

Prolactin (PRL)

Current Revision and Date ^a	Rev. 04, 2020-06		
Product Name	Atellica IM Prolactin (PRL)	REF 10995656 (50 tests)	
		REF 10995655 (250 tests)	
Abbreviated Product Name	Atellica IM PRL		
Test Name/ID	PRL		
Systems	Atellica IM Analyzer		
Materials Required but Not Provided	Atellica IM CAL B	REF 10995503 (2-pack) REF 10995504 (6-pack)	
Optional Materials	Atellica IM Multi-Diluent 1	REF 10995637 (2-pack) REF 10995638 (6-pack) REF 10995639 (vial)	
	Atellica IM PRL MCM	REF 10995657	
Specimen Types	Serum, EDTA plasma, lithium heparin plasma		
Sample Volume	25 µL		
Measuring Interval	0.30–200.00 ng/mL (6.36–4240.00 μlU/mL)		

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

Intended Use

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The Atellica[®] IM Prolactin (PRL) assay is for *in vitro* diagnostic use in the quantitative determination of prolactin in human serum and plasma (EDTA and lithium heparin) using the Atellica[®] IM Analyzer.

Summary and Explanation

Prolactin is a single-chain polypeptide hormone secreted by the anterior pituitary¹ under the control of prolactin-inhibiting factors and prolactin-releasing factors. These inhibiting and releasing factors are secreted by the hypothalamus.² Prolactin is also synthesized by the placenta and is present in amniotic fluid.

Prolactin initiates and maintains lactation in females.³ It also plays a role in regulating gonadal function in both males and females. In adults, basal circulating prolactin is present in concentrations up to 30 ng/mL (636 µIU/mL). During pregnancy and postpartum lactation, serum prolactin can increase 10- to 20-fold. Exercise, stress, and sleep also cause transient increases in prolactin levels.

Consistently elevated serum prolactin levels > 30 ng/mL (> 636 µIU/mL) in the absence of pregnancy and postpartum lactation are indicative of hyperprolactinemia, which is the most common hypothalamic-pituitary dysfunction encountered in clinical endocrinology. Hyperprolactinemia often results in galactorrhea, amenorrhea, and infertility in females, and in impotence and hypogonadism in males.⁴ Renal failure, hypothyroidism, and prolactin-secreting pituitary adenomas are also common causes of abnormally elevated prolactin levels.^{1,5,6}

Principles of the Procedure

The Atellica IM Prolactin assay is a 2-site sandwich immunoassay using direct chemiluminescent technology, which uses constant amounts of 2 antibodies. The first antibody, in the Lite Reagent, is a goat polyclonal anti-prolactin antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a mouse monoclonal anti-prolactin antibody, which is covalently coupled to paramagnetic particles.

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

Reagents

Material Description	Storage	Stability ^a
Atellica IM PRL ReadyPack [®] primary reagent pack Lite Reagent	Unopened at 2–8°C	Until expiration date on product
 5.0 mL/reagent pack Goat polyclonal anti-prolactin antibody (~0.16 μg/mL) labeled with acridinium ester in buffer; sodium azide (0.11%); preservatives Solid Phase 22.5 mL/reagent pack Mouse monoclonal anti-prolactin antibody (~3.67 μg/mL) covalently coupled to paramagnetic particles in buffer; protein stabilizers: sodium azide (0.11%): preservatives 	Onboard	28 days
Atellica IM Multi-Diluent 1 ReadyPack ancillary reagent pack ^b	Unopened at 2–8°C	Until expiration date on product
25.0 mL/pack Equine serum; sodium azide (0.1%); preservatives	Onboard	28 days
Atellica IM Multi-Diluent 1 ^b 50.0 mL/vial Equine serum; sodium azide (0.1%); preservatives	At 2–8°C	Until expiration date on product

^a Refer to Storage and Stability.

^b Refer to Optional Materials.

Warnings and Precautions

For in vitro diagnostic use.

For Professional Use.

CAUTION

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

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

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.

Note For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

Storage and Stability

Store reagents in an upright position. Protect the product from heat and light sources. Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Store Atellica IM Multi-Diluent 1 in an upright position. Atellica IM Multi-Diluent 1 is stable until the expiration date on the product when stored at 2–8°C.

