rise following ovulation.[14-16] Disorders of ovulation, including anovulation, are relatively frequent and are responsible for infertility in approximately 15-20% of patients. Progesterone levels are abnormally low in these patients during the mid-luteal phase.

Luteal phase deficiency is a reproductive disorder associated with infertility and spontaneous abortion and is thought to occur in 10% of infertile women.[17-19] The infertility and pregnancy loss associated with this disorder are thought to be attributable to inadequate development of the endometrium.[20] The failure of the endometrium to mature is thought to be caused by insufficient production of progesterone by the corpus luteum. Progesterone levels in the luteal phase are lower than normal in women with luteal phase deficiency.[21, 22]

Measurement of progesterone in the first 10 weeks of gestation has been shown to be reliable and effective for the diagnosis and treatment of patients with threatened abortion [23] and ectopic pregnancy. Suppressed progesterone levels (5 to 25 ng/mL) in the presence of detectable amounts of hCG is highly suggestive of patients with threatened abortion or ectopic pregnancy, regardless of gestational age.[24-26]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

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

1. Sample, anti-fluorescein (mouse, monoclonal) fluorescein-progesterone complex coated paramagnetic microparticles, and anti-progesterone (sheep, monoclonal) acridinium-labeled conjugate are combined to create a reaction mixture. The Progesterone present in the sample competes with the anti-fluorescein (mouse, monoclonal) fluorescein-progesterone complex coated microparticles for binding with anti-progesterone (sheep, monoclonal) acridinium-labeled conjugate to form antibody-antigen-antibody complexes.
2. After washing, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
3. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is an inverse relationship between the amount of progesterone in the sample and the RLUs detected by the ARCHITECT iSystem optics.

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

REAGENTS

Kit Contents

ARCHITECT Progesterone 7K77

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

REF	7K77-25	7K77-20	7K77-35
Σ	100	400	500
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.00 mL
CONJUGATE	1 x 17.0 mL	4 x 17.0 mL	1 x 30.88 mL
ASSAY DILUENT	1 x 8.0 mL	4 x 8.0 mL	1 x 40.70 mL

MICROPARTICLES Anti-fluorescein (mouse, monoclonal) fluorescein progesterone complex coated Microparticles in TRIS buffer with protein (bovine and murine) and surfactant stabilizers. Concentration: 0.1% solids. Preservatives: sodium azide and ProClin.

CONJUGATE Anti-progesterone (sheep, monoclonal) acridinium-labeled Conjugate in MES buffer with protein (bovine and sheep) stabilizers. Minimum concentration: 7 ng/mL. Preservatives: sodium azide and ProClin.

ASSAY DILUENT Progesterone Assay Diluent contains TRIS buffer with chemical stabilizers. Preservative: sodium azide

Other Assay-Specific Reagents

MANUAL DILUENT 1 Bottle (5.0 mL) ARCHITECT Progesterone Manual Diluent, REF 7K77-50, containing TRIS buffer. Preservative: sodium azide.

Other Reagents

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

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

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

NOTE: Bottle and volume varies based on order.

Warnings and Precautions

- **IVD**
- For *In Vitro* Diagnostic Use

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. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[27-30]

The following warnings and precautions apply to: **MICROPARTICLES** / **CONJUGATE**	
	
WARNING	Contains methylisothiazolones and sodium azide.
H317	May cause an allergic skin reaction.
EUH032	Contact with acids liberates very toxic gas.
Prevention	
P261	Avoid breathing mist / vapors / 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 water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to: **ASSAY DILUENT**	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

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

Reagent Handling

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between kits.**
- **The ARCHITECT Progesterone Reagent Kit must be maintained continuously at 2-8°C when not on-board the ARCHITECT iSystem. Performance differences may be seen if reagents are not at 2-8°C prior to loading them on the system.**
- Once the ARCHITECT Progesterone Reagent Kit has been removed from refrigerated storage (2-8°C), **immediately** place them on-board the ARCHITECT iSystem.
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the **Mixing Instructions** section below.
- **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 and 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.

Mixing Instructions

- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may 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.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**

Reagent Storage

When stored and handled as directed, reagents are stable until the expiration date.

