SIEMENS

ADVIA Centaur® XP
ADVIA Centaur® XPT
Immunoassay Systems

FSH

Current revision and date [a]	Rev. 22, 2023-03	
Product Name	ADVIA Centaur® FSH (500 tests)	REF 01360521 (110756)
	ADVIA Centaur FSH (100 tests)	REF 04912924 (110755)
Systems	ADVIA Centaur XP system ADVIA Centaur XPT system	
Materials Required but Not Provided	ADVIA Centaur Calibrator B (6 pack)	REF 00652707
	ADVIA Centaur Calibrator B (2 pack)	REF 00649625
Specimen Types	Serum, EDTA plasma, lithium heparin plasma	
Assay Range	0.3–200 mIU/mL (IU/L)	
Reagent Storage	2–8°C	
Reagent On-System Stability	High Volume Usage: 14 days Low Volume Usage: 28 days	

a A vertical bar in the page margin indicates technical content that differs from the previous version.

Intended Use

For *in vitro* diagnostic use in the quantitative determination of follicle-stimulating hormone (FSH) in serum and plasma (EDTA and lithium heparin) using the ADVIA Centaur® XP and ADVIA Centaur® XPT systems.

Summary and Explanation

Follicle-stimulating hormone (FSH) is a glycoprotein hormone with two subunits. The alpha subunit is similar to those of luteinizing hormone (LH), human chorionic gonadotropin (hCG), and thyroid-stimulating hormone (TSH).

The beta subunit is different from those of the other glycoprotein hormones and confers its biochemical specificity.[1]

FSH is secreted by the anterior pituitary in response to gonadotropin-releasing hormone (GnRH) secreted by the hypothalamus.[2] In both males and females, FSH secretion is regulated by a balance of positive and negative feedback mechanisms involving the hypothalamic-pituitary axis, the reproductive organs, and the pituitary and sex steroid hormones.[3,4] FSH and LH play a critical role in maintaining the normal function of the male and female reproductive systems.

The following table shows the target tissues and actions of FSH in females and males:

Category	Target Tissues	Actions
females	ovarian follicles	stimulates follicle development and production of estradiol and other estrogens during the follicular phase of the menstrual cycle[1]
		acts synergistically with LH to cause ovulation[2]
males	Sertoli cells in the seminiferous tubules of the testes	stimulates spermatogenesis

Abnormal FSH levels with corresponding increased or decreased levels of LH, estrogens, progesterone, and testosterone are associated with a number of pathological conditions.[2] Increased FSH levels are associated with menopause and primary ovarian hypofunction in females and primary hypogonadism in males. Decreased FSH levels are associated with primary ovarian hyperfunction in females and primary hypergonadism in males. Normal or decreased FSH levels are associated with polycystic ovary disease in females.

Principles of the Procedure

The ADVIA Centaur FSH assay is a two-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of two antibodies that have specificity for the intact FSH molecule. The first antibody, in the Lite Reagent, is a polyclonal sheep anti-FSH antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-FSH antibody, which is covalently coupled to paramagnetic particles.

Reagents

Reagent	Description	Storage	Reagent Stability
ADVIA Centaur FSH ReadyPack® primary reagent pack; Lite Reagent	5.0 mL/reagent pack polyclonal sheep anti-FSH antibody (~327.2 ng/mL) labeled with acridinium ester in buffer with sodium azide (0.1%) and preservatives	2–8°C	**Unopened:** Stable until the expiration date on the carton **On-system:** High Volume Usage: 14 days Low Volume Usage: 28 days
ADVIA Centaur FSH ReadyPack primary reagent pack; Solid Phase Reagent	22.5 mL/reagent pack monoclonal mouse anti-FSH antibody (~0.01 mg/mL) covalently coupled to paramagnetic particles in buffer with protein stabilizers, sodium azide (0.1%), and preservatives	2–8°C	**Unopened:** Stable until the expiration date on the carton **On-system:** High Volume Usage: 14 days Low Volume Usage: 28 days
ADVIA Centaur ReadyPack ancillary reagent pack; Multi-Diluent 1[a] M-DIL 1	25.0 mL/reagent pack equine serum with sodium azide (0.1%) and preservatives	2–8°C	**Unopened:** Until the expiration date on the pack **On-system:** 28 consecutive days after accessing the ancillary reagent pack
ADVIA Centaur Multi-Diluent 1[a] M-DIL 1	50 mL/vial equine serum with sodium azide (0.1%) and preservatives	2–8°C	**Unopened:** Until the expiration date on the vial

a See *Optional Materials*

Warnings and Precautions

Safety data sheets (MSDS/SDS) available on siemens-healthineers.com.

