SIEMENS Healthineers

Immunoglobulin G_2 (IgG_2)

Current Revision and Date[a]	Rev. 03, 2019-05	
Product Name	Atellica CH Immunoglobulin G_2 (IgG_2)	REF 11097616 (720 tests)
Abbreviated Product Name	Atellica CH IgG_2	
Test Name/ID	IgG_2	
Systems	Atellica CH Analyzer	
Materials Required but Not Provided	Atellica CH LSP CAL	REF 11099434
Specimen Types	Serum and plasma (lithium heparin)	
Sample Volume	2 µL	
Measuring Interval	140–3400 mg/dL (1.40–34.00 g/L)	

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

CE

Intended Use

The Atellica® CH Immunoglobulin G_2 (IgG_2) assay is for *in vitro* diagnostic use in the quantitative determination of immunoglobulin G (IgG) in human serum and plasma (lithium heparin) using the Atellica® CH Analyzer. Such measurements are used to aid in the diagnosis of abnormal protein metabolism and the body's inability to resist infectious agents.

Summary and Explanation

The Atellica CH Immunoglobulin G_2 (IgG_2) assay is based on the use of polyethylene glycol (PEG) to accelerate the antigen-antibody interaction as described in the work of Hellsing.[1-13]

Immunoglobulin G (IgG) is the largest antibody component of protein in blood. Four distinct subtypes exist: IgG1, IgG2, IgG3, and IgG4. They differentiate according to structure, ability to fix complement, ability to transport across the placenta, and half-lives. Typically, immuno-competent individuals will present with polyclonal increases in IgG while responding to infectious or inflammatory processes. Conversely, patients who present with increased susceptibility to infection should be evaluated for immunoglobulin levels, especially IgG. The presence of a monoclonal IgG paraprotein is diagnostic of multiple myeloma in conjunction with increased plasma cells in the bone marrow or with evidence of osteolytic lesions.

Quantitative determination of protein substances by immunological assays began during the early 1930s with the development of the quantitative precipitin technique by Heidelberger and Kendall. There followed numerous studies of light-scattering and turbidimetric measurements of antigen-antibody complexes.

The assays are based on the use of polyethylene glycol (PEG) to accelerate the antigen-antibody interaction as described in the work of Hellsing. The enhancing effect of polymers on the precipitin reaction was first reported in 1964 and was dependent on such factors as the concentration, molecular weight, and configuration of the added polymer.

Various disease-related conditions are associated with depressed or elevated levels of IgG:

Depressed Levels	Elevated Levels
Lymphoid aplasia	IgG myeloma
Agammaglobulinemia	Hepatitis
Heavy Chain disease	Rheumatoid arthritis
Macroglobulinemia	Acquired Immunodeficiency Syndrome
Chronic lymphocytic leukemia	

Principles of the Procedure

The Atellica CH IgG_2 assay is a PEG-enhanced immunoturbidimetric method. Sample containing human IgG is suitably diluted and then reacted with specific antiserum to form a precipitate that can be measured turbidimetrically at 340/694 nm. By constructing a calibration curve from the absorbances of calibrators, the concentration of IgG is determined.

Reagents

Material Description	Storage	Stability[a]
Atellica CH IgG_2 **Pack 1 (P1)** Well 1 (W1) Reagent 1 (R1) 10.5 mL Polyethylene glycol (6%); Tris/HCL buffer (pH 7.4) (20 mmol/L); sodium chloride (150 mmol/L); sodium azide (0.09%) Well 2 (W2) Reagent 1 (R1) 10.5 mL Polyethylene glycol (6%); Tris/HCL buffer (pH 7.4) (20 mmol/L); sodium chloride (150 mmol/L); sodium azide (0.09%) **Pack 2 (P2)** Well 1 (W1) Reagent 2 (R2) 4.3 mL Polyethylene glycol (6%); Tris/HCL buffer (pH 7.4) (20 mmol/L); sodium chloride (150 mmol/L); antihuman IgG (goat), lot-specific; sodium azide (0.09%) Well 2 (W2) Reagent 2 (R2) 4.3 mL Polyethylene glycol (6%); Tris/HCL buffer (pH 7.4) (20 mmol/L); sodium chloride (150 mmol/L); antihuman IgG (goat), lot-specific; sodium azide (0.09%)	Unopened at 2–8°C Onboard per well	Until expiration date on product 30 days

[a] Refer to *Storage and Stability*.

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

Unopened reagents are 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 30 days per well. Discard reagents at the end of the onboard stability interval. Do not use products beyond the expiration date printed on the product labeling.

Specimen Collection and Handling

Serum and plasma (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.[14]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[15]
- Follow the instructions provided with your specimen collection device for use and processing.[16]
- Allow blood specimens to clot completely before centrifugation.[17]
- Keep tubes capped at all times.[17]

Storing the Specimen

Specimens may be stored for up to 7 days at 2–8°C or stored frozen for up to 3 months at -20°C.[18,19]

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 2 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.