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/ Opened*	2-8°C	Until expiration date	May be used immediately after removal from 2-8°C storage.
On board	System temperature	30 days	Discard after 30 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

NOTE: The ARCHITECT Progesterone Reagent Kit is shipped cold and should be stored at 2-8°C after receipt. Refer to the **Reagent Handling** section in this package insert for additional information.

* Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, **immediately** 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.** For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

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 are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The ARCHITECT Progesterone assay file must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.

For detailed information on assay file installation and 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.

Alternate Result Units

Edit assay parameter "Result concentration units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default result unit	Conversion factor	Alternate result unit
ng/mL	3.18	nmol/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Validated specimen types to be used with this assay:

Specimen Types	Collection Tubes
Serum	Serum
	Serum separator tubes (SST)
Plasma	Sodium heparin
	Lithium heparin
	Potassium EDTA

- Other anticoagulants have not been validated for use with this assay.
- Literature suggests that measurable progesterone may decrease with time when stored in serum separator tubes.[31] Serum collected in serum separator tubes and stored up to 24 hours on the gel showed (on average) a 13% loss.
- The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use specimens with the following conditions:
  - obvious microbial contamination
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and 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.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for specimen collection tubes.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, centrifuge specimens before testing if
  - they contain fibrin, red blood cells, or other particulate matter or
  - they were frozen and thawed.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Specimen Storage

Specimen Type	Storage Temperature	Maximum Storage Time
Serum/Plasma	2-8°C	≤ 10 days
	-10°C or colder	> 10 days

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 10 days at 2-8°C prior to being tested.

If testing will be delayed more than 10 days, specimens should be frozen at -10°C or colder. Specimens stored frozen at -10°C or colder for 6 months showed no performance difference.

Avoid multiple freeze/thaw cycles.

Specimen Shipping

- Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

7K77 ARCHITECT Progesterone Reagent Kit

Materials Required but not Provided

- ARCHITECT Progesterone Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 7K77-01 ARCHITECT Progesterone Calibrators
- 7K77-10 ARCHITECT Progesterone Controls
- 7K77-50 ARCHITECT Progesterone Manual Diluent
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Reaction Vessels
- ARCHITECT Sample Cups
- ARCHITECT Septum
- ARCHITECT Replacement Caps
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

- Load the reagent kit on the ARCHITECT iSystem.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- Minimum sample cup volume is calculated by the system and printed on the Orderlist report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

  Maximum number of replicates sampled from the same sample cup: 10
  - Priority:

    Sample volume for first test: 100 µL

    Sample volume for each additional test from same sample cup: 50 µL

- ≤ 3 hours on board:

  Sample volume for first test: 150 µL

  Sample volume for each additional test from same sample cup: 50 µL
- > 3 hours on board: 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 Progesterone Calibrators and Controls must be mixed THOROUGHLY by low speed vortex or inversion prior to use.
  - Dispense recommended volumes into each respective sample cup.
  - Recommended volumes:

    for each calibrator: minimum 200 µL

    for each control: minimum of 150 µL
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- 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 perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Specimen Dilution Procedures

Specimens with a progesterone value exceeding 40 ng/mL are flagged with the code "> 40" and may be diluted using either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

The system performs a 1:10 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result.

Manual Dilution Procedure

Suggested dilution: 1:10

It is recommended that dilutions not exceed 1:15.

1. For a 1:10 dilution, add 50 µL of the patient specimen to 450 µL of ARCHITECT Progesterone Manual Diluent (7K77-50).
2. 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 specimen before dilution. This will be the reported result. The dilution should be performed so that the diluted result reads greater than 10.0 ng/mL for a 1:10 dilution.

   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 1.0 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

- Test Calibrators 1 and 2 in duplicate. The calibrators should be priority loaded.

  A single replicate of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.
- Calibration Range: 0 - 40 ng/mL.

  Calibration Frequency
- Once an ARCHITECT Progesterone 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 or
  - Controls are out of range.
- For best results,
  - Establish statistically-based QC ranges to monitor and control the frequency of recalibration, or
  - Establish a 30-day limit of recalibration frequency to optimize the performance of your assay.
- 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 Progesterone assay is that a single replicate of each control level be 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 Progesterone assay belongs to method group 1.

