SIEMENS

CE 0197

ADVIA Centaur® CP
Immunoassay System

Insulin (IRI)

Assay Summary

Sample Type	***Serum***
Sample Volume	***25 µL***
Calibrator	***IRI***
Sensitivity and Assay Range	***0.5–300 mU/L***

Contents

REF	Contents	Number of Tests
02230141 (128434)	1 ReadyPack® primary reagent pack containing ADVIA Centaur® IRI Lite Reagent and Solid Phase ADVIA Centaur and ADVIA Centaur CP IRI Master Curve card	100

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

Intended Use

The ADVIA Centaur CP Insulin (IRI) assay is an *in vitro* diagnostic immunoassay for the quantitative determination of insulin in serum using the ADVIA Centaur CP system. This assay is used to aid in the diagnosis and treatment of diabetes mellitus and hypoglycemia.

Materials Required But Not Provided

REF	Description	Contents
04618899 (128433)	IRI Calibrator	2 vials of low calibrator CAL L 2 vials of high calibrator CAL H

Optional Reagents

REF	Description	Contents
05080264 (129883)	ADVIA Centaur IRI Diluent DIL	2 ReadyPack ancillary reagent packs containing 10 mL/pack
01043186 (129885)	IRI Diluent DIL	20 mL/vial
128432	IRI Master Curve Material	10 x 1 mL

Summary and Explanation of the Test

Insulin is a protein hormone that is synthesized, stored, and secreted by the beta cells located in the islets of Langerhans in the pancreas. Insulin is responsible for regulating glucose concentrations in the blood. Initially in the beta cells, insulin exists as a large molecule (MW ~12000) called preproinsulin. Preproinsulin is a single-chain precursor consisting of 110 amino acids. A chain of 24 amino acids of preproinsulin is cleaved forming proinsulin (MW ~9000), the precursor of insulin and C-peptide.[1,2,3]

Proinsulin consists of two amino acid chains of insulin connected by disulfide bonds and a connective peptide, called C-peptide. The alpha (A) chain of insulin consists of 21 amino acids, the beta (B) chain of insulin consists of 30 amino acids, and C-peptide consists of 31 amino acids. Proinsulin is stored in the secretory granules in the Golgi apparatus of the beta cells until proinsulin undergoes proteolysis to form insulin (MW ~6000) and C-peptide (MW ~3000). At the cell membrane, insulin and C-peptide are released into the portal circulation in equimolar amounts.[1,2,3]

Insulin is released in response to the presence of glucose in the blood typically after the ingestion of a meal. A normal healthy individual produces 40 to 50 units of insulin each day. The half-life of insulin in serum or plasma is 5 to 10 minutes. Approximately 50% of the insulin released into the portal circulation is cleared by the liver. Insulin binds to receptor cells located on cell membranes of target tissues. The target tissues are primarily liver, fat, and muscle tissue. Insulin lowers glucose concentrations in the blood by stimulating glycogenolysis in the liver, triglyceride synthesis in adipose tissue, and protein synthesis in muscle.[1,2,3] Recent studies have indicated that insulin and insulin receptors may play a role in learning and memory. The interruption of insulin production and insulin receptor activity may lead to deficits in learning and memory formation.[4] Increased insulin production is common in the development of cancers.[5]

If insulin production is not stimulated, blood glucose levels will not be lowered and hyperglycemia results. Fasting hyperglycemia supports the diagnosis of diabetes mellitus. There are two types of diabetes mellitus: type I or insulin-dependent diabetes mellitus (IDDM) and type II or non-insulin-dependent diabetes mellitus (NIDDM). Insulin therapy is used for insulin-dependent diabetes mellitus (IDDM), patients and many non-insulin-dependent diabetes mellitus (NIDDM) patients. In type I diabetes (IDDM) there is a deficiency of insulin. This can be the result of autoimmune destruction of the beta cells or the presence of autoantibodies to insulin. Many factors can play a role in the development of Type II diabetes (NIDDM). Type II diabetes (NIDDM) can result if there is a decreased biological response to circulating insulin (insulin resistance) or if there is decreased or diminished insulin secretion due to beta cell failure.[1,2,3]

Insulin levels are not typically used in the diagnosis or management of diabetic patients. Insulin levels can be useful in evaluating patients with fasting hypoglycemia, in determining insulin resistance in the general population, and in assessing abnormalities in beta cell secretory function. Insulin levels are used in studying the pathophysiology of diabetes.[6,7]

Assay Principle

The ADVIA Centaur CP Insulin assay is a two-site sandwich immunoassay using direct chemiluminescent technology which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a monoclonal mouse anti-insulin antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-insulin antibody, which is covalently coupled to paramagnetic particles.