CAUTION

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

For Professional Use.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

For *in vitro* diagnostic use.

Preparing Reagents

All reagents are liquid and ready to use.

CAUTION

Mix all primary reagent packs by hand before loading them onto the system. Visually inspect the bottom of the reagent pack to ensure that all particles are dispersed and resuspended. For detailed information about preparing the reagents for use, refer to the system operating instructions.

The ADVIA Centaur FSH assay can be run using either the high- or low-volume usage option. If you use the low-volume usage option, you will need to modify the test definition parameters for the assay. For detailed information about modifying test definitions, refer to the system operating instructions.

- High volume usage = use of more than one primary reagent pack within the On-System Stability period indicated in the table for *High Volume Usage*.
- Low volume usage = use of less than one primary reagent pack within the On-System Stability period indicated in the table for *Low Volume Usage*.

High Volume Usage

CAUTION

Discard the primary reagent packs at the end of the *High Volume Usage* on-system stability interval.
Do not use reagents beyond the expiration date.

Low Volume Usage

Note For low volume usage, load only one primary reagent pack on the system at a time.

CAUTION

Discard the primary reagent pack at the end of the *Low Volume Usage* on-system stability interval. When the Primary Reagent Stability option is set to USE BEYOND, the system does not display a flag when the reagent exceeds the on-system stability.
Do not use reagents beyond the expiration date.

Storing and Stability

Store the reagents upright at 2–8°C.

Protect reagent packs from all heat and light sources. Reagent packs loaded on the system are protected from light. Store unused reagent packs at 2–8°C away from heat and light sources.

All reagents are stable at 2–8°C until the expiration date on the packaging.

Specimen Collection and Handling

Serum and plasma (EDTA and lithium heparin) are the recommended sample types for this assay.

The following recommendations for handling and storing blood samples are furnished by the Clinical and Laboratory Standards Institute (CLSI):[5]

- Collect all blood samples observing universal precautions for venipuncture.
- Allow samples to clot adequately before centrifugation.
- Keep tubes stoppered and upright at all times.
- Do not use samples that have been stored at room temperature for longer than 8 hours.
- Tightly cap and refrigerate specimens at 2–8°C if the assay is not completed within 8 hours.
- Freeze samples at or below -20°C if the sample is not assayed within 48 hours.
- Freeze samples only once and mix thoroughly after thawing.

The purpose of handling and storage information is to provide guidance to users. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
01360521 (110756)	5 ReadyPack primary reagent packs containing ADVIA Centaur FSH Lite Reagent and Solid Phase	500
	ADVIA Centaur FSH Master Curve card	
04912924 (110755)	1 ReadyPack primary reagent pack containing ADVIA Centaur FSH Lite Reagent and Solid Phase	100
	ADVIA Centaur FSH Master Curve card	

Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

Item	Description	
REF 00652707	ADVIA Centaur Calibrator B	6 vials of low calibrator CAL L 6 vials of high calibrator CAL H
REF 00649625	ADVIA Centaur Calibrator B	2 vials of low calibrator CAL L 2 vials of high calibrator CAL H

Optional Materials

The following materials may be used to perform this assay, but are not provided:

Item		Description	
REF	07907174 (110313)	ADVIA Centaur Multi-Diluent 1 M-DIL 1	6 ReadyPack ancillary reagent packs containing 25 mL/pack
REF	07293184 (110312)	ADVIA Centaur Multi-Diluent 1 M-DIL 1	2 ReadyPack ancillary reagent packs containing 25 mL/pack
REF	672177	ADVIA Centaur Multi-Diluent 1 M-DIL 1	50 mL/vial
REF	10996671	ADVIA Centaur FSH Master Curve Material	8 x 1 mL

Assay Procedure

For detailed instructions on performing the procedure, refer to the system operating instructions.

The system automatically performs the following actions:

- Dispenses 100 µL of sample into a cuvette.
- Dispenses 50 µL Lite Reagent and incubates for 5.0 minutes at 37°C.
- Dispenses 225 µL of Solid Phase and incubates for 2.5 minutes at 37°C.
- Separates, aspirates, and washes the cuvettes with reagent water.

  Note For information about reagent water, refer to the system operating instructions.
- Dispenses 300 µL each of Acid Reagent and Base Reagent to initiate the chemiluminescent reaction.
- Reports results according to the selected option, as described in the system operating instructions.

