Hướng dẫn sử dụng tiếng Anh

TP. Hồ Chí Minh, ngày 24 tháng 02 năm 2026

Giám đốc

Digitally signed by CÔNG TY TNHH TM DV VINH TÍN

Phạm Ngọc Dũng

en

Immunoassay

REF	CMG0101	CMG0102	CMG0103	CMG0104	CMG0105
Size	50 tests*1	100 tests*1	100 tests*2	100 tests*5	50 tests*2
REF	CMG0106	CMG0107	CMG0108	CMG0109	CMG0110
Size	50 tests*1 (S)	100 tests*1 (S)	100 tests*2 (S)	100 tests*5 (S)	50 tests*2 (S)

Insulin CLIA Microparticles

Key to Graphical Symbols Used

LOT	batch code		use by
	manufacturer	Σ	contains sufficient for <n> tests
IVD	*in vitro* diagnostic medical device		temperature limitation
REF	catalogue number		consult instructions for use
EU REP	authorized representative in the European Community		date of manufacture
UDI	unique device identification		

EU REP
QbD RepS BV
Groenenborgerlaan 16
2610 Wilrijk
Belgium

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IVD

For any technical assistance please contact us in English via Email: customerservice@autobio.com.cn

Contact your local dealers for all product related questions in your local language

Intended Purpose

The Insulin CLIA Microparticles assay is based on the fully automated chemiluminescent microparticle immunoassay (CLIA Microparticles) system for the quantitative determination of Insulin in human serum. Serum insulin determinations are performed on patients with symptoms of hypoglycemia and may be useful in classifying the different types of diabetes.

Summary

The pancreas is located behind the lower part of the stomach. It makes insulin and enzymes that help the body digest and use food. Throughout the pancreas are clusters of cells called the islets of Langerhans. Islets are made up of several types of cells, including beta cells that make insulin. Insulin is a hormone that helps the body use glucose for energy.

Human insulin is a peptide hormone composed of 51 amino acids and has a molecular weight of 5808 daltons.[1]

Insulin levels are most frequently ordered following a low glucose and/or when someone has acute or chronic symptoms of low blood sugar (hypoglycemia), Insulin and C-peptide are produced by the body at the same rate as part of the conversion of proinsulin to insulin in the pancreas. Both may be ordered to evaluate how much insulin in the blood is made by the body (endogenous) and how much is from exogenous sources. The test for insulin measures insulin from both sources while the C-peptide test reflects insulin produced by the pancreas (endogenous insulin).

Insulin concentrations tend to be higher in obese individuals, particularly those with an increased proportion of visceral (abdominal) fat.[2,3]

Measurement of circulating insulin concentrations may be useful in the diagnostic evaluation of several conditions.[4] High circulating insulin concentrations may be involved in the pathogenesis of hypertension and cardiovascular disease. Conversely, low insulin concentrations in the presence of hyperglycemia suggest insulin-deficiency, e.g. insulin-dependent or Type 1 diabetes mellitus. Measurement of immediate or first-phase insulin secretion after an acute glucose load may be predictive of Type 1 diabetes mellitus.[5]

Measurement Principle

This assay is based upon the one-step sandwich method. The sample, Insulin antibodies coated microparticles and enzyme-labeled Insulin antibodies are combined. During the incubation, Insulin present in the sample is allowed to react simultaneously with the two antibodies, resulting in the Insulin being sandwiched between the coated microparticles and enzyme-linked antibodies. After washing, a complex is generated among the coated microparticles-antibodies, the Insulin within the sample and enzyme-linked antibodies by immunological reactions. Chemiluminescent Substrate are then added and catalyzed by this complex, resulting in a chemiluminescent reaction. The resulting chemiluminescent reaction is measured as RLUs. The RLU is proportional to the concentration of Insulin in the patient sample.

Materials provided

Reagent pack provided ready to use

Components	With AutoLumo Insulin Calibrators				
Size	50 tests*1	100 tests*1	100 tests*2	100 tests*5	50 tests*2
Microparticles Solution	1.2mL	2.3mL	2.3mL*2	2.3mL*5	1.2mL*2
Enzyme Conjugate	3.0mL	5.5mL	5.5mL*2	5.5mL*5	3.0mL*2
AutoLumo Insulin Calibrators	1 set (Calibrator A and B: 2 vials of lyophilized calibrators; The matrix is Tris-NaCl buffer with BSA containing antigen for Insulin, 0.003% ProClin® 300 and 0.1% Bronidox preservative) 【Reconstitute the contents of Calibrator A and Calibrator B with exactly 1.0 mL distilled or deionized water. Allow the vial to stand closed for 15-30 minutes. Mix gently by inversion to ensure homogeneity.】				
Insulin Controls	1 set	2 sets			
	Each set containing 1 vial of lyophilized QC 1 and 1 vial of lyophilized QC 2; Tris-NaCl buffer with BSA				