The system automatically performs the following steps:

- dispenses 25 µL of sample into a cuvette
- dispenses 50 µL of Lite Reagent and incubates for 6.33 minutes at 37°C
- dispenses 250 µL of Solid Phase and incubates for 3.0 minutes at 37°C
- separates, aspirates, and washes the cuvettes with Wash 1
- dispenses 300 µL each of Acid Reagent (R1) and Base Reagent (R2) to initiate the chemiluminescent reaction
- reports results according to the selected option, as described in the system operating instructions or in the online help system

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

Specimen Collection and Handling

Serum is the recommended sample type for this assay.

The following recommendations for handling and storing blood samples are furnished by the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS):[8]

- Collect all blood samples observing universal precautions for venipuncture.
- Allow serum samples to clot adequately before centrifugation.
- Centrifuge samples at ≥ 1000 x g for 15 to 20 minutes.
- Keep tubes stoppered and upright at all times.
- Do not use samples that have been stored at room temperature for longer than 8 hours.
- Separate serum from the red blood cells before storage at 2° to 8°C or -20°C.
- Tightly cap and refrigerate specimens at 2° to 8°C if the assay is not completed within 8 hours.
- Freeze samples at or below -20°C if the sample is not assayed within 24 hours.
- Freeze samples only once and mix thoroughly after thawing.

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

- Samples are free of fibrin or other particulate matter. Remove particulates by centrifugation at ≥ 1000 x g for 15 to 20 minutes.
- Samples are free of bubbles.

Reagents

Store the reagents upright at 2–8°C.
Mix all primary reagent packs by hand before loading them onto the system. Visually inspect the bottom of the reagent pack to ensure that all particles are dispersed and resuspended. For detailed information about preparing the reagents for use, refer to the *Operator's Guide.*

Reagent Pack	Reagent	Volume	Ingredients	Storage	Stability
ADVIA Centaur IRI ReadyPack primary reagent pack	Lite Reagent	5.0 mL/ reagent pack	monoclonal mouse anti-insulin antibody (~0.24 µg/mL) labeled with acridinium ester in buffered saline with bovine serum albumin, sodium azide (< 0.1%), and preservatives	2–8°C	until the expiration date on the pack label. For onboard stability, refer to *Onboard Stability and Calibration Interval.*
	Solid Phase	25.0 mL/ reagent pack	monoclonal mouse anti-insulin antibody (~6.0 µg/mL) covalently coupled to paramagnetic particles in buffered saline with bovine serum albumin, sodium azide (< 0.1%), and preservatives	2–8°C	until the expiration date on the pack label. For onboard stability, refer to *Onboard Stability and Calibration Interval.*
ADVIA Centaur IRI DIL ReadyPack ancillary reagent pack	Insulin Diluent	10.0 mL/ reagent pack	buffered saline with casein, potassium thiocyanate (3.89%), sodium azide (< 0.1%), and preservatives	2–8°C	until the expiration date on the pack label or 21 consecutive days after accessing the ancillary reagent pack

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

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

NOTE: Sodium azide can react with copper and lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent the buildup of azides, if disposal into a drain is in compliance with federal, state, and local requirements.

For Professional Use.

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

For *In Vitro* Diagnostic Use.

Loading Reagents

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

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

Load the primary reagent packs in the primary reagent area. You can use the arrows on the end label as a placement guide. However, left, center, and right placement of the primary reagent packs is not required, because the ADVIA Centaur CP System has only one reagent probe. The system automatically mixes the primary reagent packs to maintain homogeneous suspension of the reagents. For detailed information about loading reagents, refer to the system operating instructions or to the online help system.

If automatic dilution of a sample is required, load ADVIA Centaur Insulin Diluent in the ancillary reagent area.