A direct relationship exists between the amount of FSH present in the patient sample and the amount of relative light units (RLUs) detected by the system.

Preparing the System

Ensure that the system has sufficient primary and ancillary reagent packs. For detailed information about preparing the system, refer to the system operating instructions.

Load the ReadyPack reagent packs in the primary reagent area using the arrows as a placement guide. The system automatically mixes the primary reagent packs to maintain homogeneous suspension of the reagents. For detailed information about loading reagents, refer to the system operating instructions.

If automatic dilution of a sample is required, load ADVIA Centaur Multi-Diluent 1 in the ancillary reagent entry.

Preparing the Samples

This assay requires 100 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For detailed information about determining the minimum required volume, refer to the system operating instructions

Before placing samples on the system, ensure that samples have the following characteristics:

- Samples are free of fibrin or other particulate matter.
- Samples are free of bubbles.

On-System Stability

The ADVIA Centaur FSH assay reagents are stable unopened until the expiration date on the carton or onboard the system for 14 days for high volume usage and for 28 days for low volume usage.

Performing Calibration

For calibration of the ADVIA Centaur FSH assay, use the ADVIA Centaur Calibrator B. Perform that calibration as described in the calibrator instructions for use.

Calibration Frequency

Calibrate the assay at the end of the 28-day calibration interval for high volume usage and every 14 days for low volume usage.

Note For low volume usage, perform a calibration every time you load a fresh primary reagent pack.

Additionally, the ADVIA Centaur FSH assay requires a two-point calibration:

- When changing lot numbers of primary reagent packs.
- When replacing system components.
- When quality control results are repeatedly out of range.

Performing Master Curve Calibration

The ADVIA Centaur FSH assay requires a Master Curve calibration when using a new lot number of Lite Reagent and Solid Phase. For each new lot number of Lite Reagent and Solid Phase, use the barcode reader or keyboard to enter the Master Curve values on the system. The Master Curve card contains the Master Curve values. For detailed information about entering Master Curve values, refer to the system operating instructions.

Performing Quality Control

To monitor system performance and chart trends, as a minimum requirement, two levels of quality control material should be assayed on each day that samples are analyzed. Quality control samples should also be assayed when performing a two-point calibration. Treat all quality control samples the same as patient samples.

Siemens Healthcare Diagnostics recommends the use of commercially available quality control materials with at least 2 levels (low and high). For assistance in identifying a quality control material, refer to *ADVIA Centaur Quality Control Material Supplement* available on siemens-healthineers.com.

Additional quality control material can be used at the discretion of the laboratory. Use the quality control material in accordance with the quality control instructions for use.

In addition, perform quality control:

- Following a valid calibration
- With use of a new lot of reagent
- When troubleshooting test results that do not match clinical conditions or symptoms

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Acceptable performance is achieved when the analyte values obtained are within the expected control interval for the system, as indicated by the manufacturer of the control material or within the interval determined by an internal laboratory quality control procedure.

Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the system online help.

Taking Corrective Action

If the quality control results do not fall within the Expected Values or within the laboratory's established values, do not report results. Take the following actions:

- Verify that the materials are not expired.
- Verify that required maintenance was performed.
- Verify that the assay was performed according to the instructions for use.
- Rerun the assay with fresh quality control samples.
- If necessary, contact your local technical support provider or distributor for assistance.

Results

Calculation of Results

For detailed information about how the system calculates results, refer to the system operating instructions.

The system reports FSH results in mIU/mL (common units) or IU/L (SI units), depending on the units defined when setting up the assay. The conversion formula is
1 mIU/mL = 1 IU/L.

Dilutions

The following information pertains to dilutions:

- Samples with FSH levels greater than 200 mIU/mL (IU/L) must be diluted and retested to obtain accurate results.
- Patient samples can be automatically diluted by the system or prepared manually.
- For automatic dilutions, ensure that ADVIA Centaur Multi-Diluent 1 is loaded and set the system parameters as follows:

  Dilution point: ≤ 200 mIU/mL (IU/L)

  Dilution factor: 2

  For detailed information about automatic dilutions, refer to the system operating instructions.
- Manually dilute the patient samples when patient results exceed the linearity of the assay using automatic dilution, or when laboratory protocol requires manual dilution.
- Use Multi-Diluent 1 to manually dilute patient samples, and then load the diluted sample in the sample rack, replacing the undiluted sample.
- Ensure that results are mathematically corrected for dilution. If a dilution factor is entered when scheduling the test, the system automatically calculates the result.