	containing antigen for Insulin, 0.003% ProClin® 300 and 0.1% Bronidox preservative. 【Reconstitute the contents of QC 1 and QC 2 with exactly 1.0 mL distilled or deionized water. Allow the vial to stand closed for 15-30 minutes. Mix gently by inversion to ensure homogeneity.】				
Code card	2	2	2	2	2
IFU	1	1	1	1	1
Components	**Without AutoLumo Insulin Calibrators**				
Size	50 tests*1 (S)	100 tests*1 (S)	100 tests*2 (S)	100 tests*5 (S)	50 tests*2 (S)
Microparticles Solution	1.2mL	2.3mL	2.3mL*2	2.3mL*5	1.2mL*2
Enzyme Conjugate	3.0mL	5.5mL	5.5mL*2	5.5mL*5	3.0mL*2
Insulin Controls	1 set	2 sets			
	Each set containing 1 vial of lyophilized QC 1 and 1 vial of lyophilized QC 2; Tris-NaCl buffer with BSA containing antigen for Insulin, 0.003% ProClin® 300 and 0.1% Bronidox preservative. 【Reconstitute the contents of QC 1 and QC 2 with exactly 1.0 mL distilled or deionized water. Allow the vial to stand closed for 15-30 minutes. Mix gently by inversion to ensure homogeneity.】				
Code card	2	2	2	2	2
IFU	1	1	1	1	1

Note: Volume provided is the minimum filling volume

Reagent Pack information

Microparticles Solution	Mouse monoclonal anti-Insulin coated microparticles in BIS-Tris Propane buffer containing BSA with 0.003% ProClin® 300 and 0.2% NaN_3 preservatives.
Enzyme Conjugate	Horseradish-peroxidase labeled mouse monoclonal anti-Insulin in Tris-NaCl buffer containing BSA with 0.006% ProClin® 300 and 0.02% IPBC-II preservatives.

Assay Analyzers on which the kit can be used

- AutoLumo A2000 Plus (REF:07021)
- AutoLumo A1000 (REF:07031)
- AutoLumo A1820 (REF:07072)
- AutoLumo A1860 (REF:07073)
- AutoLumo A6200 (REF:07062)
- AutoLumo A6600 (REF:07063)
- AutoLumo S900 (REF:07091)
- AutoLumo S920 (REF:07092)
- AutoLumo S960 (REF:07093)
- AutoLumo S980 (REF:07094)

The chemiluminescent microparticle immunoassay (CLIA Microparticles) is intended for use on Assay Analyzer which is AutoLumo A2000 Plus, AutoLumo A1000, AutoLumo A1820, AutoLumo A1860, AutoLumo A6200, AutoLumo A6600, AutoLumo S900, AutoLumo S920, AutoLumo S960, AutoLumo S980.

Materials Required but not Provided

1. Assay Analyzer
2. Reaction vessel(s) for sample and reagent reaction
3. Sample cup(s) or tube(s) for sample containing
4. Diluent Universal ([REF] CMO0201/CMO0202)
5. Chemiluminescent Substrate ([REF] CMO0101/CMO0102/CMO0103)
6. System Wash for washing the pipetting needles ([REF] CMO0401/ CMO0403)
7. Wash Buffer used in the washing procedure ([REF] CMO0301/CMO0302 CMO0303/CMO0304/CMO0305/CMO0306)
8. General laboratory equipment
9. AutoLumo Insulin Calibrators (only CMG0106/CMG0107/CMG0108/CMG0109/CMG0110 apply)

Metrological Traceability of Calibrators

This method has been standardized against the WHO 1st Reference Standard 83/500.