Do not use products beyond the expiration date printed on the product labeling.

Onboard Stability

Reagents are stable onboard the system for 28 days. Discard reagents at the end of the onboard stability interval.

Atellica IM Multi-Diluent 1 is stable onboard the system for 28 days.

Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

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

Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.⁷
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.⁸
- Follow the instructions provided with your specimen collection device for use and processing.⁹

- Allow blood specimens to clot completely before centrifugation.¹⁰
- Keep tubes capped at all times.¹⁰

Storing the Specimen

- 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 \leq -20°C if the sample is not assayed within 48 hours.
- Freeze samples only 1 time and mix thoroughly after thawing.

The handling and storage information provided here is based on data or references maintained by the manufacturer. 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.

Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

Preparing the Samples

This assay requires 25 μ L 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 information about determining the minimum required volume, refer to the online help.

The sample volume required to perform onboard dilution differs from the sample volume required to perform a single determination. Refer to *Dilutions*.

Note Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

Note Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.¹⁰

Note For a complete list of appropriate sample containers, refer to the online help.

Procedure

Materials Provided

The following materials are provided:

REF	Contents	Number of Tests
10995656	1 ReadyPack primary reagent pack containing Atellica IM PRL Lite Reagent and Solid Phase Atellica IM PRL master curve and test definition MCTDEF	50
10995655	5 ReadyPack primary reagent packs containing Atellica IM PRL Lite Reagent and Solid Phase Atellica IM PRL master curve and test definition MCTDEF	250

Materials Required but Not Provided

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

REF	Description	
	Atellica IM Analyzer ^a	
10995503	Atellica IM CAL B (calibrator)	2 x 5.0 mL low calibrator <code>CAL L</code> 2 x 5.0 mL high calibrator <code>CAL H</code> Calibrator lot-specific value sheet <code>CAL LOT VAL</code>
10995504	Atellica IM CAL B (calibrator)	6 x 5.0 mL low calibrator 6 x 5.0 mL high calibrator САЦ H Calibrator lot-specific value sheet САЦ LOT VAL

^a Additional system fluids are required to operate the system: Atellica IM Wash, Atellica IM Acid, Atellica IM Base, and Atellica IM Cleaner. For system fluid instructions for use, refer to the Document Library.

Optional Materials

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

REF	Description	
10995637	Atellica IM Multi-Diluent 1 (diluent)	2 ReadyPack ancillary reagent packs containing 25.0 mL/pack IIL
10995638	Atellica IM Multi-Diluent 1 (diluent)	6 ReadyPack ancillary reagent packs containing 25.0 mL/pack IIL
10995639	Atellica IM Multi-Diluent 1 (diluent)	50 mL/vial
10995657	Atellica IM PRL MCM (master curve material)	10 x 1.0 mL levels of master curve material MCM

Assay Procedure

The system automatically performs the following steps:

- 1. Dispenses 25 µL of sample into a cuvette.
- 2. Dispenses 100 µL of Lite Reagent, then incubates for 6 minutes at 37°C.
- 3. Dispenses 450 μ L of Solid Phase, then incubates for 6 minutes at 37°C.
- 4. Separates, aspirates, then washes the cuvette with Atellica IM Wash.
- 5. Dispenses 300 μ L each of Atellica IM Acid and Atellica IM Base to initiate the chemiluminescent reaction.
- 6. Reports results.

Preparing the Reagents

All reagents are liquid and ready to use. Before loading primary reagent packs onto the system, mix them by hand and visually inspect the bottom of the reagent pack to ensure that all particles are resuspended. For information about preparing the reagents for use, refer to the online help.

Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. The system automatically mixes reagent packs to maintain homogeneous suspension of the reagents. For information about loading reagent packs, refer to the online help.

For automated dilutions, ensure that Atellica IM Multi-Diluent 1 is loaded in the reagent compartment.

Master Curve Definition

Before initiating calibration on each new lot of reagent, load the assay master curve and test definition values by scanning the MCTORF 2D barcodes. For loading instructions, refer to the online help.