RESULTS

Calculation

The ARCHITECT Progesterone assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted) to generate a calibration curve.

For information on alternate result units, refer to the **INSTRUMENT PROCEDURE, Alternate Result Units** section of this package insert.

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 progesterone results are inconsistent with clinical evidence, additional testing is suggested to confirm the results.
- 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 such as ARCHITECT Progesterone that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.[32, 33]
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. 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.[34]

EXPECTED VALUES

The expected ranges for the ARCHITECT Progesterone assay were obtained by testing specimens drawn from 63 males, 36 postmenopausal females, 20 normal menstruating females, and from 100 females in the first, second, or third trimester of pregnancy. For this study, specimens from normal menstruating females were categorized as follicular phase and luteal phase. Follicular phase was defined as the period of time from 10 days to 5 days prior to the day in which LH and FSH were most elevated. The luteal phase was defined as the period of time from 4 days to 10 days after the day on which LH and FSH were most elevated.

The results are presented below.

Population	n	Progesterone Value (ng/mL) Median	Range
Normal Menstruating Females:			
Follicular Phase	91	0.1	< 0.1 - 0.3
Luteal Phase	60	8.5	1.2 - 15.9*
Postmenopausal Females:	36	0.1	< 0.1 - 0.2
Pregnant Females:			
First Trimester	35	20.9	2.8 - 147.3
Second Trimester	27	45.4	22.5 - 95.3
Third Trimester	38	87.4	27.9 - 242.5
Males:	63	< 0.1	< 0.1 - 0.2

* Luteal phase represents the central 95% interval of all values.

It is recommended that each laboratory establish its own expected ranges.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT Progesterone assay is designed to have a precision of ≤ 10% total CV for concentrations in the range of the ARCHITECT Progesterone Low Control and ≤ 7% total CV for concentrations in the ranges of the ARCHITECT Progesterone Medium and High Controls.

Precision was determined as described in the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Protocol EP5-T2.[35] A three member buffered protein based panel was assayed, using two lots of reagents, in replicates of two at two separate times per day for 20 days on two instruments. Data from this study are summarized below.*

Panel Member	Reagent Lot	Instrument	n	Mean Conc. Value (ng/mL)	Within Run SD	Within Run %CV	Total SD	Total %CV
1	1	1	80	0.8	0.046	5.5	0.052	6.2
1	1	2	80	0.8	0.045	5.4	0.048	5.8
1	2	1	80	0.8	0.027	3.4	0.038	4.7
1	2	2	80	0.8	0.037	4.7	0.044	5.6
2	1	1	80	4.8	0.073	1.5	0.101	2.1
2	1	2	80	4.7	0.111	2.4	0.135	2.9
2	2	1	80	4.7	0.097	2.1	0.111	2.4
2	2	2	80	4.5	0.082	1.8	0.129	2.8
3	1	1	80	21.2	0.340	1.6	0.445	2.1
3	1	2	80	21.1	0.459	2.2	0.542	2.6
3	2	1	80	21.0	0.400	1.9	0.529	2.5
3	2	2	80	20.4	0.374	1.8	0.805	3.9

* Representative data; results in individual laboratories may vary from these data.

Recovery

The ARCHITECT Progesterone assay is designed to have a mean recovery of 90% to 110%, inclusive.

Known concentrations of progesterone were added to five aliquots of human serum. The concentration of progesterone was determined using the ARCHITECT Progesterone assay. The percent recovery of the ARCHITECT Progesterone assay ranged from 90.0% to 107.0% with a mean of 96.4%.

Analytical Sensitivity

The ARCHITECT Progesterone assay is designed to have an analytical sensitivity of ≤ 0.1 ng/mL.

The analytical sensitivity of the ARCHITECT Progesterone assay was calculated to be better than 0.1 ng/mL (n = 36 runs). Analytical sensitivity is defined as the concentration at two standard deviations from the mean RLU value of the ARCHITECT Progesterone MasterCheck Level 0 (0.0 ng/mL), and represents the lowest measurable concentration of progesterone that can be distinguished from zero.

