

# ARCHITECT

## SYSTEM



# en

### Insulin

**REF** 8K41

F5-Y202-2/R1

# Insulin

**Customer Service: Contact your local representative or find country specific contact information on [www.abbottdiagnostics.com](http://www.abbottdiagnostics.com)**

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used			
<b>REF</b>	List Number	<b>LOT</b>	Lot Number
<b>IVD</b>	<i>In Vitro</i> Diagnostic Medical Device		Expiration Date
	Store at 2-8°C	<b>REAGENT LOT</b>	Reagent Lot
	Consult instructions for use	<b>SN</b>	Serial Number
<b>CONTROL NO.</b>	Control Number	<b>REACTION VESSELS</b>	Reaction Vessels
<b>EC REP</b>	Authorized Representative	<b>SAMPLE CUPS</b>	Sample Cups
	Manufacturer	<b>SEPTUM</b>	Septum
		<b>REPLACEMENT CAPS</b>	Replacement Caps
		<b>ASSAY CD-ROM</b>	Assay CD-ROM

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.



**WARNING:** The Insulin assay value in a given specimen, as determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the Insulin assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining insulin levels serially is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies. These specimens should not be assayed with the ARCHITECT Insulin assay. Refer to the section **LIMITATIONS OF THE PROCEDURE** in this package insert.

#### NAME

ARCHITECT Insulin

#### INTENDED USE

The ARCHITECT Insulin assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of human insulin in human serum or plasma.

#### SUMMARY AND EXPLANATION OF TEST

Insulin is a polypeptide hormone (MW 6000) composed of two nonidentical chains, A and B, which are joined by two disulfide bonds. Insulin is formed from a precursor, proinsulin (MW 9000), in the beta cells of the pancreas. In proinsulin, the A and B chains are joined by a connecting peptide, referred to as the C-peptide. Both insulin and C-peptide are stored in secretory granules of the islet cells of the pancreas and are then secreted.<sup>1</sup>

Insulin secretion follows two basic mechanisms, tonic secretion and biphasic secretion.<sup>1</sup> The basal or tonic secretion is independent of stimulation by exogenous glucose but is modulated by the fluctuations in physiological levels of glucose. The biphasic secretion is primarily a direct response from stimulation by exogenous glucose. Stimulation of insulin secretion can be caused by many factors including hyperglycemia, glucagon, amino acids, and by complex mechanisms involving growth hormone or catecholamines.<sup>1</sup> Increased levels of Insulin are found with obesity, Cushing's Syndrome, oral contraceptives, acromegaly, insulinoma and hyperthyroidism.<sup>2,3</sup> Decreased levels of insulin are found in overt diabetes mellitus (although this may not be clearly expressed in early stages of the condition) and by part of a complex mechanism involving catecholamines.<sup>1</sup>

"Immunoreactive insulin" (IRI) is a term often used to refer to the component of circulating insulin and insulin-like biological activity which can be measured using antibodies against insulin. Insulinomas may produce various forms of insulin and proinsulin-like material and show total immunoreactive insulin at normal or elevated levels.<sup>4-8</sup> Since proinsulin and insulin both contain A and B polypeptide chains, there is a possible cross-reactivity with antibodies generated against insulin. The ARCHITECT Insulin assay shows no cross-reactivity with proinsulin ( $\leq 0.1\%$  at  $10^6$  pg/mL). Another possible interference is brought about by insulin antibodies which develop in patients treated with bovine or porcine insulin.<sup>9</sup>

Immunoassays for insulin have been widely used to provide supplementary information, first, for the diagnosis of diabetes mellitus and, second, for differential diagnosis of fasting hypoglycemia to discriminate between insulinoma and factitious hypoglycemia. In these applications, the ratio of immunoreactive insulin to blood glucose (I/G) may be more valuable than the insulin level alone.<sup>1</sup> Furthermore, a single random blood sample may provide insufficient information due to wide variations in the time responses of insulin levels and blood glucose which are found among individuals and various clinical conditions. Other uses of insulin assays have been suggested by the finding of an increase in risk factors for coronary artery disease among healthy persons with hyperinsulinemia and normal glucose tolerance.<sup>10</sup>

#### BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT Insulin assay is a one-step immunoassay to determine the presence of human insulin in human serum or plasma, using CMIA technology with flexible assay protocols, referred to as Chemiflex.