Performing Calibration

For calibration of the Atellica IM PRL assay, use Atellica IM CAL B. Use the calibrators in accordance with the calibrator instructions for use.

Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

Stability Interval	Days
Lot Calibration	34
Pack Calibration	28
Reagent Onboard Stability	28

For information about lot calibration and pack calibration intervals, refer to the online help.

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

Performing Quality Control

For quality control of the Atellica IM PRL assay, use an appropriate quality control material of known analyte concentration with at least 2 levels (low and high) at least once during each day that samples are analyzed. Use the quality control material in accordance with the quality control instructions for use.

A satisfactory level of performance is achieved when the analyte values obtained are within the expected control interval for the system or within your interval, as determined by an appropriate internal laboratory quality control scheme. 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 online help. Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Test quality control samples after a successful calibration.

Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

Results

Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in ng/mL (common units) or μ IU/mL (SI units), depending on the units defined when setting up the assay.

Conversion formula: 1.00 ng/mL = 21.20 µIU/mL

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

Dilutions

The measuring interval for Atellica IM PRL is 0.30–200.00 ng/mL ($6.36-4240.00 \mu$ IU/mL). For information about dilution options, refer to the online help.

Dilute and retest samples with prolactin levels > 200.00 ng/mL (4240.00 μ IU/mL) to obtain accurate results.

For automated dilutions, ensure that Atellica IM Multi-Diluent 1 is loaded in the reagent compartment. Ensure that sufficient sample volume is available to perform the dilution and that the appropriate dilution factor is selected when scheduling the test, as indicated in the table below.

For automatic dilutions, enter a dilution setpoint \leq 200 ng/mL (4240 µIU/mL).

	Sample	Dilution	Sample Volume (µL)
I	Serum and plasma	1:2	100
I	Serum and plasma	1:5	40

If patient results exceed the measuring interval of the assay when using automated dilution, or if laboratory protocol requires manual dilution, manually dilute the patient sample.

For manual dilutions, perform the following actions:

- Use Atellica IM Multi-Diluent 1 (vial) to prepare a manual dilution.
- For information about ordering tests for manually diluted samples, refer to the online help.
- 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 the patient's medical history, clinical presentation, and other findings.

Limitations

The following information pertains to limitations of the assay:

- Pregnancy, lactation, and the administration of oral contraceptives can increase prolactin concentrations.¹
- Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay is designed to minimize interference from heterophilic antibodies.^{11,12} Additional information may be required for diagnosis.

Expected Values

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur[®] and ACS:180[™] systems. Expected values were established using the ADVIA Centaur and ACS:180 systems and confirmed by assay comparison. Refer to *Assay Comparison*.

The expected results for the Prolactin assay were established in accordance with CLSI Document C28-A2¹³ using the ACS:180 system. Data were obtained on serum samples from 661 apparently healthy individuals. Based on a central 95% interval, the following reference intervals were established:

Category	Nª	Mean (ng/mL)	Interval (ng/mL)	Mean (µIU/mL)	Interval (µIU/mL)
Females					
Nonpregnant	202	9.6	2.8–29.2	204	59–619
Pregnant	216	61.7	9.7–208.5	1308	206–4420
Postmenopausal	104	6.9	1.8–20.3	146	38–430
Males	139	7.0	2.1–17.7	148	45–375

^a Number of samples tested.

Reference intervals for the pediatric population (children and adolescents) were established in accordance with the CLSI guideline EP28-A3c¹⁴ using the ADVIA Centaur system. Samples were collected prospectively from apparently healthy pediatric subjects, using predefined inclusion criteria. Reference values were generated for subpopulations based on age and Tanner stage subgroups based on physiological development. The study was designed to establish reference values across genders, and to include approximately equal numbers of males and females within each age or Tanner stage subgroup. The subject's Tanner stage was assessed based on pubic hair and genitalia/breast development.

The reference intervals and Tanner values are based on the central 90% (5th and 95th percentiles). Where sample sizes were insufficient to calculate the 5th or 95th percentile, the minimum or maximum observed values are presented, as denoted in the tables below.

