



Testosterone

REF 7K73

B7K730

56-4969/R1



TESTOSTERONE

NOTE: This package insert must be read carefully prior to 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.

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March 2006

Key to symbols used			
REF	List Number	LOT	Lot Number
IVD	For <i>In Vitro</i> Diagnostic Use		Expiration Date
	Store at 2-8°C	REAGENT LOT	Reagent Lot
	Consult instructions for use	REACTION VESSELS	Reaction Vessels
Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland + 353-43-31000	Legal Manufacturer	SAMPLE CUPS	Sample Cups
		SEPTUM	Septum
		REPLACEMENT CAPS	Replacement Caps
		SN	Serial Number

Abbott Ireland
Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland
+ 353-43-31000

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

NAME

ARCHITECT® Testosterone

INTENDED USE

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

SUMMARY AND EXPLANATION OF TEST

Testosterone is a male sex hormone, secreted by Leydig or interstitial cells of the testes, regulated and controlled through negative feedback on the hypothalamus and pituitary gland by the pituitary hormone, luteinizing hormone (LH). Serum concentrations of testosterone will go through a sequence of rise and fall through the fetal stage until 6 months after delivery due to maternal hormonal changes. From 6 months through puberty, testosterone concentration remains at about 1 nmol/L (0.3 ng/mL). The increase of testosterone levels in males is gradual post puberty until it reaches the adult level. In females, testosterone is mainly produced by peripheral conversion of prehormones.

Typical Physiological Testosterone Levels.¹

	Male (ng/mL)	Female (ng/mL)
Prepubertal	0.01 - 1.77	0.01 - 0.20
Pubertal	0.02 - 8.00	0.02 - 0.40
Adult	2.80 - 11.00	0.15 - 0.70

Testosterone is highly protein-bound. In males, 98% of the testosterone in circulation is bound; the value is slightly lower in females. The majority of the steroid is bound to a specific binding protein, sometimes referred to as Sex Hormone Binding Globulin (SHBG) or Testosterone Binding Globulin (TeBG), and serum albumin.²

Testosterone monitoring is used clinically to diagnose and differentiate endocrine disorders. In males, these include hypogonadism, testicular failure, infertility, hypopituitarism and hyperprolactinemia. In females, polycystic ovary syndrome, adrenal hyperplasia, infertility, hirsutism, amenorrhea, obesity and virilization can cause changes in serum testosterone levels.

The ARCHITECT Testosterone assay is to be used as an aid in the investigation of infertility in males and hirsutism and virilization in females.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

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

Sample, anti-testosterone (mouse, monoclonal) coated paramagnetic microparticles, testosterone acridinium-labeled conjugate and assay diluent are combined to create the reaction mixture. Testosterone present in the sample competes with the testosterone acridinium-labeled conjugate for binding with anti-testosterone (mouse, monoclonal) coated microparticles to form an antigen-antibody complex. After washing, Pre-Trigger and Trigger Solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). An inverse relationship exists between the amount of testosterone 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

NOTE: Some kit sizes are not available in all countries; please contact your local distributor.

ARCHITECT Testosterone Reagent Kit (7K73)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL) Anti-Testosterone (mouse, monoclonal) coated Microparticles in BIS-TRIS buffer with protein (bovine) stabilizers. Preservative: antimicrobial agent.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL) Testosterone acridinium-labeled Conjugate in citrate buffer with surfactant stabilizer. Minimum concentration: 0.1 nM. Preservative: antimicrobial agent.
- **ASSAY DILUENT** 1 or 4 Bottle(s) (5.9 mL) Testosterone Assay Diluent containing surfactant in citrate buffer. Preservative: antimicrobial agent.

Manual Diluent

ARCHITECT Testosterone Manual Diluent (7K73-50)

- **MANUAL DILUENT** 1 Bottle (1 mL) of ARCHITECT Testosterone Manual Diluent containing processed bovine serum. 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 0.35N sodium hydroxide.

ARCHITECT *i* Wash Buffer

NOTE: Bottle and volume varies based on order.

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservative: antimicrobial agent.

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

- ARCHITECT *i* Trigger Solution contains sodium hydroxide (NaOH) and is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.




R41	Risk of serious damage to eyes.
S25	Avoid contact with eyes.
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S35	This material and its container must be disposed of in a safe way.
S36/39	Wear suitable protective clothing and eye/face protection.
S46	If swallowed, seek medical advice immediately and show this container or label.

- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- 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 Testosterone 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.
- Prior to placing the septum on an uncapped reagent bottle, squeeze the septum in half to confirm that the slits are open. If the slits appear sealed, continue to gently squeeze the septum to open the slits.
- 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

- 
- 2°C The ARCHITECT Testosterone 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 Testosterone 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 or assay diluent 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 Testosterone 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 refer to the ARCHITECT System Operations Manual, Section 2.