Sample, anti-insulin coated paramagnetic microparticles, and anti-insulin acridinium-labeled conjugate are combined. Insulin present in the sample binds to the anti-insulin coated microparticles and anti-insulin acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are then added to the reaction mixture; the resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of insulin in the sample and the RLUs detected by the ARCHITECT *i*\* optical system.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

\* *i* = immunoassay

#### REAGENTS

##### Reagent Kit, 100 Tests

##### ARCHITECT Insulin Reagent Kit (8K41)

- **MICROPARTICLES** 1 Bottle (6.6 mL) Microparticles: Antibody to human insulin (mouse, monoclonal) coated microparticles in MOPS buffer with protein (bovine) stabilizer. Minimum concentration: 0.08% solids. Preservatives: sodium azide and other antimicrobial agents.
- **CONJUGATE** 1 Bottle (5.9 mL) Conjugate: Acridinium-labeled antibody to human insulin (mouse, monoclonal) conjugate in MES buffer with protein (bovine) stabilizer. Minimum concentration: 0.09 µg/mL. Preservatives: sodium azide and other antimicrobial agents.

##### Other Reagents

##### ARCHITECT *i* Pre-Trigger Solution

- **PRE-TRIGGER SOLUTION** Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

##### ARCHITECT *i* Trigger Solution

- **TRIGGER SOLUTION** Trigger Solution containing 0.35N sodium hydroxide.

##### ARCHITECT *i* Wash Buffer

- **WASH BUFFER** Wash Buffer containing phosphate buffered saline solution. Preservative: antimicrobial agent.

#### WARNINGS AND PRECAUTIONS

- **IVD**
- For *In Vitro* Diagnostic Use
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.


##### Safety Precautions

- **CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens<sup>11</sup>, Biosafety Level 2<sup>12</sup> or other appropriate biosafety practices<sup>13,14</sup> should be used for materials that contain or are suspected of containing infectious agents.
- This product contains sodium azide; for a specific listing, refer to the **REAGENTS** section. Contact with acids liberates very toxic gas. This material and its container must be disposed of in a safe way.
- For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
- For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

##### Handling Precautions

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between reagent kits.**
- Before loading the ARCHITECT Insulin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
- To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
  - Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts, which have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

##### Storage Instructions

-  2°C - 8°C The ARCHITECT Insulin Reagent Kit must be stored at 2-8°C in an upright position and may be used immediately after removal from 2-8°C storage.
- When stored and handled as directed, reagents are stable until the expiration date.

- The ARCHITECT Insulin Reagent Kit may be stored on board the ARCHITECT *i* System for a maximum of 30 days. After 30 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored on or off the ARCHITECT *i* System. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

#### Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid and must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

#### INSTRUMENT PROCEDURE

- The ARCHITECT Insulin assay file must be installed on the ARCHITECT *i* System from the ARCHITECT *i* Assay CD-ROM (Addition C) prior to performing the assay. For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.
- The default result unit for the ARCHITECT Insulin assay is µU/mL. An alternate result unit, pmol/L, may be selected for reporting results by editing assay parameter "Result concentration units" to pmol/L. The conversion factor used by the system is 7.175.

#### SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

##### Specimen Types

The specimen collection tubes listed below were verified to be used with the ARCHITECT Insulin assay. Other specimen collection tubes have not been tested with this assay.