Prolactin	Pediatric	Reference	Intervals	by	Age
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Age (Years)	N ^a	Median (ng/mL)	Interval (ng/mL)	Median (µIU/mL)	Interval (µIU/mL)
Male					
2–3	12	8.6	3.6 ^b -28.6 ^c	183.4	76.3 ^b -606.3 ^c
4–9	57	7.3	4.5–18.0	154.8	95.4–382.2
10–16	203	6.3	3.2–13.5	133.6	67.8–284.9

Age (Years)	Nª	Median (ng/mL)	Interval (ng/mL)	Median (µIU/mL)	Interval (µIU/mL)
17–21	37	7.9	5.4–15.4	167.5	115.1–326.7
Female					
2–3	18	7.4	3.1 ^b -15.7 ^c	156.9	65.7 ^b -332.8 ^c
4-9	47	7.1	3.1–15.8	150.5	66.6–334.1
10–12	93	7.2	3.5–18.2	152.6	75.0-386.7
13–21	127	9.2	4.3–23.1	195.0	89.9-489.7

^a Number of samples tested.

^b Value presented is the minimum reportable value observed; insufficient sample size to calculate a 5th percentile limit.

^c Value presented is the maximum value observed; insufficient sample size to calculate a 95th percentile limit.

Tanner Stage	Nª	Median (ng/mL)	Interval (ng/mL)	Median (µIU/mL)	Interval (µIU/mL)
Male					
1	74	7.2	3.7–18.5	153.7	78.4–391.1
2	65	5.9	2.4–13.7	125.1	49.4–289.4
3	63	5.7	3.5–11.9	120.8	74.2–252.7
4	59	7.4	3.2–15.5	156.9	67.8–328.6
5	48	7.7	4.9–14.5	162.2	105.6-306.9
Female					
1	74	7.2	3.1–18.7	152.6	65.7–395.9
2	47	6.9	3.7–21.8	146.3	78.9–461.7
3	65	8.5	4.0-18.2	180.2	84.0-386.5
4	47	9.2	4.0-20.8	195.0	84.8-439.3
5	52	8.8	4.3–24.9	185.5	90.4–526.4

Prolactin Pediatric Reference	Values	Characterized	by	Tanner	Stage
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^a Number of samples tested.

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.¹⁴ Consider these values as guidance only.

Performance Characteristics

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur and ACS:180 systems. Some performance characteristics for the Atellica IM assay were established using the ADVIA Centaur or ACS:180 systems.

Measuring Interval

The Atellica IM PRL assay provides results from 0.30–200.00 ng/mL ($6.36-4240.00 \mu IU/mL$). The lower end of the measuring interval is defined by the design requirement for the analytical sensitivity. Report results below the measuring interval as < 0.30 ng/mL ($6.36 \mu IU/mL$). When sample results exceed the measuring interval, refer to *Dilutions*.

Specificity

Cross-reactivity was determined in accordance with CLSI Document EP7-A2¹⁵ using the ADVIA Centaur system. Potential cross-reactants were added to serum samples containing prolactin. The following results were obtained.

	Prolactin Value		Prolactin Value			
	Without Cross-Reactant	With Cross-Reactant	Without Cross-Reactant	With Cross-Reactant		
Cross-Reactant	(ng/mL)	(ng/mL)	(µIU/mL)	(µIU/mL)		
TSH; 1000 μIU/mL	8.16	8.55	173	181		
	42.82	43.40	908	920		
	109.68	107.30	2325	2275		
LH; 250 mIU/mL	8.16	8.84	173	187		
	42.82	43.13	908	914		
	109.68	104.88	2325	2223		
hCG; 200,000 mIU/mL	8.16	8.30	173	176		
	42.82	40.28	908	854		
	109.68	109.60	2325	2324		
FSH; 250 mIU/mL	8.16	8.40	173	178		
	42.82	42.66	908	904		
	110.08	105.05	2325	2227		
hGH; 500 ng/mL	4.51	4.56	96	97		
	42.82	42.22	908	895		
	109.68	108.22	2325	2294		
hPL; 12.5 μg/mL	2.50	2.51	53	53		
	35.13	36.40	745	772		
	88.67	88.18	1880	1869		

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

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.¹⁶ The assay is designed to have an analytical sensitivity of \leq 0.30 ng/mL (6.36 µIU/mL), a limit of blank (LoB) \leq 0.30 ng/mL (6.36 µIU/mL), and a limit of detection (LoD) \leq 0.60 ng/mL (12.72 µIU/mL).

