SIEMENS Healthineers

Total hCG (ThCG)

Current Revision and Date[a]	Rev. 04, 2022-10	
Product Name	Atellica IM Total hCG (ThCG)	REF 10995690 (90 tests) REF 10995689 (450 tests)
Abbreviated Product Name	Atellica IM ThCG	
Test Name/ID	ThCG	
Systems	Atellica CI Analyzer	
Materials Required but Not Provided	Atellica IM CAL B	REF 10995503 (2-pack) REF 10995504 (6-pack)
Optional Materials	Atellica IM ThCG DIL	REF 10995691 (2-pack) REF 10995692 (6-pack) REF 10995693 (vial)
	Atellica IM ThCG MCM	REF 10995694
Specimen Types	Serum, EDTA plasma, lithium heparin plasma	
Sample Volume	25 µL	
Measuring Interval	2.0–1000.0 mIU/mL (IU/L)	

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

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Intended Use

The Atellica® IM Total hCG (ThCG) assay is for *in vitro* diagnostic use in the quantitative determination of human chorionic gonadotropin (hCG) in human serum or plasma (EDTA or lithium heparin) using the Atellica® CI Analyzer.

The results obtained from hCG specimens are used as an aid in the assessment of pregnancy status. This assay detects the intact hCG molecule and free beta-subunits of the hCG molecule.

Summary and Explanation

Human chorionic gonadotropin (hCG) is a glycoprotein with 2 non-covalently bound subunits. The alpha subunit is similar to those of luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH).[1,2]

The beta subunit of hCG differs from other pituitary glycoprotein hormones, which results in its unique biochemical and immunological properties. hCG is synthesized by the cells of the placenta and is involved in maintaining the corpus luteum during pregnancy. It is detected as early as 1 week after conception.[1]

In pregnancy, the levels of hCG increase exponentially for about 8–10 weeks after the last menstrual cycle. Later in pregnancy, about 12 weeks after conception, the concentration of hCG begins to fall as the placenta begins to produce steroid hormones.

Other sources of elevated hCG values are ectopic pregnancy, threatened abortion, and recent termination of pregnancy.

Principles of the Procedure

The Atellica IM ThCG assay is a 2-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of 2 antibodies. The first antibody, in the Lite Reagent, is a goat polyclonal anti-hCG antibody that has been affinity purified and labeled with acridinium ester. The second antibody, in the Solid Phase, is a purified mouse monoclonal anti-hCG antibody, which is covalently coupled to paramagnetic particles. These 2 antibodies are specific for different epitopes that are present on both the free ß-subunit and the ß-subunit of intact hCG.

A direct relationship exists between the amount of hCG 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 ThCG ReadyPack® primary reagent pack **Lite Reagent** 4.5 mL/reagent pack Goat polyclonal anti-hCG antibody (~0.1 µg/mL) labeled with acridinium ester in buffered saline; sodium azide (0.1%); preservatives **Solid Phase** 20.3 mL/reagent pack Mouse monoclonal anti-hCG antibody (~0.02 mg/mL) covalently coupled to paramagnetic particles in buffered saline; sodium azide (0.1%); preservatives	Unopened at 2–8°C Onboard	Until expiration date on product 70 days
Atellica IM ThCG DIL ReadyPack ancillary reagent pack[b] 25.0 mL/pack Buffered heat-treated equine serum; EDTA; sodium azide (< 0.1%); preservatives	Unopened at 2–8°C Onboard	Until expiration date on product 28 days
Atellica IM ThCG DIL[b] 50.0 mL/vial Buffered heat-treated equine serum; EDTA; 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.

For Prescription Use Only.

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-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.

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 ThCG DIL in an upright position. Unopened Atellica IM ThCG DIL 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

Discard reagents at the end of the onboard stability interval.

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

For information about product onboard stability, refer to *Reagents*.