Warnings and Precautions

For AutoLumo Insulin Calibrators, Insulin Controls, Microparticles Solution and Enzyme Conjugate, which all contain reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3- one (3:1), the following statements apply:

GHS 07
Warning

H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
P261Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

1. For professional laboratory use. For *In Vitro* Diagnostic Use.
2. Follow the instruction for use carefully. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this instruction for use.
3. Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
4. Refer to the material safety data sheet and product labeling for any chemical hazards that may be present in this assay.
5. Handle the potentially contaminated materials and wastes safely according to local requirement.
6. CAUTION: It is recommended that all materials of animal origin be considered potentially infectious. This assay contains materials of animal origin. Bovine components originate from countries where BSE has not been reported.
7. Do not smoke, drink, eat or use cosmetics in the working area.
8. Wear protective clothing and disposable gloves when dealing with samples and reagents. Wash hands after operations.
9. Use caution when handling patient samples to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
10. Conduct the assay away from bad ambient conditions. e.g. ambient air containing high concentration corrosive gas such as sodium hypochlorite acid, alkaline, acetaldehyde and so on, or containing dust.
11. Do not use reagents beyond the labeled expiry date.
12. Do not mix or use components from kits with different batch codes.
13. When storing the calibrators, be certain the vials are securely sealed.
14. Ensure the microparticles are re-suspended before loading it on the analyzer.
15. Avoid foam formation in all reagents and samples.
16. Do not substitute any reagent in this kit from other manufacturers.
17. When any damage to the protective packaging is observed, do not use the kit.
18. Any serious incident shall be reported to manufacturer and competent authority of the Member State in which user and/or patient is established.

19. Only trained and experienced persons can perform this assay. The measurement procedure described in the instruction for use supplied by this assay should be used for the training.

Storage

1. Store the unopened kit at 2-8 ℃ up to the stated expiration date. Do not freeze. Avoid strong light.
2. Refrigerate the reagent pack at 2-10℃ for a minimum of 2 hours prior to use.
3. Store the unsealed reagents pack upright on the analyzer for a maximum of 28 days. Once they are removed from the analyzer, store them in the refrigerator in an upright position.
4. Seal and return the reconstituted calibrators at 2-8 ℃ immediately after the experiment, under which conditions the stability will be retained for 2 months. For longer use, it should be divided into aliquots as needed and stored below -20°C, under which condition the stability will be retained for 3 months, but avoid multiply freeze-thaw cycles.
5. Seal and return the remaining controls at 2-8°C immediately after the experiment, under which conditions the stability will be retained for 2 months. For longer use, store the reconstituted controls at -20°C for no more than 3 months. Avoid multiple freeze-thaw cycles.

Sample

1. Human serum (plain tube, coagulation tube and separation gel tube) could be used for this assay.
2. Collect venous blood in accordance with correct medical practices.
3. Do not use heat-inactivated samples. Do not use sodium azide preservative in samples.
4. Sediments and suspended solids in samples may interfere with the test result which should be removed by centrifugation. Ensure that complete clot formation in serum samples has taken place prior to centrifugation. Some samples, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the sample is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results. Be sure that the samples are not decayed prior to use.
5. Prior to shipment, it is recommended that samples be removed from the clot, serum separator or red blood cells.
6. Insufficient processing of sample or disruption of the sample during transportation may cause depressed results.
7. Avoid grossly hemolytic, lipemic or turbid samples.
8. Centrifuge the thawed samples containing red blood cells or particulate matter, or which are hazy or cloudy in appearance prior to use to ensure consistency in the results.
9. Note that interfering levels of fibrin may be present in samples that do not have obvious or visible particulate matter.
10. If proper sample collection and preparation cannot be verified, or if samples have been disrupted due to transportation or sample handling, an additional centrifugation step is recommended. Centrifugation conditions should be sufficient to remove particulate matter.
11. For optimal results, inspect all samples for bubbles. Remove bubbles with a tip prior to analysis. Use a new tip for each sample to prevent cross contamination.
12. When processing samples in primary tubes, follow the instructions of the tube manufacturer.

Sample storage

Cap and store the samples at room temperature for no more than 8 hours, for longer use samples should be capped and stored at 2-8 ℃ up to 48 hours. Or freeze the samples that need to be stored or transported for more than 48 hours at -20 ℃. Avoid multiple freeze-thaw cycles. Mix thawed samples thoroughly by low speed vortex or by inverting 10 times. Visually inspect the samples, if layering or stratification is observed, continue mixing until samples are visibly homogeneous. After thawing, bring to room temperature and mix well by gently shaking.

Measurement Procedure

1. Check the consumable materials

- Verify adequate volume of consumable materials is present prior to running the test.
- Refer to the Assay Analyzer's operation manual.

2. Load the kit

- Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the analyzer until it is well mixed. Don't invert the opened (punctured) packs. If necessary, shake gently to mix horizontally after the first loading. Please avoid bubbles during mixing.
- Scan the code card of the reagent pack to automatically obtain the required parameters for the test.
- If the code cannot be read in exceptional cases, they can be recognized manually.
- Refer to the Assay Analyzer's operation manual.