Representative detection capability data are shown below. Assay results obtained at individual laboratories may vary from the data presented.

Analytical sensitivity is defined as the concentration of prolactin that corresponds to the RLUs that are 2 standard deviations more than the mean RLUs of 20 replicate determinations of the prolactin zero standard. This response is an estimate of the minimum detectable concentration with 95% confidence. The analytical sensitivity for the Atellica IM PRL assay is 0.20 ng/mL (4.24 µIU/mL).

The LoB corresponds to the highest measurement result that is likely to be observed for a blank sample. The LoB of the Atellica IM PRL assay is 0.06 ng/mL (1.27 µIU/mL).

The LoD corresponds to the lowest concentration of prolactin that can be detected with a probability of 95%. The LoD for the Atellica IM PRL assay is 0.35 ng/mL (7.42 μ IU/mL), and was determined using 384 determinations, with 320 blank and 64 low-level replicates, and an LoB of 0.06 ng/mL (1.27 μ IU/mL).

Precision

Precision was determined in accordance with CLSI Document EP05-A3.¹⁷ Samples were assayed on an Atellica IM Analyzer in duplicate in 2 runs per day for 20 days. The assay was designed to have within-laboratory precision of ≤ 0.21 ng/mL (4.45 µIU/mL) SD for samples < 3.00 ng/mL (63.60 µIU/mL), $\leq 7\%$ CV for samples from 3.00–99.00 ng/mL (63.60–2098.80 µIU/mL), and $\leq 12\%$ CV for samples from 100.00–200.00 ng/mL (2120.00–4240.00 µIU/mL). The following results were obtained:

		Mean		Repeatability			Within-Laboratory Precision		
				S	Dpp	CVc		SD	CV
Sample Type	Na	(ng/mL)	(µIU/mL)	(ng/mL)	(µIU/mL)	(%)	(ng/mL)	(µIU/mL)	(%)
Serum A	80	2.30	48.76	0.04	0.85	N/A ^d	0.09	1.91	N/A ^d
Serum B	80	182.25	3863.70	5.72	121.26	3.1	8.91	188.89	4.9
Control 1	80	5.72	121.26	0.10	2.12	1.7	0.20	4.24	3.5
Control 2	80	16.69	353.83	0.24	5.09	1.4	0.56	11.87	3.3
Control 3	80	37.23	789.28	0.55	11.66	1.5	0.87	18.44	2.3

^a Number of samples tested.

^b Standard deviation.

^c Coefficient of variation.

^d Not applicable.

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

Assay Comparison

The Atellica IM PRL assay is designed to have a correlation coefficient of \ge 0.95 and a slope of 1.0 ± 0.1 compared to the ADVIA Centaur PRL assay. Assay comparison was determined using the weighted least squares linear regression model in accordance with CLSI Document EP09-A3.¹⁸ The following results were obtained:

The relationship between the Atellica IM and ADVIA Centaur PRL assays is described by this equation:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N ^a	r ^b
Serum	ADVIA Centaur PRL	y = 0.94x + 0.26 ng/mL (y = 0.94x + 5.51 µIU/mL)	0.99–198.43 ng/mL (20.99–4206.72 μIU/mL)	113	1.00

^a Number of samples tested.

^b Correlation coefficient.

The relationship between the ADVIA Centaur and ACS:180 Prolactin assays is described by this equation:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	Nª	r ^b
Serum	ACS:180 PRL	y = 1.00x + 0.56 ng/mL (y = 1.00x + 11.87 µIU/mL)	1.4–185.1 ng/mL (29.3–3925.0 μIU/mL)	279	0.99

^a Number of samples tested.

^b Correlation coefficient.