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.[17]

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
11097616	**Pack 1 (P1)** Well 1 (W1) 10.5 mL of Atellica CH IgG_2 Reagent 1 Well 2 (W2) 10.5 mL of Atellica CH IgG_2 Reagent 1 **Pack 2 (P2)** Well 1 (W1) 4.3 mL of Atellica CH IgG_2 Reagent 2 Well 2 (W2) 4.3 mL of Atellica CH IgG_2 Reagent 2	4 x 180

Materials Required but Not Provided

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

REF	Description	
	Atellica CH Analyzer[a]	
11099434	Atellica CH LSP CAL (calibrator)	1 x 1.0 mL calibrator level 1 CAL 1 1 x 1.0 mL calibrator level 2 CAL 2 1 x 1.0 mL calibrator level 3 CAL 3 1 x 1.0 mL calibrator level 4 CAL 4 1 x 1.0 mL calibrator level 5 CAL 5 1 x 1.0 mL calibrator level 6 CAL 6 Calibrator lot-specific value sheet CAL LOT VAL
	Commercially available quality control materials	

[a] Additional system fluids are required to operate the system: Atellica CH Diluent, Atellica CH Wash, Atellica CH Conditioner, Atellica CH Cleaner, Atellica CH Reagent Probe Cleaner 1, Atellica CH Reagent Probe Cleaner 2, Atellica CH Reagent Probe Cleaner 4, Atellica CH Lamp Coolant, and Atellica CH Water Bath Additive. For system fluid instructions for use, refer to the Document Library.

Assay Procedure

The system automatically performs the following steps:

1. For serum/plasma, dispenses 11 µL of primary sample and 224.4 µL of Atellica CH Diluent into a dilution cuvette.
2. Dispenses 80 µL of Reagent 1 into a reaction cuvette.
3. Dispenses 2 µL of pre-diluted sample into a reaction cuvette.
4. Measures the absorbance after sample addition.
5. Dispenses 16 µL of Reagent 2 into a reaction cuvette.
6. Mixes and incubates the mixture at 37°C.
7. Measures the absorbance after Reagent 2 addition.
8. Reports results.

Test Duration: 10 minutes

Preparing the Reagents

All reagents are liquid and ready to use.

Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. For information about loading reagent packs, refer to the online help.

Performing Calibration

For calibration of the Atellica CH IgG_2 assay, use Atellica CH LSP CAL. 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	60
Pack Calibration	30
Reagent Onboard Stability	30

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 CH IgG_2 assay, use at least two levels (low and high) of the appropriate quality control material of known analyte concentration. Use the quality control material in accordance with the quality control instructions for use.

For the assigned values, refer to the lot-specific value sheet provided. A satisfactory level of performance is achieved when the analyte values obtained are within the expected control range for the system or within your range, 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.

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 mg/dL (common units) or g/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: mg/dL x 0.01 = g/L

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

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 Atellica CH IgG_2 assay is limited to the detection of immunoglobulin G (IgG) in human serum and plasma (lithium heparin).

Do not use hemolyzed samples.

A number of substances cause physiological changes in serum or plasma analyte concentrations. A comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. Consult listed reference for specific details on known potential interfering substances.[20]

As with any chemical reaction, you must be alert to the possible effect on results of unknown interferences from medications or endogenous substances. The laboratory and physician must evaluate all patient results in light of the total clinical status of the patient.

Expected Values

Reference Interval

A reference interval for healthy adults was established in accordance with CLSI Document EP28-A3c and verified on the Atellica CH Analyzer.[21]

The reference interval for immunoglobulin G (IgG) is 650–1600 mg/dL (6.50–16.00 g/L) for adults.[22]

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results. Consider these values as guidance only.[21]

Performance Characteristics

Measuring Interval

The Atellica CH IgG_2 assay provides results from 140–3400 mg/dL (1.40–34.00 g/L). The system flags all values that are outside the specified measuring interval.

Extended Measuring Interval

An automatic repeat condition for this assay extends the measuring interval to 70–34,000 mg/dL (0.70–340.00 g/L) for serum and plasma. You may configure the system to trigger an automatic repeat. Automatic repeat results will be flagged **Autorepeat**.

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[23] The assay is designed to have a limit of blank (LoB) ≤ limit of detection (LoD) and LoD ≤ 140 mg/dL (≤ 1.40 g/L).

The LoD corresponds to the lowest concentration of immunoglobulin G that can be detected with a probability of 95%. The LoD for the Atellica CH IgG_2 assay is 21 mg/dL (0.21 g/L), and was determined using 180 determinations, with 60 blank and 120 low level replicates, and a LoB of 7 mg/dL (0.07 g/L).

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

Precision

Precision was determined in accordance with CLSI Document EP05-A3.[24] Samples were assayed on an Atellica CH Analyzer in duplicate in 2 runs per day for 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Designed to be ≤	Within-Lab Precision		Designed to be ≤
Sample Type	N	Mean mg/dL (g/L)	SD[a] mg/dL (g/L)	CV[b] (%)	CV (%)	SD mg/dL (g/L)	CV (%)	CV (%)
Serum Pool	80	806 (8.06)	12.9 (0.129)	1.6	5.0	14.1 (0.141)	1.8	7.0
Plasma Pool	80	1112 (11.12)	13.2 (0.132)	1.2	4.0	16.0 (0.160)	1.4	6.0
QC	80	2309 (23.09)	17.9 (0.179)	0.8	4.0	36.3 (0.363)	1.6	6.0

[a] Standard deviation.
[b] Coefficient of variation.