ASSAY PARAMETERS

The default values for the assay parameters used in the ARCHITECT Testosterone assay are contained in the categories listed below. Assay parameters that can be edited contain a (>). In order to obtain values for the parameters with an asterisk (*), review the category-specific Details for assay parameters dialog windows. For detailed information on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

General Parameters

Name: > Testost
Assay type: One Step 25
Assay number: 231

Pretreatment option: None
Assay version: *
Assay availability: > *
Cal version: *
Assay status: > *

Dilution Parameters

Manual dilution: Yes
Default dilution: > Undiluted
Dilution range (Low): 0.08
Dilution range (High): 15.0

Result Units

Result concentration units: > ng/mL
Result decimal places: > 2

Calibration Parameters

Mode: Adjust
Data reduction method: 4PLC Y
Adjustment method: Parameter Adjustment
Replicates: > 2
Cal A: 0.0
Cal B: 0.2
Cal C: 1.0
Cal D: 2.5
Cal E: 7.0
Cal F: 15.0
Cal 1: 1.0
Cal 2: 15.0

Results Parameters

Normal range: > *
Extreme range: > *

- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.
- The default result unit for the ARCHITECT Testosterone assay is ng/mL. Alternate result units, nmol/L or ng/dL, may be selected for reporting results by editing assay parameter "Result concentration units" to nmol/L or ng/dL. The conversion factor used by the system is 3.47 for nmol/L and 100 for ng/dL.

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 anticoagulant tubes may be used in the ARCHITECT Testosterone assay. Other anticoagulants have not been validated for use with the ARCHITECT Testosterone assay. Follow the 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 Testosterone 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 6 months showed no performance difference.
- 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.
- ARCHITECT Testosterone Calibrators and Controls should be thawed and mixed by gentle inversion prior to use.

PROCEDURE

Materials Provided:

- 7K73 ARCHITECT Testosterone Reagent Kit

Materials Required but not Provided:

- ARCHITECT *i* System
- ARCHITECT *i* Assay CD-ROM
- 7K73-01 ARCHITECT Testosterone Calibrators
- 7K73-10 ARCHITECT Testosterone Controls
- 7K73-50 ARCHITECT Testosterone 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 Testosterone 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. Squeeze the septum to confirm that the slits are open. 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 Testosterone 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: 150 µL for the first Testosterone test plus 100 µL for each additional Testosterone test from the same sample cup
 - ≤ 3 hours onboard: 150 µL for the first Testosterone test plus 100 µL for each additional Testosterone 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.
- To obtain the recommended volume requirements for the ARCHITECT Testosterone Calibrators and Controls, hold the bottles **vertically** and dispense 8 drops of each calibrator or 4 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 assay-specific diluent, conjugate and microparticles into the RV
 - Mixes, incubates and washes the reaction mixture
 - Adds Pre-Trigger and Trigger Solutions
 - Measures chemiluminescent emission to determine the quantity of testosterone 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 which read >15.0 ng/mL may be diluted with the ARCHITECT Testosterone Manual Diluent (7K73-50).

- Manual dilutions should be performed as follows:
 - The suggested dilution for Testosterone is 1:4.
 - For a 1:4 dilution, add 100 µL of the patient specimen to 300 µL of ARCHITECT Testosterone Manual Diluent.
 - 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. The dilution should be performed so that the reported result reads greater than 3.0 ng/mL.
 - If the operator does not enter the dilution factor, the reported result will be that of the diluted sample. This result should be greater than 0.75 ng/mL.

- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- To perform an ARCHITECT Testosterone calibration, test Calibrators 1 and 2 in duplicate. A single sample of all levels of testosterone controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the package insert. Calibrators should be priority loaded.
- Calibrator range: 0.0 - 15.0 ng/mL.
- Once an ARCHITECT Testosterone 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 Testosterone 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 package insert.

Verification of Assay Claims

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

RESULTS

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

Alternate Result Units

- The default unit for the ARCHITECT Testosterone assay is ng/mL.
- Alternate result units available are as follows:
 - When the alternate result unit, nmol/L, is selected, the conversion factor used by the system is 3.47.
Conversion formula:
(Concentration in ng/mL) x (3.47) = nmol/L
 - When the alternate result unit, ng/dL*, is selected, the conversion factor used by the system is 100.
Conversion formula:
(Concentration in ng/mL) x (100) = ng/dL

* i Assay CD-ROM version 6.0 and higher will be required to install this alternate result unit (ng/dL).

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 testosterone 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.^{3,4} Additional information may be required for diagnosis.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.⁵ Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.

