



C-Peptide Fast Test Kit (Immunofluorescence Assay)

Instructions for Use

INTENDED USE

C-Peptide Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of C-Peptide in human serum and plasma samples. The test is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion.

For professional and laboratory use only.

SUMMARY

C-Peptide is a 31-amino acid polypeptide with a molecular weight of approximately 3020 Da. During insulin biosynthesis, pancreatic β -cells cleave proinsulin into insulin and C-Peptide, which are released into the bloodstream in a 1:1 ratio. Since C-Peptide is minimally extracted by the liver and is primarily metabolized and excreted by the kidneys, it has a longer half-life (about 35 minutes) than insulin, making it a more stable indicator of β -cell secretory function.

C-peptide is a key biomarker for pancreatic β -cell function. Decreased levels indicate impaired insulin secretion (e.g., type 1 diabetes) or exogenous insulin suppression, while elevated levels suggest β -cell hyperfunction (e.g., insulinoma). In hypoglycemia evaluation, it complements insulin testing and helps distinguish endogenous hyperinsulinemia (elevated C-peptide) from exogenous insulin administration (non-elevated). For patients with anti-insulin antibodies, C-peptide reliably assesses residual β -cell function. This assay enables longitudinal monitoring of diabetes progression, indirect assessment of endogenous insulin secretion, and informs clinical decision-making regarding therapeutic strategies.

PRINCIPLE

The C-Peptide Fast Test Kit (Immunofluorescence Assay)

is a lateral flow immunoassay based on a sandwich design. After the sample is applied to the test strip, the fluorescently labeled anti-C-Peptide antibody binds to target C-Peptide molecules in the sample, forming a labeled antigen-antibody complex. The complex migrates through capillary action to the detection zone, where it is captured by another anti-C-Peptide antibody coated on the nitrocellulose membrane, ultimately forming a fluorescent double-antibody sandwich complex. The fluorescence intensity at the test line demonstrates a proportional correlation with the C-Peptide concentration in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the C-Peptide in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/Getein 1150/Getein 1180		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2x12 T/kit	2x24 T/kit	2x48 T/kit
C-Peptide test card	10 pcs	25 pcs	10 pcs	25 pcs	2 cartridges, 12 pcs in each	2 cartridges, 24 pcs in each	2 cartridges, 48 pcs in each
Disposable pipet	10 pcs	25 pcs	10 pcs	25 pcs	/	/	/
Sample diluent	10 tubes	25 tubes	10 tubes	25 tubes	1 box	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	/	/	1 pc in each cartridge	1 pc in each cartridge	1 pc in each cartridge

- Main key components in the kit
 - Fluorescently labelled anti-C-Peptide antibody and anti-C-Peptide antibody.
- Main key components in Sample diluent for Getein 1100/Getein 1150/Getein 1160/Getein 1180
 - Phosphate buffer (20 mmol/L), NaN_3 (< 0.1%).
- Main key components in Sample diluent for Getein 1600/Getein 1200
 - Phosphate buffer (20 mmol/L), NaN_3 (< 0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1200);
 - Box with pipette tips (96 tips/box);
 - Mixing plate (1 piece/box).

Note:

- The SD card, also known as the standard curve data card, stores standard curve data for the specific test items and uses RFID technology to transfer the data to

- analyzer via touch.
- The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
- Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
 Getein 1150 Immunofluorescence Quantitative Analyzer
 Getein 1160 Immunofluorescence Quantitative Analyzer
 Getein 1180 Immunofluorescence Quantitative Analyzer
 Getein 1200 Immunofluorescence Quantitative Analyzer
 Getein 1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4-30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1150/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/ Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Do not reuse the test card and disposable pipet.
- Handle all specimens as potentially infectious. The foil bag is non-degradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- This test can be used for serum and plasma. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
- Serum and plasma are stable for 4 hours at room temperature (15–30°C), 3 days at 2–8°C, and 1 month at -20°C.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- SAMPLE VOLUME (for Getein 1100/Getein 1150/Getein 1160/Getein 1180):** 100 μL .

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver **100 μL** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop **100 μL** of sample mixture into the sample well on the test card.
- Reaction time: 15 minutes.** After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
- Select the corresponding sample type on the analyzer (refer to the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use. Horizontally place the test card.
- Deliver **100 μL** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop **100 μL** of sample mixture into the

sample well on the test card.
 5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1150:

- 1) Turn on the instrument and enter the sample test interface. Insert the test card and scan the QR code (**On the outer packaging box**) to complete calibration as prompted by the instrument.
- 2) Select the corresponding "Sample" mode on the analyzer (refer to the analyzer user manual for details).
- 3) Deliver **100 µL** of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop **100 µL** of sample mixture into the sample well on the test card.
- 4) Press the "Start" button immediately after sample loading. The analyzer will initiate a 15-minute reaction countdown, and the test results will be automatically displayed on the screen upon completion.

For Getein 1200/Getein 1600:

- 1) Place the reagent cartridge in the cartridge zone. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- 2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- 3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument. Getein 1200/Getein 1600 will do the testing and print the result automatically.

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Concentration (Max)
Hemoglobin	5 g/L
Triglyceride	25 g/L
Bilirubin	0.1 g/L

EXPECTED VALUE

The expected normal value for C-Peptide and was determined by testing samples from 286 apparently healthy individuals. The reference range of C-Peptide is 1.10 ng/mL- 4.40 ng/mL calculated by using normal distribution methods (5th to 95th percentile). Each laboratory should verify the transferability of the expected values to its own population, and if necessary, determine its own expected values according to good laboratory practice.

PERFORMANCE CHARACTERISTICS

Measuring range	0.05 ng/mL- 30.00 ng/mL
Limit of Detection	≤ 0.05 ng/mL
Within-run Precision	≤ 10%
Between-lot Precision	≤ 15%

REFERENCES

1. Clark P M. Assays for insulin, proinsulin(s) and C-peptide. Annals of Clinical Biochemistry, 1999, 36 (Pt 5) (5):541-564.
2. Toern C .C-peptide and autoimmune markers in diabetes. Clinical Laboratory, 2003, 49(1-2):1-10.
3. Vanbuecken D E, Greenbaum C J. Residual C-peptide in type 1 diabetes: what do we really know? Pediatric Diabetes, 2014, 15(2):84-90.
4. Maddaloni E, Bolli G B, Frier B M, et al. C-peptide determination in the diagnosis of type of diabetes and its management: A clinical perspective. Diabetes, obesity & metabolism, 2022, 24(10):1912-1926
5. Leighton E, Sainsbury C A R, Jones G C. A practical review of C-Peptide testing in diabetes. Diabetes therapy, 2017, 8(3): 475-487.
6. Funakoshi S, Fujimoto S, Hamasaki A, et al. Utility of indices using C - peptide levels for indication of insulin therapy to achieve good glycemic control in Japanese patients with type 2 diabetes. Journal of diabetes investigation, 2011, 2(4): 297-303.
7. Rubenstein AH, Kuzuya H, Horwitz DL. Clinical Significance of Circulating C-Peptide in Diabetes

Mellitus and Hypoglycemic Disorders. Arch Intern Med. 1977;137(5):625–632.

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on C-Peptide Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Keep dry
	Keep away from sunlight		Caution
	Unique device identifier		

Thank you for purchasing C-Peptide Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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