- Human serum (including serum collected in serum separator tubes)
- Human plasma collected in:
  - Potassium EDTA
  - Sodium heparin
  - Sodium EDTA
  - Sodium fluoride
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The ARCHITECT *i* System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the ARCHITECT Insulin assay.

##### Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - grossly hemolyzed
  - obvious microbial contamination
  - cadaver specimens or any other body fluids
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal results, inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

##### Preparation for Analysis

- Sample should be tested as soon as possible after drawing for the reason that the determined value may show lower levels because of insulin degrading enzyme existing in the red blood cell.
- Follow the tube manufacturer's processing instructions for serum and plasma collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens must be mixed THOROUGHLY after thawing, by vortexing. Thawed samples containing particulate matter, or which are hazy or cloudy in appearance, must be centrifuged prior to use to ensure consistency in the results.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.

- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.

#### Storage

- If testing will be delayed, serum or plasma should be removed from the clot, serum separator, or red blood cells. Specimens may be stored for up to 7 days at -10°C or colder prior to being tested.
- Avoid multiple freeze/thaw cycles.

#### Shipping

- Before shipping specimens, it is recommended that specimens be removed from the clot, red blood cells, or separator gel.
- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Specimens may be shipped on dry ice. Do not exceed the storage time limitations listed above.

#### PROCEDURE

##### Materials Provided:

- 8K41 ARCHITECT Insulin Reagent Kit

##### Materials Required but not Provided:

- ARCHITECT *i* System
- 6L81 ARCHITECT *i* [ASSAY CD-ROM] - US - Addition C
- 8K30 ARCHITECT *i* [ASSAY CD-ROM] - VWW (excluding US) - Addition C
- 8K41-02 ARCHITECT Insulin Calibrators
- 8K41-11 ARCHITECT Insulin Controls
- ARCHITECT *i* [PRE-TRIGGER SOLUTION]
- ARCHITECT *i* [TRIGGER SOLUTION]
- ARCHITECT *i* [WASH BUFFER]
- ARCHITECT *i* [REACTION VESSELS]
- ARCHITECT *i* [SAMPLE CUPS]
- ARCHITECT *i* [SEPTUM]
- ARCHITECT *i* [REPLACEMENT CAPS]
- Pipettes or pipette tips (optional)

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

##### Assay Procedure

- Before loading the ARCHITECT Insulin Reagent Kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles remain adhered to the bottle, continue inverting the bottle until the microparticles have been completely resuspended.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
  - Once the microparticles have been resuspended, place a septum on the bottle. For instructions on placing septums on bottles, refer to the **Handling Precautions** section of this package insert.
- Load the ARCHITECT Insulin Reagent Kit on the ARCHITECT *i* System.
  - Verify that all necessary assay reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present before running the test.
  - Priority: 150 µL for the first ARCHITECT Insulin test plus 24 µL for each additional ARCHITECT Insulin test from the same sample cup.
  - ≤ 3 hours on board: 150 µL for the first ARCHITECT Insulin test plus 24 µL for each additional ARCHITECT Insulin test from the same sample cup.
  - > 3 hours on board: additional sample volume is required. For information on sample evaporation and volumes, refer to the ARCHITECT System Operations Manual, Section 5.
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.

- Prepare calibrators and controls.
  - Mix ARCHITECT Insulin Calibrators and Controls by gentle inversion before use.
  - To obtain the recommended volume requirements for the ARCHITECT Insulin Calibrators and Controls, hold the bottles **vertically** and dispense 4 drops of each calibrator or 4 drops of each control into each respective sample cup.
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
- For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
- For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