Onboard Stability and Calibration Interval

Onboard Stability	Calibration Interval
42 days	42 days

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

- when changing lot numbers of primary reagent packs
- when replacing system components
- when quality control results are repeatedly out of range
- when you load a fresh primary reagent pack after the 42-day calibration interval is over.

NOTE:

- If you replace the primary reagent pack before the 42-day calibration interval is over, you do not need to recalibrate as long as the reagent pack is from the same lot.
- Discard the primary reagent packs at the end of the onboard stability interval.
- Do not use reagents beyond the expiration date.

Master Curve Calibration

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

Performing Quality Control

To monitor system performance and chart trends, as a minimum requirement, assay 2 levels of quality control material on each day that samples are analyzed. Assay quality control samples when performing a 2-point calibration. Treat all quality control samples the same as patient samples.

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

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

In addition, perform quality control:

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

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

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

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

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

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

Sample Volume

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 detailed information about determining the minimum required volume, refer to the system operating instructions or to the online help system.

NOTE: The sample volume required to perform onboard dilution differs from the sample volume required to perform a single determination. Refer to the following information for the sample volume required to perform onboard dilutions:

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

Assay Procedure

For detailed procedural information, refer to the system operating instructions or to the online help system.

Procedural Notes

Calculations

For detailed information about how the system calculates results, refer to the system operating instructions or to the online help system. The system reports insulin results in mU/L.

Dilutions

- Samples with insulin levels greater than 300 mU/L must be diluted and retested to obtain accurate results.
- Samples can be automatically diluted by the system or prepared manually.
- For automatic dilutions, ensure that Insulin Diluent is loaded and set the system parameters as follows:

  Dilution Setpoint: ≤ 300 mU/L

  Dilution factor: 2, 5

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

High Dose Hook Effect

Patient samples with high insulin levels can cause a paradoxical decrease in the RLUs (high dose hook effect). In this assay, patient samples with insulin levels as high as 3000 mU/L will assay greater than 300 mU/L.

Disposal

Dispose of hazardous and biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all federal, state, and local requirements.

Limitations

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.[9] Patients routinely exposed to animals or to animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis.

Insulin autoantibodies in human serum may interfere and cause discordant results.

Serum specimens that are . . .	Demonstrate ≤ 6% change in results up to . . .
hemolyzed	125 mg/dL of hemoglobin
lipemic	1000 mg/dL of lipid
icteric	20 mg/dL of bilirubin
proteinemic	12 g/dL of protein

Endogenous interfering substances were determined for the ADVIA Centaur Insulin assay on the ADVIA Centaur system.

Expected Results

The reference range was established on the ACS:180® system. Serum samples were obtained from 145 apparently healthy individuals who had normal hemoglobin A1c and glucose levels after a 12-hour fast. Ninety-five percent of the values for these individuals fell in the range of 3.0 to 25.0 mU/L with an overall range of 2.6 to 37.6 mU/L and a median value of 6.1 mU/L.

This study was not repeated on the ADVIA Centaur CP system. However, equivalence between the ADVIA Centaur CP system and the ACS:180 system was established in separate studies. Refer to *Method Comparison*.

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.[10]

Performance Characteristic

Specificity

The cross-reactivity of the ADVIA Centaur Insulin assay was determined by spiking serum samples with the following compounds at the indicated levels. These compounds did not have a significant effect on the insulin measurement.

Substance	Amount Added	Mean % Recovery
Proinsulin	1 µg/mL	100.8
C-peptide	500 ng/mL	95.1
Gastrin-1	1 µg/mL	96.6
Glucagon	1 µg/mL	100.2
Secretin	1 µg/mL	101.6

Interference testing was determined for the ADVIA Centaur Insulin assay, according to CLSI Document EP7-A2.[11]

Sensitivity and Assay Range

The ADVIA Centaur CP Insulin assay measures insulin concentrations up to 300 mU/L with a minimum detectable concentration of 0.5 mU/L. Analytical sensitivity is defined as the concentration of insulin that corresponds to the RLUs that are two standard deviations greater than the mean RLUs of 20 replicate determinations of the Insulin zero standard.