Interpretation of Results

Results of this assay should always be interpreted in conjunction with patient's medical history, clinical presentation and other findings.

Limitations

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.[6] 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 expected results for the ACS:180® FSH assay were previously established. Data was obtained on serum samples from 524 apparently healthy individuals. Based on a central 95% interval, the following reference ranges were established:

Sample Category	N	Median (mIU/mL) (IU/L)	Range (mIU/mL) (IU/L)
Females			
Normally menstruating			
Follicular Phase	95	5.6	2.5–10.2
Midcycle Peak	49	9.0	3.4–33.4
Luteal Phase	99	2.9	1.5–9.1
Pregnant	92	0.0	< 0.3
Postmenopausal	72	64.3	23.0–116.3
Males			
13–70 years	117	4.5	1.4–18.1

These results were confirmed for the ADVIA Centaur FSH assay by analyzing 288 samples in the range of 0.4 to 175.1 mIU/mL (IU/L). Refer to *Accuracy* / *Method Comparison*.

As with all diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.[7]

Performance Characteristics

Analytical Measuring Range

The ADVIA Centaur FSH assay measures follicle-stimulating hormone (FSH) concentrations from 0.3–200 mIU/mL (IU/L).

Detection Capability

The ADVIA Centaur FSH assay measures FSH concentrations up to 200 mIU/mL (IU/L) with a minimum detectable concentration (analytical sensitivity) of 0.3 mIU/mL (IU/L). Analytical sensitivity is defined as the concentration of FSH that corresponds to the RLUs that are two standard deviations greater than the mean RLUs of 9 replicate determinations of the FSH zero standard.

Detection capability was determined in accordance with CLSI Document EP17 A2.[8] The following results were obtained:

Method	Result mIU/mL (IU/L)
Limit of Blank (LoB)	0.23
Limit of Detection (LoD)	0.37
Limit of Quantitation (LoQ)	0.45

Assay results obtained at individual laboratories may vary from the data presented.

The LoB corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have an LoB ≤ 0.30 mIU/mL (IU/L).

The LoD corresponds to the lowest concentration of follicle-stimulating hormone that can be detected with a probability of 95%. The LoD was determined using 750 determinations, with

250 blank and 500 low-level replicates, and an LoB of 0.23 mIU/mL (IU/L). The assay is designed to have an LoD ≤ 0.60 mIU/mL (IU/L).

The LoQ corresponds to the lowest amount of follicle-stimulating hormone in a sample at which the within laboratory CV is ≤ 20%. The LoQ was determined using multiple patient samples in the interval 0.25–4.13 mIU/mL (IU/L). All samples were assayed in 5 replicates in each of 10 runs using 2 reagent lots, over a period of 5 days. The assay is designed to have an LoQ ≤ 1.20 mIU/mL (IU/L).

Specificity

The cross-reactivity of the ADVIA Centaur FSH assay with TSH, LH, hCG, prolactin, and hGH was determined by adding these hormones to serum samples containing FSH. The level of FSH in the samples was then determined.

Cross-reactant	FSH value without cross-reactant (mIU/mL) (IU/L)	FSH value with cross-reactant (mIU/mL) (IU/L)
TSH; 1000 µIU/mL	2.7	3.4
	29.7	30.3
	62.0	63.0
LH; 300 mIU/mL	2.7	2.8
	30.3	29.9
	62.5	64.3
hCG; 200,000 mIU/mL	2.7	4.9
	29.5	31.7
	62.2	65.5
Prolactin; 400 ng/mL	2.8	2.7
	30.2	30.0
	61.9	62.3
hGH; 100 ng/mL	2.7	2.7
	30.5	30.3
	64.5	63.1

Interference testing was determined according to CLSI Document EP7-P.[9]

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[10] Samples were assayed in duplicate in 2 runs per day for 20 days. The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Specimen Type	N [a]	Mean mIU/mL (IU/L)	SD [b] mIU/mL (IU/L)	CV [c] (%)	SD mIU/mL (IU/L)	CV (%)
Serum A	80	1.93	0.12	N/A [d]	0.16	N/A
Serum B	80	50.12	1.43	2.9	2.20	4.4
Serum C	80	178.17	4.76	2.7	8.13	4.6
Plasma, EDTA A	80	6.52	0.32	4.9	0.38	5.9
Plasma, EDTA B	80	24.68	0.59	2.4	0.84	3.4
Plasma, Heparin	80	24.08	0.79	3.3	1.04	4.3
Control 1	80	6.89	0.22	3.2	0.31	4.5
Control 2	80	25.71	0.43	1.7	0.65	2.5
Control 3	80	62.07	1.24	2.0	1.93	3.1

a Number of results.
b Standard deviation.
c Coefficient of variation.
d Not applicable.