#### Specimen Dilution Procedures

- Specimens with an insulin value exceeding 300 µU/mL are flagged with the code ">300.0" and may be diluted using either the Automated Dilution Protocol or the Manual Dilution Procedure.
- If the Automated Dilution Protocol is chosen, the system performs a 1:2 dilution of the specimen and automatically calculates the concentration of the undiluted specimen and reports the result.
- Manual dilutions should be performed as follows:
  - The suggested dilution for the ARCHITECT Insulin assay is 1:10.
  - For a 1:10 dilution, add 20 µL of the patient specimen to 180 µL of ARCHITECT Insulin Calibrator A (8K41-02).
  - To avoid contamination of Calibrator A, dispense several drops of Calibrator A into a clean test tube prior to pipetting.
  - The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The dilution should be performed so that the diluted result reads greater than 3.0 µU/mL.
- For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

#### Calibration

- To perform an ARCHITECT Insulin calibration, test Calibrators A, B, C, D, E and F in duplicate. A single sample of all levels of insulin controls must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrators should be priority loaded.
- Calibration Range: 0 - 300 µU/mL.
- Once an ARCHITECT Insulin calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used.
  - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

#### QUALITY CONTROL PROCEDURES

The recommended control requirement for the ARCHITECT Insulin assay is that a single sample of each control be tested once every 24 hours each day of use. If your laboratory quality control procedures require more frequent use of controls to verify test results, follow those procedures. Additional controls may be tested in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's quality control policy.

Each laboratory should establish control ranges to monitor the acceptable performance of the assay. If a control is out of its specified range, the associated test results are invalid and samples must be retested. Recalibration may be indicated.

#### Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

#### RESULTS

The ARCHITECT Insulin assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y weighted) to generate a calibration curve.

#### Alternate Result Units

- Conversion Formula: (Concentration in µU/mL) x (7.175) = pmol/L

#### Flags

- Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

#### Measurement Range (Reportable Range)

The measurement range for the ARCHITECT Insulin assay is 1.0 µU/mL to 300.0 µU/mL.

#### LIMITATIONS OF THE PROCEDURE

- If the insulin results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays.<sup>15</sup> 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.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA).<sup>16,17</sup> Specimens containing HAMA may produce anomalous values when tested with assay kits (such as ARCHITECT Insulin) that employ mouse monoclonal antibodies.<sup>17</sup>
- Insulin levels may be measured lower in patients with insulin autoimmune syndrome or familial high pro-insulinemia.
- Hemolyzed samples should not be used, since enzymatic degradation of insulin may occur and result in lower assay values.<sup>18,19</sup> However, purified hemoglobin up to 500 mg/dL has been shown not to interfere.
- Specimens from patients treated with bovine or porcine insulin may contain insulin antibodies which could show interference in the assay.<sup>9</sup>

#### EXPECTED VALUES

It is recommended that each laboratory establish its own normal range. The reference ranges vary between countries due to differences in body size and nutrition.

#### SPECIFIC PERFORMANCE CHARACTERISTICS

##### Precision

The ARCHITECT Insulin assay precision is ≤ 7% total CV. A study was performed as described in the National Committee for Clinical Laboratory Standards (NCCLS) Protocol EP5-A2.<sup>20</sup> Seven samples consisting of four serum based panels and three Insulin Controls were assayed in replicates of two at two separate times per day for twenty days (n=80 for each sample), using three lots of reagents. Data from this study are summarized in the following table.

Sample	Lot	Mean insulin (µU/mL)	Repeatability		Within-laboratory	
			SD	%CV	SD	%CV
Low Control	1	7.47	0.270	3.6	0.334	4.5
	2	7.61	0.322	4.2	0.395	5.2
	3	7.64	0.266	3.5	0.360	4.7
Medium Control	1	38.35	0.785	2.0	0.889	2.3
	2	37.80	0.647	1.7	1.041	2.8
	3	38.47	0.792	2.1	0.910	2.4
High Control	1	119.41	2.135	1.8	2.456	2.1
	2	118.56	2.198	1.9	2.507	2.1
	3	121.10	2.447	2.0	2.795	2.3
Panel 1	1	8.35	0.260	3.1	0.354	4.2
	2	8.66	0.261	3.0	0.399	4.6
	3	8.76	0.298	3.4	0.311	3.6
Panel 2	1	18.24	0.738	4.0	0.816	4.5
	2	18.38	0.381	2.1	0.656	3.6
	3	18.68	0.395	2.1	0.551	3.0
Panel 3	1	53.73	1.007	1.9	1.333	2.5
	2	53.19	1.185	2.2	1.528	2.9
	3	55.08	1.261	2.3	1.392	2.5
Panel 4	1	164.51	2.810	1.7	3.111	1.9
	2	164.19	3.286	2.0	3.540	2.2
	3	168.47	3.950	2.3	3.950	2.3

