ARCHITECT

SYSTEM

en

FSH

REF 7K75

48-6281/R7

B7K750

Read Highlighted Changes
Revised November, 2009

FSH

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	CAL 1	Calibrator (1, 2)
IVD	*In Vitro* Diagnostic Medical Device	CONTROL L	Control Low, Medium, High (L, M, H)
LOT	Lot Number	ASSAY CD-ROM	Assay CD-ROM
	Expiration Date	SAMPLE CUPS	Sample Cups
2°C 8°C	Store at 2-8°C	SEPTUM	Septum
		REPLACEMENT CAPS	Replacement Caps
	Consult instructions for use	REACTION VESSELS	Reaction Vessels
		REAGENT LOT	Reagent Lot
	Manufacturer	SN	Serial Number

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

Abbott

NAME

ARCHITECT FSH

INTENDED USE

The ARCHITECT FSH assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of follicle stimulating hormone (FSH) in human serum and plasma.

SUMMARY AND EXPLANATION OF TEST

Human Follicle Stimulating Hormone (FSH, follitropin) is a glycoprotein of approximately 30,000 daltons which, like luteinizing hormone (LH, lutropin), human chorionic gonadotropin (hCG) and thyroid stimulating hormone (TSH, thyrotropin), consists of two noncovalently associated subunits designated α and β.[1] The α subunit of FSH contains 92 amino acids and is very similar to the α subunits of LH, hCG, and TSH.[1] The β subunit of FSH is unique and confers its immunological and functional specificity.[1]

FSH and LH control growth and reproductive activities of the gonadal tissues.[2,3] FSH promotes follicular development in the ovary and gametogenesis in the testis.[3,4] The gonadotroph cells of the anterior pituitary secrete both FSH and LH in response to gonadotropin releasing hormone (LHRH or GnRH) from the medial basal hypothalamus.[5] Both FSH and LH are secreted in a pulsatile manner, with rapid fluctuations over the normal range.[3,6,7] The pulsatility of FSH is less pronounced than that of LH. Release of both FSH and LH from the pituitary is under negative feedback control by the gonads.[5]

FSH in mature females acts to stimulate development of the ovarian follicles. Circulating FSH levels vary throughout the menstrual cycle in response to estradiol and progesterone. A small, but significant increase in circulating FSH accompanies the mid-cycle LH surge. However, the physiological significance of this increase is unknown. Circulating levels of FSH decline in the luteal phase in response to estradiol and progesterone production by the developing corpus luteum.[2,5]

At menopause, ovarian function is diminished with concomitant decrease in estradiol secretion. FSH and LH then increase significantly in response to diminished feedback inhibition of gonadotropin release.[8,9] In males, FSH, LH, and testosterone regulate spermatogenesis by the Sertoli cells in the seminiferous tubules of the testes. FSH is less sensitive to feedback inhibition by testosterone than is LH and is thought to be regulated independently by the inhibitory peptide inhibin produced by the Sertoli cells.[10,11]

Because of the negative feedback mechanisms regulating gonadotropin release, elevated concentrations of LH and FSH are indicative of gonadal failure when accompanied by low concentrations of the gonadal steroids. In males, these observations suggest primary testicular failure or anorchia.[4] FSH may also be elevated in Klinefelter's syndrome (seminiferous tubule dysgenesis) or as a consequence of Sertoli cell failure.[4] In females, situations in which FSH is elevated and gonadal steroids are depressed include menopause, premature ovarian failure, and ovariectomy, while with polycystic ovarian syndrome the LH/FSH ratio may be increased.[7]

Abnormal FSH concentrations may also indicate dysfunction of the hypothalamic-pituitary axis. In sexually mature adults, FSH deficiency, together with low concentrations of LH and sex steroids, may indicate panhypopituitarism.[7] This can result either from a decrease in the release of GnRH or from a lack of response of the pituitary to GnRH. Determination of serum FSH, following administration of GnRH, may allow differentiation of these two conditions.[5,7] The use of oral contraceptives usually results in reduction of gonadotropin levels due to negative feedback by these steroids.[5]

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

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

In the first step, sample and anti-β FSH coated paramagnetic microparticles are combined. FSH present in the sample binds to the anti-β FSH coated microparticles. After washing, anti-α FSH 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 FSH 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.