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.[3]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[4]
- Follow the instructions provided with your specimen collection device for use and processing.[5]

- Allow blood specimens to clot completely before centrifugation.[6]
- Keep tubes capped at all times.[6]

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 ≤ -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 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 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.[6]

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
10995690	1 ReadyPack primary reagent pack containing Atellica IM ThCG Lite Reagent and Solid Phase ThCG master curve and test definition MC TDEF	90
10995689	5 ReadyPack primary reagent packs containing Atellica IM ThCG Lite Reagent and Solid Phase ThCG master curve and test definition MC TDEF	450

Materials Required but Not Provided

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

REF	Description	
	Atellica CI Analyzer[a]	
10995503	Atellica IM CAL B (calibrator)	2 x 5.0 mL low calibrator CAL | L 2 x 5.0 mL high calibrator CAL | H Calibrator lot-specific value sheet CAL | LOT | VAL
10995504	Atellica IM CAL B (calibrator)	6 x 5.0 mL low calibrator CAL | L 6 x 5.0 mL high calibrator CAL | H Calibrator lot-specific value sheet CAL | LOT | VAL

[a] Additional system fluids are required to operate the system. 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	
10995691	Atellica IM ThCG DIL (diluent)	2 ReadyPack ancillary reagent packs containing 25.0 mL/pack DIL
10995692	Atellica IM ThCG DIL (diluent)	6 ReadyPack ancillary reagent packs containing 25.0 mL/pack DIL
10995693	Atellica IM ThCG DIL (diluent)	50.0 mL/vial DIL
10995694	Atellica IM ThCG 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 50 µL of Lite Reagent and 225 µL of Solid Phase, then incubates for 8 minutes at 37°C.
3. Separates, aspirates, then washes the cuvette with Atellica IM Wash.
4. Dispenses 300 µL each of Atellica IM Acid and Atellica IM Base to initiate the chemiluminescent reaction.
5. 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 ThCG DIL 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 MC TDEF 2D barcodes. For loading instructions, refer to the online help.

Performing Calibration

For calibration of the Atellica IM ThCG 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	49
Pack Calibration	35
Reagent Onboard Stability	70

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 ThCG 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 system 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 mIU/mL (common units) or IU/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: 1 mIU/mL (common units) = 1 IU/L (SI units)

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

Dilutions

The measuring interval is 2.0–1000.0 mIU/mL (IU/L). For information about dilution options, refer to the online help.

Dilute and retest samples with hCG levels > 1000.0 mIU/mL (IU/L) to obtain accurate results.

For automated dilutions, ensure that Atellica IM ThCG DIL 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 automated dilutions, enter a dilution setpoint ≤ 1000 mIU/mL (IU/L).

Sample	Dilution	Sample Volume (µL)
Serum and plasma	1:5	40
Serum and plasma	1:10	40
Serum and plasma	1:100	40
Serum and plasma	1:200	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 ThCG DIL (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

This test may be used for detecting pregnancy by the first day of the missed menstrual period.

All *in vitro* assays can generate erroneous results, both clinically false positive results (test results suggesting a condition that is absent) and clinically false negative results (test results failing to identify a condition that is present).

There are many possible causes for these types of discordant results. Erroneous results may occur due to interference from identifiable serum constituents or patient-specific serum constituents.

Erroneous results due to interference are repeatable over time.

Persistent serum hCG results in the range of 10.0–100.0 mIU/mL (more typically 10.0–50.0 mIU/mL) over several months suggest that the patient's blood may contain an interfering substance and produce erroneous results.

Identified sources of interference that have the potential to bind to and interfere with any component of the assay include:

- plasma components (clotting factors)
- serum proteins (such as rheumatoid factor)
- anti-idiotype antibodies

Interference can also be caused by:

- drugs and drug metabolites
- cross-reacting substances

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.[7,8]

If an aberrant or abnormal result, as defined by the laboratory protocol, occurs, laboratory personnel should first make certain that the system is performing and is operated and maintained in accordance with the product labeling. The user should then follow the laboratory protocol for advising the clinician of a result that appears to have deviated from the norms established by the laboratory.

Test results alone are not diagnoses of medical conditions. For example, low titer elevations of hCG can occur in normal non-pregnant subjects. A physician's diagnosis involves evaluation of the test result in conjunction with, and in the context of, the patient's medical history, physical examination, and other test results—sometimes in consultation with other medical experts.