Agreement of the assays may vary depending on the study design, comparative assay, and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Specimen Equivalency

Specimen equivalency was determined with the Deming linear regression model in accordance with CLSI Document EP09-A3.¹⁸ The following results were obtained:

Tube (y) vs. Serum (x)	Nª	Sample Interval	Slope	Intercept	r ^b
EDTA plasma	66	2.71–180.00 ng/mL (57.45–3816.00 μlU/mL)	1.01	-0.18 ng/mL (-3.82 μIU/mL)	0.99
Lithium heparin plasma	64	2.71–196.91 ng/mL (57.45–4174.49 μlU/mL)	1.02	0.10 ng/mL (2.12 μIU/mL)	0.99

^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 using the ADVIA Centaur XP system in accordance with CLSI Document EP07-ed3.¹⁹ The following results were obtained:

Substance	Substance Test Concentration	Analyte Concentration ng/mL (µIU/mL)	Bias (%)
EDTA	5.4 mg/mL	10.59 (224.51)	3
		134.40 (2849.28)	-4
Heparin	45 U/mL	12.58 (266.70)	-1
		128.68 (2728.02)	1

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

Hemolysis, Icterus, and Lipemia (HIL)

Interference testing was performed in accordance with CLSI Document EP7-A2.¹⁵ The following results were obtained:

Serum specimens that are	Have an insignificant effect on the assay up to		
hemolyzed	500 mg/dL of hemoglobin		
icteric	20 mg/dL of bilirubin		
lipemic	1000 mg/dL of triglycerides		

Results were established using the ADVIA Centaur system.

Dilution Recovery

Six human serum samples in the range of 158.9–178.5 ng/mL (3368.0–3784.4 µIU/mL) of prolactin 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 89%–108% with a mean of 98%.

Sample	Dilution	Observed (ng/mL)	Expected (ng/mL)	Observed (µIU/mL)	Expected (µIU/mL)	Recovery (%)
1	_	178.5	_	3784.4	_	_
	1:2	87.9	89.3	1863.5	1892.1	98
	1:4	43.0	44.6	911.6	946.2	96
	1:8	20.7	22.3	439.3	473.0	93
	1:16	10.1	11.2	213.5	236.6	90
	Mean					95
2	_	173.5	_	3678.0	_	_
	1:2	83.7	86.7	1773.8	1838.9	97
	1:4	41.1	43.4	870.9	919.4	95
	1:8	19.3	21.7	409.8	459.8	89
	1:16	9.4	10.8	198.9	229.8	90
	Mean					93
3	_	158.9	_	3368.0	_	_
	1:2	81.7	79.4	1731.0	1683.9	103
	1:4	37.4	39.7	792.9	842.1	94
	1:8	19.7	19.9	416.8	421.0	99
	1:16	9.1	9.9	193.8	210.5	92
	Mean					97
4	_	159.9	_	3390.7	_	_
	1:2	78.7	80.0	1667.4	1695.4	98

Sample	Dilution	Observed (ng/mL)	Expected (ng/mL)	Observed (µIU/mL)	Expected (µIU/mL)	Recovery (%)
	1:4	39.7	40.0	842.5	847.8	99
	1:8	18.3	20.0	387.8	423.8	92
	1:16	9.2	10.0	195.7	212.0	92
	Mean					95
5	—	162.9	_	3453.7	_	_
	1:2	86.0	81.5	1823.2	1727.0	106
	1:4	41.5	40.7	880.7	863.5	102
	1:8	22.0	20.4	465.3	431.6	108
	1:16	11.0	10.2	233.0	215.8	108
	Mean					106
6	_	178.0	_	3772.8	_	_
	1:2	93.6	89.0	1984.5	1886.4	105
	1:4	46.9	44.5	993.6	943.2	105
	1:8	23.3	22.2	493.8	471.5	105
	1:16	10.5	11.1	221.5	235.7	95
	Mean					102
Mean						98

Results were established using the ADVIA Centaur system. Assay results obtained at individual laboratories may vary from the data presented.

Spiking Recovery

Varying amounts of prolactin were added to 6 samples with endogenous prolactin levels of 4.1–15.2 ng/mL (86.9–322.2 μ IU/mL). The recoveries ranged from 94%–109% with a mean of 102%.