NOTE: Reagent Kit Configurations vary based on order.

ARCHITECT FSH Reagent Kit (7K75)

- **MICROPARTICLES** 1 or 4 Bottle(s) (6.6 mL/27.0 mL) anti-β FSH (mouse, monoclonal) coated Microparticles in MES buffer with protein (murine and caprine) stabilizers. Preservative: antimicrobial agents.
- **CONJUGATE** 1 or 4 Bottle(s) (5.9 mL/26.3 mL) anti-α FSH (mouse, monoclonal) acridinium-labeled Conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 45 ng/mL. Preservative: antimicrobial agents.

Assay 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 2[13] or other appropriate biosafety practices[14,15] should be used for materials that contain or are suspected of containing infectious agents.
- This product contains sodium azide (the microparticles). Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- For information on the safe disposal of sodium azide and 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 FSH 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.
- **Septa MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septa 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

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The ARCHITECT FSH 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 FSH 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 septa 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 refrigerated storage off the system, the reagent kit must be discarded.** After reagents are removed from the system, initiate a reagent 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 FSH assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM prior to performing the assay. For detailed information 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 FSH assay is mIU/mL. An alternate result unit, IU/L, may be selected for reporting results by editing assay parameter "Result concentration units", to IU/L. The conversion factor used by the system is 1.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Human serum (including serum collected in serum separator tubes) or plasma collected in lithium heparin, sodium heparin, or potassium EDTA may be used in the ARCHITECT FSH assay. Other anticoagulants have not been validated for use with the ARCHITECT FSH assay. Follow the tube 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 FSH 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 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 may be shipped under thermally controlled refrigerated conditions or 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

- 7K75 ARCHITECT FSH Reagent Kit

Materials Required but not Provided

- ARCHITECT *i* System
- ARCHITECT *i* **ASSAY CD-ROM**
- 7K75-01 ARCHITECT FSH Calibrators
- 7K75-10 ARCHITECT FSH 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 FSH 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 FSH Reagent Kit on the ARCHITECT *i* System. Verify that all necessary assay reagents are present. Ensure that septa 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: 75 µL for the first FSH test plus 25 µL for each additional FSH test from the same sample cup
  - ≤ 3 hours onboard: 150 µL for the first FSH test plus 25 µL for each additional FSH 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 FSH Calibrators and ARCHITECT FSH Controls should be mixed by gentle inversion prior to use.
- To obtain the recommended volume requirements for the ARCHITECT FSH 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 FSH 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 an FSH value exceeding 150.00 mIU/mL are flagged with the code " >150.00" and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

- If using the Automated Dilution Protocol, the system performs a 1:5 dilution of the specimen and automatically calculates the concentration of the undiluted specimen and reports the result.
- Manual dilutions should be performed as follows:
  - The suggested dilution for FSH is 1:5. It is recommended dilutions not exceed 1:5.
  - For a 1:5 dilution, add 20 µL of the patient specimen to 80 µL of ARCHITECT *i* 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. The result (before dilution factor is applied) should be greater than 0.25 mIU/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 0.25 mIU/mL.
- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- To perform an ARCHITECT FSH calibration, test Calibrators 1 and 2 in duplicate. A single sample of all levels of FSH 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.
- Calibration Range: 0.00 - 150.00 mIU/mL.
- Once an ARCHITECT FSH 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 FSH 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 FSH assay belongs to method group 1.

RESULTS

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

Alternate Result Units

- The default result unit for the ARCHITECT FSH assay is mIU/mL. When the alternate result unit, IU/L, is selected, the conversion factor used by the system is 1.
- Conversion Formula: (Concentration in mIU/mL) x (1) = IU/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 FSH 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.

EXPECTED VALUES

The suggested normal range for the ARCHITECT FSH assay represents the FSH values obtained from 150 normal males, 34 post-menopausal females (not on hormone replacement therapy) and 44 normal cycling females. For this study, the follicular phase was defined as the period of time from 10 to 4 days prior to the mid-cycle peak. The luteal phase was defined as the period of time from 4 to 10 days following the mid-cycle peak. Cycle days were synchronized to the mid-cycle peak (the day when LH values are most elevated). The results are presented in the following table. (NOTE: 44 women participated in the study for serial blood draws. At the time of testing for ARCHITECT FSH, only 42 of the mid-cycle samples were available for testing. Samples from all 44 women were included in the Follicular and Luteal Phase expected values testing.)