EXPECTED VALUES

The expected ranges for the ARCHITECT Testosterone assay were obtained by testing specimens drawn from 77 premenopausal females, 20 postmenopausal females, and 82 males. For this study, specimens from premenopausal females were categorized as ovulating, and using oral contraceptives. Male specimens were categorized as less than 50 years old, and 50 years and older. The results are presented in the following table.

Population	n	Testosterone Value (ng/mL)			Maximum
		Minimum	2.5 Percentile	97.5 Percentile	
Females	97	0.09	0.13	1.08	1.30
Premenopausal	77	0.09			1.09
Ovulating	52	0.09			1.09
Using Oral Contraceptives	25	0.13			0.83
Postmenopausal	20	0.12			1.30
Males	82	1.56	1.66	8.11	8.77
<50 years old	70	1.66			8.77
50 years and older	12	1.56			5.63

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

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

Precision was determined as described in the National Committee for Clinical Laboratory Standards (NCCLS) Protocol EP5-T2.⁶ A three member processed bovine serum based panel was assayed, using a single lot of reagents, in replicates of two at two separate times per day for 20 days. Data from this study is summarized in the following table.

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	0.83	0.033	4.0	0.055	6.6
1	1	2	80	0.82	0.037	4.5	0.065	8.0
2	1	1	80	5.04	0.094	1.9	0.184	3.7
2	1	2	80	4.87	0.118	2.4	0.209	4.3
3	1	1	80	10.11	0.201	2.0	0.317	3.1
3	1	2	80	9.93	0.212	2.1	0.360	3.6

Recovery

Known concentrations of testosterone were added to four normal human serum samples. The concentration of testosterone was determined using the ARCHITECT Testosterone assay and the resulting percent recovery was calculated.

Sample	Endogenous Testosterone Concentration (ng/mL)	Testosterone Added (ng/mL)	Observed Testosterone Concentration (ng/mL)	% Recovery*
1	6.04	1.51	7.61	104
		3.22	9.21	98
		6.92	12.76	97
2	3.94	1.51	5.37	95
		3.22	7.20	101
		6.92	10.78	99
3	2.43	1.51	4.11	111
		3.22	5.78	104
		6.92	9.42	101
4	0.54	1.51	2.05	100
		3.22	3.76	100
		6.92	7.66	103

Average Recovery: 101%

$$*\% \text{ Recovery} = \frac{\text{Observed Testosterone Conc. (ng/mL)} - \text{Endogenous Testosterone Conc. (ng/mL)}}{\text{Testosterone Added (ng/mL)}} \times 100$$

Sensitivity

Functional

The functional sensitivity of the ARCHITECT Testosterone assay was calculated to be 0.14 ng/mL (95% confidence interval of 0.11 to 0.17 ng/mL).

Functional sensitivity is defined as the concentration of testosterone that can be measured with a CV of 20%. This was determined by testing processed human serum samples ranging up to 6.03 ng/mL. Each sample was tested one time per day for 10 days on each of two ARCHITECT *i* Systems using two reagent lots. The %CV was calculated and plotted against the mean concentration. The functional sensitivity value represents the concentration interpolated from the fitted curve at the 20% CV level.

Analytical

The analytical sensitivity of the ARCHITECT Testosterone assay is better than 0.08 ng/mL (n=24 runs in replicates of 10). Analytical sensitivity is defined as the concentration at two standard deviations from the ARCHITECT Testosterone MasterCheck™ Level 0 (0.0 ng/mL), and represents the lowest measurable concentration of testosterone that can be distinguished from zero.

Specificity

The specificity of the ARCHITECT Testosterone assay was determined by studying cross reactivity of the structurally similar compounds below. Aliquots of processed human serum were supplemented to the concentrations indicated with the potential cross reactants and assayed for testosterone. The percent cross reactivity of the compounds is listed in the following table for the ARCHITECT Testosterone assay.

Cross Reactant	Cross Reactant Added (ng/mL)	% Cross Reactivity
Aldosterone	8000	0.01
Androstenedione	1000	0.10
5 α -Androstane-3 β ,17 β -diol	1000	0.15
Androstendiol	100	0.02
Androstenedione	1000	1.41
	100	1.04
Androsterone	1000	0.03
Corticosterone	1000	0.01
Desoxycorticosterone (DOC)	1000	0.02
Dihydroandrosterone	1000	0.19
5 α -Dihydrotestosterone (DHT)	100	2.11
Epiandrosterone	1000	0.01
Epitestosterone	1000	0.15