Method Comparison

For 225 serum samples in the range of 0.61 to 296.6 mU/L, the relationship between the ADVIA Centaur CP Insulin assay and the ADVIA Centaur Insulin assay is described by the equation:

ADVIA Centaur CP Insulin assay = 0.98 (ADVIA Centaur Insulin assay) + 0.07 mU/L

Correlation coefficient (r) = 0.996

For 50 serum samples in the range of 2.93 to 294 mU/L, the relationship between the ADVIA Centaur CP Insulin assay and the ACS:180 Insulin assay is described by the equation:

ADVIA Centaur CP Insulin assay = 1.03 (ACS:180 Insulin assay) + 1.81 mU/L

Correlation coefficient (r) = 0.980

Dilution Recovery

Five human serum samples in the range of 140.4 to 271.5 mU/L of insulin were serially diluted 1:2, 1:4, and 1:8 with Insulin Diluent and assayed for recovery and parallelism. The recoveries ranged from 83.1% to 118.1% with a mean of 94.4%.

Sample	Dilution	Observed (mU/L)	Expected (mU/L)	Recovery %
1	—	147.1		
	1:2	72.2	73.6	98.2
	1:4	32.9	36.8	89.4
	1:8	15.8	18.4	85.8
	Mean			91.1
2	—	140.4		
	1:2	72.8	70.2	103.7
	1:4	32.4	35.1	92.1
	1:8	15.5	17.6	88.2
	Mean			94.7
3	—	186.4		
	1:2	90.6	93.2	97.2
	1:4	41.4	46.6	88.7
	1:8	19.7	23.3	84.7
	Mean			90.2
4	—	205.8		
	1:2	99.4	102.9	96.6
	1:4	43.6	51.5	84.8
	1:8	21.4	25.7	83.1
	Mean			88.2
5	—	271.5		
	1:2	160.3	135.7	118.1
	1:4	90.6	80.2	113.0
	1:8	41.7	45.3	92.0
	Mean			107.7
Mean				**94.4**

Dilution recovery was determined for the ADVIA Centaur CP Insulin assay.

Spiking Recovery

Varying amounts of insulin were added to six serum samples with endogenous insulin levels ranging from 2.6 to 7.6 mU/L. The amount of insulin that was added varied from 25.7 to 51.4 mU/L. When compared to the expected value, the measured (recovered) values of insulin averaged 108.5% with a range of 103.8% to 113.8%.

Sample	Amount Added (mU/L)	Observed (mU/L)	Expected (mU/L)	Recovery %
1	—	2.9		
	25.7	30.3	28.6	105.9
2	—	2.6		
	51.4	58.4	53.9	108.3
3	—	4.8		
	25.7	33.2	30.5	108.9
4	—	4.3		
	51.4	61.3	55.7	110.1
5	—	8.1		
	25.7	35.1	33.8	103.8
6	—	7.2		
	51.4	66.7	58.6	113.8
Mean				**108.5**

Spiking recovery was determined for the ADVIA Centaur Insulin assay on the ADVIA Centaur system.

Precision

Precision was evaluated according to the CLSI protocol EP5-A2.[12] Three samples were assayed 4 times in each of 20 runs, on 2 ADVIA Centaur CP systems (n = 160 for each sample), over a period of 20 days. The following results were obtained:

Mean Insulin (mU/L)	Within-run % CV	Between-run % CV	Total % CV
13.81	2.4	1.8	3.0
76.62	2.4	2.1	3.2
142.31	2.8	1.8	3.3

Based on internal testing on the ADVIA Centaur CP system, the overall reproducibility is estimated to be ≤ 11% CV for samples tested and includes multiple reagent lots, instruments, days, and replicates. Performance of the assay at individual laboratories may vary.

Standardization

The ADVIA Centaur CP Insulin assay is standardized against World Health Organization (WHO) 1st IRP 66/304. Assigned values of calibrators are traceable to this standardization.

Technical Assistance

According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

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

siemens-healthineers.com

References

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11. Clinical and Laboratory Standards Institute (formerly NCCLS). *Interference Testing in Clinical Chemistry;* Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2005. NCCLS document EP7-A2.
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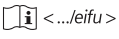
Definition of Symbols

The following symbols may appear on the product labeling:

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

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

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

[b] ISO 15223-1:2020-04

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

[d] IVDR REGULATION (EU) 2017/746

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

[f] Indicates Assay-eNote

Made by Minaris Medical Co., Ltd. for:

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