3. Calibration

- Scan the code card to automatically obtain the required parameters for the test.
- Transfer the calibrators into the sample cups or tubes and place them on the sample position.
- Load the sample cups or tubes and input calibration information on the system software interface.
- Select "run" to start the test and the calibration curve of the system is determined, calibration is required every 28 days.
- Renew the calibration under the following situations:
  - A reagent kit with new batch code is used
  - Beyond the expiration date of a calibration curve
  - Important parts of the analyzer are replaced or repaired
  - Other cases requiring re-calibration
- Refer to the Assay Analyzer's operation manual.

4. Quality Control

Quality control materials are essential for monitoring the system performance of immunochemical assays. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Quality control results that do not fall within acceptable ranges may indicate invalid test results.

Use the quality control procedure on the system, which could be performed automatically.

- Scan the code card to automatically obtain the essential information for the test.
- Select quality control procedure on the system software interface and click "run" to start the test

Note:

- The quality controls must be tested using quality control procedure, otherwise it will result in incorrect results.
- The quality control should be re-established if the control and/or reagent lot is changed.
- Different batches of Controls should not be cross-used.
- When the Controls fail to fall within the expected control interval, associated test results may be invalid and may require retesting. Assay retest may be necessary.

It is recommended that each laboratory develops its suitable quality control program complying with applicable government regulations and local guidelines.

5. Order tests

- Place the sample cups or tubes on the sample position. And for the minimum sample volume required, please refer to the Assay Analyzer's manual.
- Load the sample cups or tubes and input the sample information on the system software interface.
- Select "run" to start the test, the analyzer automatically operates tests.

  Refer to the Assay Analyzer's operation manual.

6. Dilute the sample

- This test measures concentrations within the range of 0.5-300 μIU/mL. If Insulin concentrations above the measuring range to be expected, it is recommended to dilute samples with Diluent Universal, the recommended dilution is 1:4 of this test, under this condition, allowing samples to be up to approximately 1500 μIU/mL. Samples may be diluted manually or automatically:

  • For manually dilution, Diluent Universal sample is used to dilute the samples. After dilution, multiply the result by the

dilution factor.

• For automatic dilution, samples may be diluted with the program of the analyzer. Diluent Universal is used to dilute the samples. The software automatically takes the dilution into account when reporting the result.

Measurement Results

The sample test results are determined automatically by the system software. The amount of Insulin in the samples is determined from the measured light production by means of the stored calibration data. Refer to the Assay Analyzer's operation manual on reviewing the stored data. The Insulin result alone is not conclusive for diabetes and need to be combined with the patient's physical signs and other test results.

Conversion formula: µIU/mL × 6.945 = pmol/L

pmol/L × 0.144 = µIU/mL

Reference Interval

Normal range (the 2.5th and 97.5th percentiles) of 1.5 – 25 µIU/mL was obtained by testing serum samples from 182 individuals from fasting males and females defined as normal by a clinician. It is recommended that each laboratory establish its own normal range which may be unique to the population it serves depending upon geographical, patient, dietary, or environmental factors.

Limitations of the Procedure

1. This assay is intended as an aid for the clinical diagnosis. Conduct this assay in conjunction with clinical examination, patient's medical history and other test results.
2. If the results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
3. Heterophilic antibodies and rheumatoid factors in samples may interfere with test results. Heterophilic antibodies in human serum can react with reagent immunoglobulin, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis. This kind of samples is not suitable to be tested by this assay.
4. Patients who have received mouse monoclonal antibodies for either diagnosis or therapy can develop HAMA (human Anti-mouse antibodies). HAMA can produce either falsely high or falsely low values in immunoassays which use mouse monoclonal antibodies. Additional information may be required for diagnosis.

Performance Characteristics

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

1. Trueness

The WHO reference standard was used and diluted into 3 different concentrations respectively. These samples were tested in replicates using 1 reagent lot. Data from this study are summarized in the following table.