Assay results obtained at individual laboratories may vary from the data presented.

The assay was designed to have the following precision.

Concentration Interval	Design Requirements	
mIU/mL (IU/L)	Repeatability (Within-Run)	Within-Laboratory (Total Precision)
≤ 3.00	≤ 0.15 mIU/mL (IU/L) SD	≤ 0.21 mIU/mL (IU/L) SD
3.01–50.00	≤ 5% CV	≤ 7% CV
50.01–200.00	≤ 7% CV	≤ 10% CV

Accuracy / Method Comparison

For 288 samples in the range of 0.4 to 175.1 mIU/mL (IU/L), the relationship between the ADVIA Centaur FSH assay and the ACS:180 FSH assay is described by the equation:

ADVIA Centaur FSH = 1.02 (ACS:180 FSH) + 0.48 mIU/mL

Correlation coefficient (r) = 0.99

Specimen Equivalency

Specimen equivalency was determined with the Deming linear regression model in accordance with CLSI Document EP09-A3.[11] The following results were obtained:

Tube (y) vs. Serum (x)	N [a]	Sample Interval	Slope	Intercept	r [b]
EDTA plasma	80	0.94–180.46 mIU/mL (IU/L)	0.95	-0.81 mIU/mL (IU/L)	1.00
Lithium heparin plasma	79	0.94–180.46 mIU/mL (IU/L)	1.00	0.28 mIU/mL (IU/L)	1.00

a Number of samples tested.
b Correlation coefficient.

The assay is designed to have a slope of 0.90–1.10 for alternate tube types versus serum.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Interference testing was performed in accordance with CLSI Document EP07-A2.[12] The following results were obtained:

Substance	Substance Test Concentration	Analyte Concentration mIU/mL (IU/L)	Bias (%)
EDTA	5.4 mg/mL	23.47	-3
		147.49	-3
Heparin	75 U/mL	18.27	-3
		145.09	2

Assay results obtained at individual laboratories may vary from the data presented.

Hemolysis, Icterus, and Lipemia

Serum specimens that are . . .	Have an insignificant effect on the assay up to . . .
hemolyzed	150 mg/dL of hemoglobin
lipemic	1000 mg/dL of triglycerides
icteric	20 mg/dL of bilirubin

Dilution Recovery

Seven human serum samples in the range of 92.6 to 179.0 mIU/mL (IU/L) of FSH were diluted 1:2, 1:4, 1:8, and 1:16 with Multi-Diluent 1 and assayed for recovery and parallelism. The recoveries ranged from 85.0% to 102.6% with a mean of 91.2%.

Sample	Dilution	Observed (mIU/mL) (IU/L)	Expected (mIU/mL) (IU/L)	Recovery %
1	—	138.0		
	1:2	67.9	69.0	98.4
	1:4	33.4	34.5	96.8
	1:8	15.8	17.2	91.9
	1:16	8.1	8.6	94.2
	Mean			95.3
2	—	172.8		
	1:2	86.4	86.4	100.0
	1:4	41.0	43.2	94.9
	1:8	19.3	21.6	89.4
	1:16	9.5	10.8	88.0
	Mean			93.1
3	—	92.6		
	1:2	43.6	46.3	94.2
	1:4	20.2	23.2	87.1
	1:8	10.4	11.6	89.7
	1:16	4.9	5.8	84.5
	Mean			88.9
4	—	139.6		
	1:2	67.4	69.8	96.6
	1:4	31.5	34.9	90.3
	1:8	15.0	17.5	85.7
	1:16	7.5	8.7	86.2
	Mean			89.7
5	—	179.0		
	1:2	91.8	89.5	102.6
	1:4	41.6	44.8	92.9
	1:8	20.4	22.4	91.1

Sample	Dilution	Observed (mIU/mL) (IU/L)	Expected (mIU/mL) (IU/L)	Recovery %
	1:16	9.7	11.2	86.6
	Mean			93.3
6	—	116.4		
	1:2	56.8	58.2	97.6
	1:4	25.0	29.1	85.9
	1:8	12.7	14.6	87.0
	1:16	6.2	7.3	84.9
	Mean			88.9
7	—	134.1		
	1:2	61.1	67.1	91.1
	1:4	30.8	33.5	91.9
	1:8	14.8	16.8	88.1
	1:16	7.2	8.4	85.7
	Mean			89.2
Mean				**91.2**

Spiking Recovery

Varying amounts of FSH were added to five samples with endogenous FSH levels of 1.1 to 7.5 mIU/mL (IU/L). The recoveries ranged from 90.5% to 116.9% with a mean of 103.7%.