Specificity

The specificity of the ARCHITECT Progesterone assay was determined by studying the cross reactivity of the compounds listed below. Human serum specimens containing essentially no residual progesterone were supplemented with potential cross reactants at the concentrations listed and tested for progesterone. Cross reactivity is stated below.

Cross Reactant	Cross Reactant Concentration (ng/mL)	% Cross Reactivity
Corticosterone	1000	4.6
Danazol	1000	0.1
11-Deoxycorticosterone	1000	1.8
20 α-hydroxyprogesterone	1000	0.2
20 β-hydroxyprogesterone	1000	0.3
17-Hydroxyprogesterone	1000	2.9
Medroxyprogesterone	1000	0.1
19-Nor-4-androsten-3, 17-dione	1000	0.1
Norethindrone	1000	0.1
19-Nortestosterone	1000	0.1
5 α-Pregnan-3, 20-dione	1000	3.3
5 α-Pregnan-3 α-ol-20-one	1000	0.9
5 α-Pregnan-3 β-ol-20-one	1000	0.3
5 Pregnan-3-ol-20-one	1000	3.9
Pregnanolone	1000	1.3
Pregnenolone	1000	0.1
Testosterone	1000	0.2

Cross reactivity of the following compounds was undetectable.

Cross Reactant	Cross Reactant Concentration (ng/mL)
Aldosterone	1000
Allopregnanediol	1000
Androstenediol	1000
Androstenedione	1000
Clomiphene Citrate	1000
Cortisol	1000
11-Deoxycortisol	1000
Desogestrel	1000
DHEA	1000
DHEA-S	100000
Dihydrotestosterone	1000
Estradiol (17β)	1000
Estriol	1000
Estrone	1000
Ethisterone	1000
Ethynyl-Estradiol	1000
Ethynodiol diacetate	1000
17-Hydroxypregnenolone	1000
Medroxyprogesterone Acetate	1000
Methylprednisolone	1000
Norethindrone Acetate	1000
Norgestrel	1000
Normethandrone	1000
5 β-Pregnane	1000
5 β-Pregnan-3 α, 20 α-diol	1000
Pregnenolone 3 Sulfate	1000
Spironolactone	1000

Interference

Potential interference from hemoglobin, bilirubin, triglycerides, and protein was studied in the ARCHITECT Progesterone assay. The ARCHITECT Progesterone assay demonstrated the interference stated below.

Hemoglobin	< 10% at 500 mg/dL
Bilirubin	< 10% at 20 mg/dL
Triglycerides	< 10% at 1000 mg/dL
Protein	< 10% at 4 g/dL and 12 g/dL

Accuracy by Correlation

The ARCHITECT Progesterone assay is designed to have a slope of 0.8 to 1.2, inclusive, and a correlation coefficient of ≥ 0.95 when compared to a commercially available assay.

The ARCHITECT Progesterone assay was compared to a commercially available diagnostic kit. The results of the specimen testing are shown below.‡

Abbott ARCHITECT Progesterone vs. commercially available diagnostic kit

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares Linear Regression	199	-0.4	0.81	0.990
Passing-Bablok Linear Regression*	199	-0.4	0.83	0.990

‡ Representative data: variables such as differences in sampling size and sample population may impact the correlation of the assay; therefore, results in individual laboratories may vary from these data.

In this evaluation, serum samples tested ranged from 0.1 ng/mL to 36.0 ng/mL with the ARCHITECT Progesterone assay.

* A linear regression method with no special assumptions regarding the distribution of the samples and the measurement errors.[36]

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Key to Symbols

	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
ASSAY DILUENT	Assay Diluent
CONJUGATE	Conjugate
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL NO.	Control Number
DISTRIBUTED IN THE USA BY	Distributed in the USA by
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MANUAL DILUENT	Manual Diluent
MICROPARTICLES	Microparticles
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCT OF IRELAND	Product of Ireland
REACTION VESSELS	Reaction Vessels
REAGENT LOT	Reagent Lot
REF	List Number
REPLACEMENT CAPS	Replacement Caps
SAMPLE CUPS	Sample Cups
SEPTUM	Septum
SN	Serial number
TRIGGER SOLUTION	Trigger Solution
WARNING: SENSITIZER	Warning: May cause an allergic reaction.
WASH BUFFER	Wash Buffer

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