This kit is not intended for any use other than assessment of pregnancy status.

Expected Values

The reagent formulations used on the Atellica CI Analyzer are the same as those used on the ADVIA Centaur® system and the Atellica IM Analyzer. Expected values established using the ADVIA Centaur system were confirmed by assay comparison. Refer to *Assay Comparison*.

Data were obtained on 366 serum samples from 192 apparently healthy non-pregnant females and 174 apparently healthy postmenopausal females using the Atellica IM Analyzer. The expected value range of non-pregnant females was 1.5–4.2 mIU/mL (IU/L) and the postmenopausal female population was 1.8–10.1 mIU/mL (IU/L), as shown in the table below.

Sample Category	N[a]	Median mIU/mL (IU/L)	Reference Interval mIU/mL (IU/L) 2.5–97.5 Percentile
Non-Pregnant Females (Age: 17–54)	192	2.0	1.5–4.2
Postmenopausal Females Age: ≥ 41	174	3.9	1.8–10.1

[a] Number of samples.

The levels of hCG found during normal pregnancy were determined using the ADVIA Centaur system, and the 95% intervals are presented in the following table. The production of hCG is extremely rapid following conception and is variable among individuals. A negative value does not rule out pregnancy. A patient with a negative value should be redrawn in 2 days and assayed again because hCG values in normal pregnancy double every 48 hours.

Gestational Age	n[a]	Median mIU/mL (IU/L)	Expected hCG Values mIU/mL (IU/L)
2–4 weeks	34	334	39.1–8388
5–6 weeks	76	19,220	861–88,769
6–8 weeks	58	43,326	8636–218,085
8–10 weeks	65	106,397	18,700–244,467
10–12 weeks	62	82,199	23,143–181,899
13–27 weeks	51	28,800	6303–97,171
28–40 weeks	48	15,881	4360–74,883

[a] Number of samples.

Whenever possible, gestational ages were determined by sonography. Otherwise, gestational ages were calculated from the date of the last menstrual cycle.

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[9] Consider these values as guidance only.

Performance Characteristics

The reagents used on the Atellica CI Analyzer are the same as those used on the Atellica IM Analyzer. Some performance characteristics were established using the Atellica IM Analyzer.

Measuring Interval

The Atellica IM ThCG assay is linear from 2.0–1000.0 mIU/mL (IU/L). The lower limit of the measuring interval is defined by the design requirement for the analytical sensitivity. Report results below the measuring interval as < 2.0 mIU/mL (IU/L). When sample results exceed the measuring interval, refer to *Dilutions*.

Specificity

The cross-reactivity of the Atellica IM ThCG assay with TSH, LH, FSH, prolactin, and hGH was determined by adding these hormones to serum samples containing hCG.

Substance	hCG Value Without Cross-Reactant mIU/mL (IU/L)	hCG Value With Cross-Reactant mIU/mL (IU/L)
TSH (300 µIU/mL)	< 2.0	< 2.0
	7.4	6.8
	47.1	42.9
	451.7	434
LH (200 mIU/mL)	< 2.0	< 2.0
	7.4	6.8
	47.1	46.8
	451.7	455.3
FSH (200 mIU/mL)	< 2.0	< 2.0
	7.4	6.3
	47.1	45.7
	451.7	446.4
PRL (1000 ng/mL)	< 2.0	< 2.0
	7.4	6.9
	47.1	46.3
	451.7	444.9
hGH (500 ng/mL)	< 2.0	< 2.0
	7.4	6.5
	47.1	46.4
	451.7	452.3

Interference testing was performed in accordance with CLSI Document EP07-A2[10] using the Atellica IM Analyzer. Assay results obtained at individual laboratories may vary from the data presented.

Detection Capability

Analytical Sensitivity	2.0 mIU/mL (IU/L)
Limit of Blank (LoB)	2.0 mIU/mL (IU/L)
Limit of Detection (LoD)	3.0 mIU/mL (IU/L)
Limit of Quantitation (LoQ)	3.0 mIU/mL (IU/L)

Analytical sensitivity is defined as the concentration of hCG that corresponds to the RLUs that are two standard deviations more than the mean RLUs of 20 replicate determinations of the ThCG zero standard. The response is an estimate of the minimum detectable concentration with 95% confidence.

