GP

CE IVD

Insulin

Fast Test Kit

(Immunofluorescence Assay)

Instructions for Use

INTENDED USE

Insulin Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of insulin in human serum and plasma samples. This test is used to aid in the diagnosis of glucose metabolism disorders and the evaluation of pancreatic islet function. For professional and laboratory use only.

SUMMARY

Insulin is a 51-amino acid, disulfide-linked polypeptide secreted by pancreatic β-cells. Its secretion is a highly regulated physiological process primarily controlled by blood glucose levels, while also being influenced by neural, hormonal and nutritional signals. Serum insulin testing is primarily indicated for patients presenting with hypoglycemic symptoms and serves as an adjunct in differentiating diabetes mellitus subtypes. In type I diabetes mellitus, pancreatic β-cell function is severely impaired, with near-total absence of endogenous insulin secretion, necessitating exogenous insulin administration to maintain glycemic control and sustain normal glucose metabolism. In contrast, patients with type II diabetes or other diabetes subtypes retain insulin secretory capacity, though they may exhibit either insufficient insulin secretion or develop insulin resistance. In the former case, circulating insulin levels may be subnormal, while in the latter, cells develop insulin resistance and fail to effectively utilize endogenous insulin, typically resulting in normal or elevated serum insulin concentrations (due to compensatory hyperinsulinemia by the pancreas to maintain glucose homeostasis, albeit with progressively diminishing efficacy).

Measuring the level of Insulin in serum/plasma helps evaluate pancreatic β-cell function and provides valuable reference for diabetes classification and insulin resistance research.

PRINCIPLE

Insulin Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay designed in a sandwich format. After the sample is applied to the test strip, the fluorescence labelled Insulin monoclonal antibody binds with the Insulin in the sample to form a marked antigen-antibody complex. This complex moves to the detection zone on the test card by capillary action and is captured by another Insulin monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of Insulin in the sample. The fluorescent signal intensity can then be analyzed by an appropriate device to quantitatively detect the Insulin in the sample.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1150		Getein 1200/Getein 1600		
	10 T/kit	25 T/kit	10 T/kit	25 T/kit	2×12 T/kit	2×24 T/kit	2×48 T/kit
Insulin 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	/	/	/
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

- Fluorescence labelled Insulin monoclonal antibody, Insulin monoclonal antibody.

Consumables for Getein 1200/Getein 1600

- Box with pipette tips (96 tips/box)
- Mixing plate (1 piece/box)

Note:

1. 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 analyzers via touch.
2. The standard curve data for Getein 1150 is written to the QR code on the outer packaging box.
3. 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 exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Do not reuse the test card and disposable pipet.
6. 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.
7. 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

1. This test can be used for serum and plasma samples.
2. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma samples. Samples should be free of hemolysis.
3. It is recommended to test the sample within 4 hours after collection. If testing is delayed, serum and plasma samples are stable for 2 days when stored at 2–8°C and 6 months when stored at -20°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.
5. SAMPLE VOLUME (**for Getein 1100/Getein 1150/Getein 1160/Getein 1180**): 100 μL.

TEST PROCEDURE

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

For Getein 1100:

1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform “SD card” calibration when using a new batch of kits.
2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
4) Use disposable pipet or pipette to drop ***100 μL*** of sample into the sample well on the test card.
5) ***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:

1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform “SD card” calibration when using a new batch of kits.
2) Select the corresponding “Sample” on the analyzer according to the sample type (see the instructions of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Use disposable pipet or pipette to drop ***100 μL*** of sample 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) Use disposable pipet or pipette to drop ***100 μL*** of sample 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 which can calibrate automatically.
2) Put the consumables 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. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	18 g/L
Bilirubin	10 mg/dL

EXPECTED VALUE

The expected normal value for Insulin was determined by testing samples from apparently healthy individuals. The reference range of Insulin is 2.6 μU/mL to 24.9 μU/mL calculated by using normal distribution methods (95% confidence interval).

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	1.0–300.0 μU/mL
Detection of Limit	≤ 1.0 μU/mL
Within-Run Precision	≤ 15%
Between-Lot Precision	≤ 20%

REFERENCES

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3. Chevenne D, Letailleur A, Trivin F, et al. Effect of Hemolysis on the Concentration of Insulin in Serum Determined by RIA and IRMA. Clin Chem 1998;44(2):354-356.
4. Atkinson MA, Maclaren NK. The pathogenesis of insulin-dependent diabetes mellitus. N Engl J Med 1994; 331: 1853-1858.
5. E.G E, Akshay K, M. E J, et al. The relationship of glucose-stimulated insulin secretion to cerebral glucose metabolism and cognition in healthy middle-aged and older adults[J]. Neurobiology of Aging, 2021, 105174-185.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Insulin Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details 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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EU REP	Authorized representative
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Keep dry
	Keep away from sunlight		Caution
UDI	Unique device identifier		

Thank you for using Insulin Fast Test Kit (Immunofluorescence Assay). Please read the Instructions for use carefully before operating to ensure proper use.

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Catalogue number	Applicable analyzer	Package specification
IF1146-10T	Getein 1100	10 T/kit
IF1146	Getein 1100	25 T/kit
IF8146-10T	Getein 1150	10 T/kit
IF8146	Getein 1150	25 T/kit
IF5146-10T	Getein 1160	10 T/kit
IF5146	Getein 1160	25 T/kit
IF3146-10T	Getein 1180	10 T/kit
IF3146	Getein 1180	25 T/kit
IF4146-24T	Getein 1200	2×12 T/kit
IF4146	Getein 1200	2×24 T/kit
IF4146-96T	Getein 1200	2×48 T/kit
IF2146-24T	Getein 1600	2×12 T/kit
IF2146	Getein 1600	2×24 T/kit
IF2146-96T	Getein 1600	2×48 T/kit