Sample	Amount Added (ng/mL)	Observed (ng/mL)	Amount Added (µIU/mL)	Observed (µIU/mL)	Recovery (%)
1	—	4.1	_	86.9	_
	51.7	58.9	1096.0	1248.7	106
	104.1	112.3	2206.9	2380.8	104
	154.0	163.1	3264.8	3457.7	103
	Mean				104
2	—	6.5	—	137.8	_
	51.7	63.0	1096.0	1335.6	109
	104.1	113.0	2206.9	2395.6	102
	154.0	161.2	3264.8	3417.4	101

Sample	Amount Added (ng/mL)	Observed (ng/mL)	Amount Added (µIU/mL)	Observed (µIU/mL)	Recovery (%)
	Mean				104
3	_	5.0	—	104.9	_
	51.7	60.9	1096.0	1291.1	108
	104.1	114.4	2206.9	2425.3	105
	154.0	160.2	3264.8	3396.2	101
	Mean				105
4	_	14.9	—	315.9	_
	38.6	56.2	818.3	1191.4	107
	77.7	90.1	1647.2	1910.1	97
	115.2	132.5	2442.2	2809.0	102
	Mean				102
5	—	15.2	—	322.2	_
	38.6	55.6	818.3	1178.7	105
	77.7	87.9	1647.2	1863.5	94
	115.2	124.8	2442.2	2645.8	95
	Mean				98
6	_	10.2	_	216.2	_
	38.6	51.1	818.3	1083.3	106
	77.7	83.6	1647.2	1772.3	95
	115.2	130.9	2442.2	2775.1	105
	Mean				102
Mean					102

Results were established using the ADVIA Centaur system. Assay results obtained at individual laboratories may vary from the data presented.

High-Dose Hook Effect

High prolactin concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with prolactin concentrations as high as 30,000 ng/mL (636,000 μ IU/mL) will report > 200 ng/mL (> 4240 μ IU/mL). Results were established using the Atellica IM Analyzer.

Standardization

The Atellica IM PRL assay standardization is traceable to the World Health Organization (WHO) 3rd IRP for human Prolactin (84/500). Assigned values for calibrators are traceable to this standardization.

Technical Assistance

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

siemens.com/healthineers

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Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
T Rev. 01	Version of instructions for use
i siemens.com/healthcare i siemens.com/document-library	Internet URL address to access the electronic instructions for use
Rev. REVISION	Revision
\wedge	Caution Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device.
S	Biological risks Potential biological risks are associated with the medical device.
	Corrosive
	Dangerous to environment
	Irritant Oral, dermal, or inhalation hazard
	Inhalation hazard Respiratory or internal health
	Flammable Flammable to extremely flammable

Symbol	Symbol Title and Description
	Oxidizing
\bigtriangledown	
	Explosive
	Тохіс
$\stackrel{\vee}{\diamondsuit}$	Compressed gas
× 巻	Keep away from sunlight Prevent exposure to sunlight and heat.
<u>tt</u>	Up Store in an upright position.
	Do not freeze
2°C / 8°C	Temperature limit Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines.
	Handheld barcode scanner
IVD	In vitro diagnostic medical device
∑_(n)	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.</n>
RxOnly	Prescription device (US only) Applies only to United States-registered IVD assays. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.
()	Mixing of substances Mix product before use.
g mL	Reconstitute and mix lyophilized product before use.
\rightarrow	Target
← →	Interval
	Legal Manufacturer

Symbol	Symbol Title and Description
EC REP	Authorized Representative in the European Community
R	Use-by date Use by the designated date.
LOT	Batch code
REF	Catalog number
E.	Recycle
PRINTED WITH SOY INK	Printed with soy ink
CE	CE Mark
	CE Mark with notified body ID number Notified body ID number can vary.
YYYY-MM-DD	Date format (year-month-day)
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.
UNITS C	Common Units
UNITS SI	International System of Units
MATERIAL	Material
MATERIAL ID	Unique material identification number
CONTROL NAME	Name of control
CONTROL TYPE	Type of control

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