The LoB corresponds to the highest measurement result likely to be observed for a blank sample with a probability of 95%.

The LoD corresponds to the lowest concentration of hCG that can be detected with a probability of 95%.

The LoQ corresponds to the lowest amount of hCG in a sample at which the within laboratory CV is ≤ 20%.

Detection capability was determined in accordance with CLSI Document EP17-A2.[11]

Precision

Precision on an Atellica CI Analyzer was determined in accordance with CLSI Document EP05-A3.[12] Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for 20 days. The assay was designed to have within-laboratory precision of ≤ 0.5 mIU/mL (IU/L) SD for samples at < 5.0 mIU/mL (IU/L), ≤ 10% CV for samples from 5.0–9.9 mIU/mL (IU/L), and ≤ 7% CV for samples from 10.0–1000.0 mIU/mL (IU/L). The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Sample 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	9.3	0.34	3.7	0.75	8.1
Serum B	80	13.9	0.29	2.1	0.78	5.6
Serum C	80	135.0	2.47	1.8	7.74	5.7
Serum D	80	394.4	6.81	1.7	20.10	5.1
Serum E	80	739.8	15.49	2.1	37.85	5.1
Control 1	80	7.4	0.24	3.2	0.45	6.1
Control 2	80	26.2	0.32	1.2	1.36	5.2
Control 3	80	184.5	3.22	1.7	9.35	5.1

[a] Number of samples tested.
[b] Standard deviation.
[c] Coefficient of variation.

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

Assay Comparison

Assay comparison was determined with the weighted Deming regression model in accordance with CLSI Document EP09c-ed3.[13]

Agreement of the assays may vary depending on the study design, comparative assay, and population tested.

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Atellica IM ThCG on Atellica IM Analyzer	y = 1.02x - 0.7 mIU/mL (IU/L)	7.0–930.3 mIU/mL (IU/L)	107	0.998
Serum	ADVIA Centaur® ThCG	y = 1.01x + 3.1 mIU/mL (IU/L)	3.0–969.6 mIU/mL (IU/L)	107	0.996

[a] Number of samples tested.
[b] Correlation coefficient.

The assay is designed to have a correlation coefficient of ≥ 0.95 and a slope of 1.0 ± 0.1.

Specimen Equivalency

Specimen equivalency was determined with the weighted Deming regression model in accordance with CLSI Document EP09c-ed3.[13]

Agreement of the specimen types may vary depending on the study design and sample population used.

Tube (y) vs. Serum (x)	N[a]	Sample Interval	Slope	Intercept	r[b]
Dipotassium EDTA plasma	116	3.8–959.2 mIU/mL (IU/L)	1.02	-1.4 mIU/mL (IU/L)	1.00
Lithium heparin plasma	134	3.8–959.2 mIU/mL (IU/L)	1.05	0.2 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.

Results were established using the Atellica IM Analyzer. Assay results obtained at individual laboratories may vary from the data presented.

Interferences

Interference testing was performed in accordance with CLSI Document EP07-ed3[14] using the Atellica IM Analyzer.

Substance	Substance Test Concentration	Analyte Concentration mIU/mL (IU/L)	Bias (%)
Dipotassium EDTA	9.0 mg/mL	21.1	1.5
		626.4	0.7
Heparin	75 U/mL	25.4	1.8
		668.9	0.7

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

Interference testing was performed in accordance with CLSI Document EP07-A2[10] using the Atellica IM Analyzer.

The following substances were added to serum samples containing different concentrations of hCG. The table below shows the percent bias for each set of samples with hCG values in the range of 16.5–465.0 mIU/mL (IU/L).