		FSH Value (mIU/mL)	
	n	Mean	Range (central 95%)
Males	150	3.37	0.95 - 11.95
Normally Menstruating Females			
Follicular Phase	144	4.95	3.03 - 8.08
Mid-Cycle Peak	42	9.62	2.55 - 16.69
Luteal Phase	138	2.75	1.38 - 5.47
Post-menopausal Females	34	59.71	26.72 - 133.41

It is recommended that each laboratory establish its own reference range that is appropriate for the laboratory's patient population (i.e., a normal range that reflects the type of specimen and demographic variables such as age and sex, as applicable).

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT FSH Assay is designed to have a total CV of ≤ 10% for concentrations in the range of the Low, Medium and High Controls. Precision was determined as described in Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) Protocol EP5-T2.[19] A three member calf serum based panel was assayed, using two lots of reagents, on two instruments, in replicates of two at two separate times per day for 20 days. Data from this study are summarized in the following table.

Panel Member	Reagent Lot	Instrument	n	Mean Conc. (mIU/mL)	Within Run SD	Within Run %CV	Total SD	Total %CV
1	1	1	80	5.08	0.143	2.8	0.181	3.6
1	1	2	80	5.16	0.171	3.3	0.217	4.2
1	2	1	80	5.55	0.156	2.8	0.204	3.7
1	2	2	80	5.64	0.239	4.2	0.262	4.6
2	1	1	80	25.09	0.686	2.7	0.965	3.8
2	1	2	80	24.95	0.715	2.9	0.895	3.6
2	2	1	80	26.83	0.727	2.7	0.868	3.2
2	2	2	80	26.98	0.767	2.8	1.103	4.1
3	1	1	80	74.72	2.080	2.8	3.027	4.1
3	1	2	80	72.35	1.864	2.6	2.419	3.3
3	2	1	80	78.12	2.554	3.3	3.211	4.1
3	2	2	80	76.54	2.311	3.0	2.582	3.4

Accuracy by Recovery

Accuracy by recovery of this assay was designed to be ± 15% of spike level. Known concentrations of World Health Organization (WHO) 1st International Standard (IS) FSH 92/510 were added to 11 aliquots of human serum at 2 concentration levels (20 mIU/mL and 40 mIU/mL). The concentration of FSH was determined using the ARCHITECT FSH assay. The mean recovery of WHO 1st IS FSH is 96.05%.

Analytical Sensitivity

The analytical sensitivity of the ARCHITECT FSH assay was calculated to be better than 0.05 mIU/mL (n = 36 runs). Analytical sensitivity is defined as the concentration at two standard deviations from the ARCHITECT FSH MasterCheck Level 0 (0.00 mIU/mL), and represents the lowest measurable concentration of FSH that can be distinguished from zero.

Specificity

The specificity of the ARCHITECT FSH assay was determined by studying the cross-reactivity of LH, TSH, and hCG. Aliquots of processed bovine serum were supplemented with 250 mIU/mL LH, 100 µIU/mL TSH, and 200,000 mIU/mL hCG and assayed for FSH. The cross-reactivity was calculated as a percent cross-reactivity and was shown to be 0.002% for LH, 0.043% for TSH and 0.001% for hCG.

Interference

Potential interference from hemoglobin, bilirubin, triglycerides, and protein was studied in the ARCHITECT FSH assay. The ARCHITECT FSH 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 g/dL and 12 g/dL

Correlation

The ARCHITECT FSH assay was compared to the AxSYM FSH assay. The result of the specimen testing is shown in the following table.**

Abbott ARCHITECT FSH vs. Abbott AxSYM FSH

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares Linear Regression	627	-0.09	1.02	0.99
Passing-Bablok Linear Regression*	627	-0.12	1.03	0.99

In this evaluation, serum specimens ranged from 0.46 to 120.45 mIU/mL with the ARCHITECT FSH assay.

* A linear regression method with no special assumptions regarding the distribution of the samples and measurement errors.[20]

** 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.

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Abbott Ireland
Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland
+353-43-3331000

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and
ABBOTT 65205 Wiesbaden, Germany

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