Cross Reactant	Cross Reactant Added (ng/mL)	% Cross Reactivity
4-Estren-17 α -ol-3-one	100	0.01
Estrone	1000	0.01
Ethisterone	50	0.06
Etiocholan-3,17-dione	1000	0.01
Etiocholan-3 α ,17 β -diol	2000	0.09
Etiocholan-3 β ,17 β -diol	1000	0.07
11 β -Hydroxyandrostenedione	1000	0.04
19-Hydroxyandrostenedione	1000	0.08
17-Hydroxyprogesterone	1000	0.01
6 β -Hydroxytestosterone	100	8.26
	10	7.20
11 β -Hydroxytestosterone	100	14.10
	10	13.60
19-Hydroxytestosterone	100	2.14
	10	2.20
11-Ketotestosterone	10	22.30
Methyltestosterone	100	0.07
19-Nortestosterone	50	3.18
Progesterone	1000	0.02
Spirolactone	1000	0.01

The following compounds showed no (0.00%) cross reactivity.

Cross Reactant	Cross Reactant Concentration (ng/mL)
Amitriptyline HCl	1000
Clomiphene citrate	1000
Cortisol	1000
Cortisone	1000
Cyproterone acetate	1000
Danazol	1000
Dehydroepiandrosterone (DHEA)	100000
Dehydroepiandrosterone sulfate	1000
11-Deoxycortisol	1000
Desogestrel	100
Dexamethasone	1000
17 α -Estradiol	1000
17 β -Estradiol (Estradiol)	1000
Estriol	1000
Ethinylestradiol	1000
Ethinodiol diacetate	50
Flunisolide	1000
Fluoxymesterone	1000
17-Hydroxypregnenolone	1000
Lynestrenol	1000
Medroxyprogesterone acetate	1000
Mestranol	1000
Norethindrone	50
Norethindrone acetate	50
Norethynodrel	50
Norgestimate	1000
Norgestrel (Levonorgestrel)	50
Oxymetholone	100
	10
Prednisone	800
Salbutamol	1000
Stanozolol	1000
Testosterone enanthate	100
	10
Triamcinolone	50

Interference

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

- Hemoglobin - <10% at 150 mg/dL
- Bilirubin - <10% at 20 mg/dL
- Triglycerides - <10% at 2000 mg/dL
- SHBG - <10% at 96 nM

Accuracy by Correlation

The ARCHITECT Testosterone assay was compared to a commercially available diagnostic kit and to gas chromatography/mass spectrometry (GC/MS). The results of the specimen testing are shown in the following table.

Abbott ARCHITECT Testosterone vs.
Chiron Diagnostics ACS:180® Testosterone

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares Linear Regression	607	-0.02	0.89	0.986
Passing-Bablok Linear Regression*	607	-0.03	0.89	0.986

In this evaluation, serum specimens tested ranged from 0.09 to 12.02 ng/mL with the ARCHITECT Testosterone assay and from 0.13 to 13.24 ng/mL with the ACS:180® Testosterone assay.

Abbott ARCHITECT Testosterone vs. GC/MS

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares Linear Regression	102	0.02	0.97	0.996
Passing-Bablok Linear Regression*	102	0.12	0.95	0.996

In this evaluation, serum specimens tested ranged from 0.15 to 13.48 ng/mL with the ARCHITECT Testosterone assay and from 0.10 to 13.36 ng/mL with GC/MS.

* A linear regression method with no special assumptions regarding the distribution of the samples and the measurement errors.⁷

BIBLIOGRAPHY

1. Burtis CA and Ashwood ER, Ed. Tietz Textbook of Clinical Chemistry, 2nd Edition, W.B. Saunders Company (1994): 1850-51.
2. Dunn JF, Nisula BC and Rodbard D. *J of Clinical Endocrinology and Metabolism*, 1981;53:58-68.
3. Primus FJ, Kelley EA, Hansen HJ, Goldenberg DM. "Sandwich"-Type Immunoassay of Carcinoembryonic Antigen in Patients Receiving Murine Monoclonal Antibodies for Diagnosis and Therapy. *Clin Chem* 1988;34:261-4.
4. Schroff RW, Foon KA, Beatty SM, Oldham RK, Morgan AC Jr. *Human Anti-Murine Immunoglobulin Responses in Patients Receiving Monoclonal Antibody Therapy*. *Cancer Res* 1985;45:879-85.
5. Boscato LM and Stuart MC. *Heterophilic Antibodies: A Problem for All Immunoassays*. *Clin Chem* 1988; 34:27-33.
6. National Committee for Clinical Laboratory Standards, Evaluation of Precision Performance of Clinical Chemistry Devices - Second Edition; Tentative Guideline. NCCLS Document EP5-T2. Villanova, PA: NCCLS, March 1992.
7. Passing H, Bablok W. A New Biometrical Procedure for Testing the Equality of Measurements from Two Different Analytical Methods. *J Clin Chem. Clin Biochem*. 1983;21:709-20.

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