Substance	Substance Test Concentration	Analyte Concentration mIU/mL (IU/L)	Percent Bias
Acetaminophen	20 mg/dL	16.9	0.0
	20 mg/dL	465.0	0.9
Acetylsalicylic acid	65 mg/dL	16.9	-1.4
	65 mg/dL	451.9	2.7
Heparin	7200 IU/dL	17.1	-4.4
	7200 IU/dL	458.4	-2.0
Human Serum Albumin	6 mg/dL	16.5	1.5
	6 mg/dL	461.9	-0.1
Ibuprofen	3000 mg/dL	16.6	3.8
	3000 mg/dL	459.1	1.4

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica IM ThCG assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances were tested at the levels indicated in the table below.

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Substance	Substance Test Concentration	Analyte Concentration mIU/mL (IU/L)	Percent Bias
Hemoglobin	500 mg/dL (5.00 g/L)	17.6	-4.4
	500 mg/dL (5.00 g/L)	473.6	-0.2
Bilirubin, conjugated	40 mg/dL (474 µmol/L)	17.3	-3.7
	40 mg/dL (474 µmol/L)	457.3	-0.5
Bilirubin, unconjugated	40 mg/dL (684 µmol/L)	17.1	-1.2
	40 mg/dL (684 µmol/L)	461.9	-0.4
Lipemia (Intralipid®)	3000 mg/dL (34 mmol/L)	17.2	5.2
	3000 mg/dL (34 mmol/L)	436.1	0.0

Results were established using the Atellica IM Analyzer. Assay results obtained at individual laboratories may vary from the data presented.

Dilution Recovery

Four human serum samples in the range of 685.4–1062.4 mIU/mL (IU/L) of hCG were diluted 1:2, 1:4, 1:8, 1:16 with ThCG Diluent and assayed for recovery. The recoveries ranged from 98.4%–108.1% with a mean recovery of 102.6%.

Sample	Dilution	Observed mIU/mL (IU/L)	Expected mIU/mL (IU/L)	Recovery %
Serum 1	—	727.6	727.6	—
	1:2	387.2	363.8	106.4
	1:4	182.1	181.9	100.1
	1:8	90.8	90.9	99.9
	1:16	49.2	45.5	108.1
	Mean			103.6
Serum 2	—	768.2	768.2	—
	1:2	412.0	384.1	107.3
	1:4	194.2	192.1	101.1
	1:8	95.6	96.0	99.6
	1:16	48.0	48.0	99.9
	Mean			102.0
Serum 3	—	1062.4	1062.4	—
	1:2	561.3	531.2	105.7
	1:4	278.6	265.6	104.9
	1:8	136.5	132.8	102.8
	1:16	68.5	66.4	103.1
	Mean			104.1
Serum 4	—	685.4	685.4	—
	1:2	355.1	342.7	103.6
	1:4	174.0	171.3	101.6
	1:8	84.8	85.7	99.0
	1:16	42.2	42.8	98.4
	Mean			100.7

Results were established using the Atellica IM Analyzer. Assay results obtained at individual laboratories may vary from the data presented.

Spiking Recovery

Varying amounts of hCG were added to 5 samples with endogenous hCG levels of 9.6–25.5mIU/mL (IU/L). The recoveries ranged from 91%–116% with a mean of 99.4%.

Sample	Amount Added mIU/mL (IU/L)	Observed mIU/mL (IU/L)	Recovery %
1	0	25.5	—
	55	82.1	103
	110	127.8	93
	220	240.3	98
	405	496.8	116
	879	829.5	91
	Mean		100
2	0	21.2	—
	55	84.4	115
	110	128.9	98
	220	229.7	95
	405	472.9	111
	879	838.6	93
	Mean		103
3	0	9.6	—
	55	65.2	101
	110	112.6	94
	220	219.4	95
	405	454.0	110
	879	817.1	92
	Mean		98
4	0	23.4	—
	55	78.8	101
	110	127.6	95
	220	228.3	93
	405	482.1	113
	879	821.5	91
	Mean		99
5	0	14.6	—
	55	68.9	99

Sample	Amount Added mIU/mL (IU/L)	Observed mIU/mL (IU/L)	Recovery %
	110	116.3	93
	220	215.9	92
	405	458.9	110
	879	824.7	92
	Mean		97

Results were established using the Atellica IM Analyzer. Assay results obtained at individual laboratories may vary from the data presented.