Sample	Amount Added (mIU/mL) (IU/L)	Observed (mIU/mL) (IU/L)	Recovery %
1	—	3.1	
	15	18.5	102.7
	39	38.4	90.5
	63	70.4	106.8
	77	83.5	104.4
	116	126.8	106.6
	Mean		102.2
2	—	1.1	
	15	17.1	106.7
	39	37.1	92.3
	63	70.6	110.3
	77	91.1	116.9
	116	126.1	107.8
	Mean		106.8
3	—	7.5	
	15	24.3	112.0
	39	45.4	97.2
	63	78.5	112.7
	77	95.1	113.8
	116	134.7	109.7
	Mean		109.1
4	—	5.1	
	15	20.5	102.7
	39	42.8	96.7
	63	73.8	109.1
	77	83.6	102.0
	116	111.7	91.9
	Mean		100.5

Sample	Amount Added (mIU/mL) (IU/L)	Observed (mIU/mL) (IU/L)	Recovery %
5	—	2.2	
	15	16.8	97.3
	39	39.9	96.7
	63	64.8	99.4
	77	83.9	106.1
	116	117.9	99.7
	Mean		99.8
Mean			**103.7**

High-Dose Hook Effect

Patient samples with high FSH levels can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with FSH levels as high as 1000 mIU/mL (IU/L) will assay greater than 200 mIU/mL (IU/L).

Standardization

The ADVIA Centaur FSH assay standardization is traceable to World Health Organization (WHO) 2nd International Standard for human FSH (IS 94/632). A comparison over the full assay range gave the following correlation:

ADVIA Centaur FSH = 0.91 (WHO) - 0.18 mIU/mL

r = 0.999

Assigned values for calibrators are traceable to this standardization.

Technical Assistance

For customer support, please contact your local technical support provider or distributor.

siemens-healthineers.com

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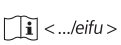
10. Clinical and Laboratory Standards Institute. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition.* Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document EP05-A3.
11. Clinical and Laboratory Standards Institute. *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2013. CLSI Document EP09-A3.
12. Clinical and Laboratory Standards Institute. *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. CLSI Document EP07-A2.

Trademarks

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Manufacturer	5.1.1[a]		Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]		Authorized representative in Switzerland	Proprietary
	Catalog number	5.1.6[a]		Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]		Contains sufficient for <n> tests	5.5.5[a]
	Internet URL address to access the electronic instructions for use	Proprietary		Version of Instructions for Use	Proprietary
	*In vitro* diagnostic medical device	5.5.1[a]		Revision	Proprietary
	Prescription device (US only)	FDA[c]		Unique Device Identifier	5.7.10[b]
	CE Marking with Notified Body	EU IVDR[d]		CE Marking	EU IVDR[d]
	Temperature limit	5.3.7[a]		Keep away from sunlight	5.3.2[a]
	Upper limit of temperature	5.3.6[a]		Lower limit of temperature	5.3.5[a]
	Do not re-use	5.4.2[a]		Do not freeze	Proprietary
	Recycle	1135[e]		This way up	0623[e]
	Biological risks	5.4.1[a]		Caution	5.4.4[a]
	Common Units	Proprietary		Document face up[f]	1952[e]
YYYY-MM-DD	Date format (year-month-day)	N/A		International System of Units	Proprietary
	Target	Proprietary	YYYY-MM	Date format (year-month)	N/A
				Interval	Proprietary

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	Handheld barcode scanner	Proprietary	CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary
LOT DTL	Lot details	Proprietary	MC DEF	Master Curve definition	Proprietary
CAL LOT VAL	Calibrator lot value	Proprietary	CONTROL LOT VAL	Quality control lot value	Proprietary

a International Standard Organization (ISO). ISO 15223-1 Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied.

b ISO 15223-1:2020-04

c Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.

d IVDR REGULATION (EU) 2017/746

e International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.

f Indicates Assay-eNote

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