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

Assay Comparison

The Atellica CH IgG_2 assay is designed to have a correlation coefficient of > 0.950 and a slope of 1.0 ± 0.10 compared to ADVIA® Chemistry 1800 IgG_2. Assay comparison was determined using the weighted Deming linear regression model in accordance with CLSI Document EP09-A3.[25] The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	ADVIA Chemistry 1800 IgG_2	y = 0.99x + 4 mg/dL (y = 0.99x + 0.04 g/L)	148–3593 mg/dL (1.48–35.93 g/L)	115	0.999

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

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

Specimen Equivalency

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09-A3.[25] The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Lithium heparin plasma	Serum	y = 1.01x - 26 mg/dL (y = 1.01x - 0.26 g/L)	252–2498 mg/dL (2.52–24.98 g/L)	54	0.998

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

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

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH IgG_2 assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in serum in accordance with CLSI Document EP07-A2 using the Atellica CH IgG_2 assay.[26]

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 Common Units (SI Units)	Analyte Concentration mg/dL (g/L)	Percent Bias
Hemoglobin	1000 mg/dL (0.625 mmol/L) 1000 mg/dL (0.625 mmol/L)	509 (5.09) 2114 (21.14)	-1 -2
Bilirubin, conjugated	50 mg/dL (855 µmol/L) 50 mg/dL (855 µmol/L)	498 (4.98) 1904 (19.04)	2 -1
Bilirubin, unconjugated	50 mg/dL (855 µmol/L) 50 mg/dL (855 µmol/L)	514 (5.14) 1890 (18.90)	-1 -2
Lipemia (Intralipid®)	1000 mg/dL (11.3 mmol/L) 1000 mg/dL (11.3 mmol/L)	518 (5.18) 1959 (19.59)	5 -1

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

High-Dose Hook Effect

High IgG levels can cause a paradoxical decrease in signal as a result of the high-dose hook effect. In this assay, IgG levels as high as 70,000 mg/dL (700 g/L) will assay > 3400 mg/dL (34 g/L).

Standardization

The Atellica CH IgG_2 assay is traceable to the Institute for Reference Materials and Measurements (IRMM) reference material CRM-470.

Assigned values for calibrators are traceable to this standardization.[27]

Technical Assistance

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

siemens.com/healthineers

References

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   c. *J Exper Med.* 1935;63:697–720.

2. Libby RL. New and rapid quantitation technique for the determination of potency of types I and II antipneumococcal serum. *J Immunol.* 1938;34:269.

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7. Marrack JR, Richards CB. Light scattering studies of the formation of aggregates in mixtures of antigen and antibody. *J Immunol.* 1971;20:1019–1038.

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10. Hellsing K, Laurent TC. The influence of dextran on the precipitin reaction. *Acta Chem Scand.* 1964;18:1303.

11. Hellsing K. The effect of dextran on the reaction between iodine-125 labeled human serum albumin and gamma G-globulin from rabbit anti-albumin sera. *Acta Chem Scand.* 1966;20:1251.

12. Hellsing K. The effect of hyaluronate, chondroitin sulfate and chondroitin sulphate-protein complex on the precipitin reaction. *Biochem J.* 1969;112:475.

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15. 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.

16. 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.

17. 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.

18. Schreiber W, Rausch S, Lammers M. Choice of specimen for immunonephelometric protein assays. *Clin Chim Acta.* 2005;355:S407

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21. 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.

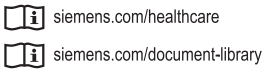
22. Tietz NW. *Clinical Guide to Laboratory Tests.* 3rd ed. Philadelphia, PA: WB Saunders Company; 1995: 358–359.

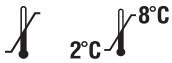
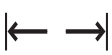
23. Clinical and Laboratory Standards Institute. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI Document EP17-A2.

24. 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.
25. 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.
26. 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.
27. Data on file at Siemens Healthcare Diagnostics.

Definition of Symbols

The following symbols may appear on the product labeling:

Symbol	Symbol Title and Description
	Consult instructions for use
	Version of instructions for use
	Internet URL address to access the electronic instructions for use
	Revision
	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.
	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
	Oxidizing

Symbol	Symbol Title and Description
	Explosive
	Toxic
	Compressed gas
	Keep away from sunlight Prevent exposure to sunlight and heat.
	Up Store in an upright position.
	Do not freeze
	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
	Contains sufficient for <n> tests Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol.
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.
	Reconstitute and mix lyophilized product before use.
	Target
	Interval
	Legal Manufacturer
EC REP	Authorized Representative in the European Community
	Use-by date Use by the designated date.

Symbol	Symbol Title and Description
LOT	Batch code
REF	Catalog number
	Recycle
PRINTED WITH SOY INK	Printed with soy ink
CE	CE Mark
CE 0088	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

Legal Information

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