High-Dose Hook Effect

High hCG concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with hCG concentrations as high as 400,000 mIU/mL (IU/L) will report > 1000.0 mIU/mL (IU/L). Results were established using the Atellica CI Analyzer.

Standardization

The Atellica IM ThCG assay is standardized against the World Health Organization (WHO) 4th IS 75/589 reference material. Assigned values for calibrators are traceable to this standardization.

Technical Assistance

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

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References

1. Russell PT. Pregnancy and fetal function. In: Kaplan LA, Pesce AJ, eds. *Clinical Chemistry: Theory, Analysis, Correlation*. 2nd ed. St. Louis: CV Mosby; 1989:572.
2. Kaplan LA. Human chorionic gonadotropin. In: Kaplan LA, Pesce AJ, eds. *Clinical Chemistry: Theory, Analysis, Correlation*. 2nd ed. St. Louis: CV Mosby; 1989:938–944.
3. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
4. Clinical and Laboratory Standards Institute. *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2007. CLSI Document GP41-A6.
5. Clinical and Laboratory Standards Institute. *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP39-A6.
6. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.
7. Kricka LJ. Human anti-animal antibody interferences in immunological assays. *Clin Chem*. 1999;45(7):942–956.
8. Vaidya HC, Beatty BG. Eliminating interference from heterophilic antibodies in a two-site immunoassay for creatine kinase MB by using F(ab')2 conjugate and polyclonal mouse IgG. *Clin Chem*. 1992;38(9):1737–1742.

9. Clinical and Laboratory Standards Institute. *Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document EP28-A3c.
10. 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.
11. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.
12. 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.
13. 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; 2018. CLSI Document EP09c-ed3.
14. Clinical and Laboratory Standards Institute. *Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2018. CLSI Document EP07-ed3.

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]	EC REP	Authorized representative in the European Community	5.1.2[a]
	Use-by date	5.1.4[a]	CH REP	Authorized representative in Switzerland	Proprietary
REF	Catalog number	5.1.6[a]	LOT	Batch code	5.1.5[a]
	Consult Instructions for Use	5.4.3[a]	Σ	Contains sufficient for <n> tests	5.5.5[a]
< .../eifu >	Internet URL address to access the electronic instructions for use	Proprietary	Rev. XX	Version of Instructions for Use	Proprietary
IVD	*In vitro* diagnostic medical device	5.5.1[a]	Rev. REVISION	Revision	Proprietary
RxOnly	Prescription device (US only)	FDA[b]	UDI	Unique Device Identifier	5.7.10[c]
CE XXXX	CE Marking with Notified Body	EU IVDR[d]	CE	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]

Symbol	Symbol Title	Source	Symbol	Symbol Title	Source
	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]
UNITS C	Common Units	Proprietary	UNITS SI	International System of Units	Proprietary
YYYY-MM-DD	Date format (year-month-day)	N/A	YYYY-MM	Date format (year-month)	N/A
	Document face up[f]	1952[e]		Handheld barcode scanner	Proprietary
	Target	Proprietary		Mixing of substances	5657[g]
CHECKSUM	Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid.	Proprietary		Interval	Proprietary
MATERIAL ID	Unique material identification number	Proprietary	MATERIAL	Material	Proprietary
CONTROL TYPE	Type of control	Proprietary	CONTROL NAME	Name of control	Proprietary
CONTROL LOT VAL	Quality control lot value	Proprietary	CAL LOT VAL	Calibrator 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] Federal Register. Vol. 81, No 115. Wednesday, June 15, 2016. Rules and Regulations: 38911.
[c] ISO 15223-1:2020-04
[d] IVDR REGULATION (EU) 2017/746
[e] International Standard Organization (ISO). ISO 7000 Graphical symbols for use on equipment.
[f] Indicates Assay-eNote
[g] International Electrotechnical Commission (IEC). IEC 60417-1 Graphical symbols for use on equipment – Part 1: Overview and Application

Legal Information

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