Concentration (µIU/mL)	Replicate 1	Replicate 2	Mean	Bias
5	4.78	4.8	4.79	-4.20%
20	20.56	20.12	20.34	1.70%
50	52.34	52.26	52.3	4.60%

2. Measurement Precision

A study based on CLSI EP5-A3 using clinical samples and control matrix samples spiked with high-value of Insulin antigen into 3 concentrations(high, medium and low). 3 human serum clinical samples (1, 2 and 3) and 3 control matrix samples (4, 5 and 6) were prepared and assayed. Each sample was tested twice a day with 2 hours apart in duplicate for 20 days using one instrument and 3 reagent lots. Data from this study are summarized in the following table.*

Sample type	Sample No.	Sample Conc. (µIU/mL)	Reagent batch No.	n	Repeatability (%)	Within-laboratory precision (%)
Clinical sample	1	19.58	1	80	3.01	3.86
	2	70.86	1	80	3.11	4.28
	3	103.68	1	80	3.14	4.75
Quality control sample	4	11.57	1	80	1.43	3.04
	5	58.83	1	80	1.94	3.24
	6	143.806	1	80	1.64	3.47
Clinical sample	1	19.58	2	80	3.09	4.83
	2	70.86	2	80	3.01	5.02
	3	103.68	2	80	3.76	4.96
Quality control sample	4	11.57	2	80	1.86	4.35
	5	58.83	2	80	2.00	3.25
	6	143.806	2	80	1.97	4.29
Clinical sample	1	19.58	3	80	3.05	3.74
	2	70.86	3	80	3.46	3.95
	3	103.68	3	80	3.18	3.99
Quality control sample	4	11.57	3	80	2.60	3.78
	5	58.83	3	80	2.50	3.71
	6	143.806	3	80	2.61	4.01

*Representative data; results in individual laboratories may vary from these data

3. Sensitivity

Limit of Blank: 0.1 µIU/mL.

Limit of Detection: 0.3 µIU/mL.

Limit of Quantitation: 0.5 µIU/mL.

4. Analytical Specificity

Cross reaction: A study was performed to evaluate the potential cross-reactivity of the assay with other substances that are similar in structure to Insulin. Serum samples were spiked with multiple concentrations of the substance below.

Samples containing substances at the concentrations listed below do not affect the concentration of Insulin reported.

Substances	Concentration tested	Cross-reactivity %
C-Peptide	10 µg/mL	n.d.*
Glucagon	10 µg/mL	n.d.
Somatomedin (Insulin-like growth factor 1-IGF-1)	10 µg/mL	0.035
Porcine insulin	0.5ng/mL	95.9

n. d. = not detectable

The concentrations of proinsulin and split products of fasting healthy subjects are 100 times lower than the C-peptide concentrations and therefore the cross-reactivity is of no clinical significance.

Interference: The effect of the following endogenous substances on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances	Concentration tested
Bilirubin	60 mg/dL
Hemoglobin	250 mg/dL
Triglycerides	3000 mg/dL

The effect of the following clinical drugs on assay performance was tested. Interferences were tested up to the listed concentrations and different degrees of interference on results was observed.

Clinical drugs	Concentration tested
Humulin 70/30	100 µIU/mL
Novolin N	100 µIU/mL
Novolin 30R	100 µIU/mL
Novolin R	100 µIU/mL
Insulin glargine	100 µIU/mL
Insulin aspart	100 µIU/mL
Insulin detemir	100 µIU/mL

Insulin lispro	100 μIU/mL

5. Method Comparison

A comparison study was performed where samples were tested using this assay and a commercially available immunoassay kit. Data were analyzed and are summarized in the following table.

Correlation Method	Number of Samples	Range of tested samples (μIU/mL)	Total coincidence rate
Linear Regression	245	0.5-300	0.9973

6. High Dose Hook Effect

There is no high-dose hook effect at Insulin concentrations up to 20000μIU/mL.

Literature References

1. Chopra IJ, Ho RS, Lam R. An improved radioimmunoassay of triiodothyronine in serum: its application to clinical and physiological studies. *J. Lab. Clin. Med*. 1972;80(5):729-739.

2. Young DS. Effects of drugs on clinical laboratory tests. *Ann. Clin. Biochem*. 1997;34(Pt 6):579-581.

3. Santini F, Pinchera A, Ceccarini G, et al. Evidence for a role of the type III-iodothyronine deiodinase in the regulation of 3,5,3'-triiodothyronine content in the human central nervous system. *Eur. J. Endocrinol.* 2001;144(6):577-583.

4. Nikkilä EA, Kekki M. Plasma triglyceride metabolism in thyroid disease. *J. Clin. Invest.* 1972;51(8):2103-2114.

The Summary of Safety & Performance (SSP) Report can be found here: https://ec.europa.eu/tools/eudamed; If not available, please email us using email address in the first page of IFU.