##### Recovery

Known amounts of human insulin were added to normal human serum and plasma samples. The concentration of insulin was determined using the ARCHITECT Insulin assay and the resulting percent recovery was calculated.

Sample Type	Recovery				
	Endogenous Level (μU/mL)	Insulin Added (μU/mL)	Insulin Observed (μU/mL)	Percent Recovery	
Serum	1	4.79	19.67	23.22	93.6
		4.79	60.57	60.30	91.6
		4.79	199.23	188.38	92.1
	2	13.72	19.67	32.44	95.1
		13.72	60.57	72.58	97.2
		13.72	199.23	200.24	93.6
	3	11.53	19.67	30.23	95.1
		11.53	60.57	68.07	93.4
		11.53	199.23	192.99	91.1
	4	5.01	19.67	23.86	95.8
		5.01	60.57	62.33	94.6
		5.01	199.23	190.64	93.2
	5	2.04	19.67	20.52	93.9
		2.04	60.57	59.12	94.2
		2.04	199.23	186.72	92.7
Plasma	1	6.00	19.67	25.26	97.9
		6.00	60.57	64.80	97.1
		6.00	199.23	193.50	94.1
	2	6.23	19.67	25.77	99.3
		6.23	60.57	67.78	101.6
		6.23	199.23	201.71	98.1
	3	8.77	19.67	27.59	95.7
		8.77	60.57	66.30	95.0
		8.77	199.23	194.45	93.2
	4	8.17	19.67	26.94	95.4
		8.17	60.57	63.57	91.5
		8.17	199.23	195.50	94.0
	5	6.11	19.67	24.54	93.7
		6.11	60.57	62.93	93.8
		6.11	199.23	190.73	92.7

$$\% \text{ Recovery} = \frac{\text{Insulin Observed } (\mu\text{U/mL}) - \text{Endogenous Level } (\mu\text{U/mL})}{\text{Insulin Added } (\mu\text{U/mL})} \times 100$$

#### Analytical Sensitivity

Analytical sensitivity is defined as the lower limit of detection and is estimated as the mean of the blank sample plus 2 times the SD obtained from the blank sample. The ARCHITECT Insulin assay is designed to have a sensitivity of  $\leq 1.0 \mu\text{U/mL}$ .

#### Specificity

The specificity of the ARCHITECT Insulin assay was determined by testing sera containing the compounds listed below. These compounds showed less than 10% interference in the ARCHITECT Insulin assay at the levels indicated.

Test Compound	Test Concentration
Bilirubin	20 mg/dL
Hemoglobin	500 mg/dL
Total Protein	12 g/dL
Triglycerides	3000 mg/dL

The cross-reactivity with Proinsulin (1,000,000 pg/mL), with C-Peptide (10,000,000 pg/mL) and with Glucagon (10,000,000 pg/mL) was determined as below in the ARCHITECT Insulin assay.

Substance	Concentration	Cross-reactivity (%)
Proinsulin	$10^6$ pg/mL	$\leq 0.1$
C-Peptide	$10^7$ pg/mL	$\leq 0.001$
Glucagon	$10^7$ pg/mL	$\leq 0.001$

#### Carryover

No detectable carryover (less than  $0.5 \mu\text{U/mL}$ ) was observed when a sample containing  $15,000 \mu\text{U/mL}$  of insulin was assayed.

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