INSULIN-CHECK-1

Quantitative determination of Insulinin whole blood, plasma or serum samples
Ref. 12091 (20 tests) / Ref. 12091-10T (10 tests)
FOR EASY READER® AND EASY READER+® USE ONLY

I- PRINCIPLE

Human insulin is a peptide hormone produced in the pancreas in the Langerhans islets ß-cells as a proinsulin precursor which is then converted into C. peptide and insulin. Insulin is the main hormone involved in the control of glucose metabolism.
ß-cells in the Langerhans islets release insulin in two phases. The first phase release is rapidly triggered in response to increased blood glucose levels. The second phase is a sustained, slow release of newly formed vesicles triggered independently of sugar.
Insulin concentrations are severely reduced in insulin-dependent diabetes mellitus and some other conditions such as hypopituitarism. Insulin levels are raised in non-insulin-dependent diabetes mellitus, obesity, inulinoma and some endocrine dysfunctions such as Cushion's syndrome and acromegaly.
INSULIN-CHECK-1 is a rapid quantitative assay for the detection of insulin in serum, plasma or whole blood samples. The method is based on an unique combination of monoclonal dye conjugate and polyclonal solid phase antibodies to identify insulin in the test samples with a high degree of specificity.
As the test sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the insulin forming an antibody-antigen complex. This complex binds to the anti-insulin antibody in the reaction zone (T) and produces a pink-rose coloured band. In the absence of insulin, there is no line in the reaction zone (T). The mixture continues flowing through the absorbent device past the reactive zone (T) and control zone (C). Unbound conjugate binds to the reagents in the control zone (C), producing a pink-rose coloured band, demonstrating that the reagents are functioning correctly.

II- INSULIN-CHECK-1 KIT COMPONENTS

Each kit contains everything needed to perform 10 or 20 tests.

1- INSULIN-CHECK-1 reaction devices :	10	20
2- Disposable plastic pipettes :	10	20
3- Diluent in a dropper bottle :	2.5mL	5mL
4- Instruction leaflet :	1	1

5- Controls (Optional):
Positive control (ref. V1290) and Negative control (ref. V1291): a freeze-dried preparation of a non-infectious compound in diluted human serum, tested and found negative for anti-HIV, anti-HCV and HBs antigen, containing 0.05 % sodium azide is optionally available as a positive and negative control (1x 0.25 mL). The concentration range is indicated on the vial label.

III- STORAGE AND STABILITY

1- All INSULIN-CHECK-1 kit components should be stored between +4°C and +30°C.
2- **Do not freeze the test kit**.
3- INSULIN-CHECK-1 is stable until the expiry date stated on the package label.

IV- PRECAUTIONS

1- This test is designed for *in vitro* diagnostic use and professional use only.
2- Read the instruction carefully before using this test.
3- Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving them for at least one hour. Alternatively, they can be treated with 0.5% to 1% solution of sodium hypochlorite for one hour before disposal.
4- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples.
5- Do not eat, drink or smoke in the area where specimens and kit reagents are handled.
6- Avoid any hands contact with eyes or nose during specimen collection and testing.
7- Do not use beyond the expiry date which appears on the package label.
8- Do not use a test from a damaged protective wrapper.

V- SPECIMEN COLLECTION AND PREPARATION

1- INSULIN-CHECK-1 is to be performed on human serum, plasma or whole blood.
2- The specimen should be collected under the standard laboratory conditions (aseptically in such a way as to avoid haemolysis).
3- If anticoagulant is needed, only EDTA or heparin should be used.
4- Each specimen should be treated as if potentially infectious.
5- Whole blood samples should be tested immediately (< 4 hours). Finger prick samples should be assayed just after collection.
6- If the test is to be run within 48 hours after collection the specimen should be stored in the refrigerator (+2°C to +8°C). If testing is delayed more than 48 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.
7- In case of cloudiness, high viscosity or presence of particulate matter into the serum specimen, it should be diluted with equal volume (V/V) of diluting buffer (not provided but available upon request) before testing.

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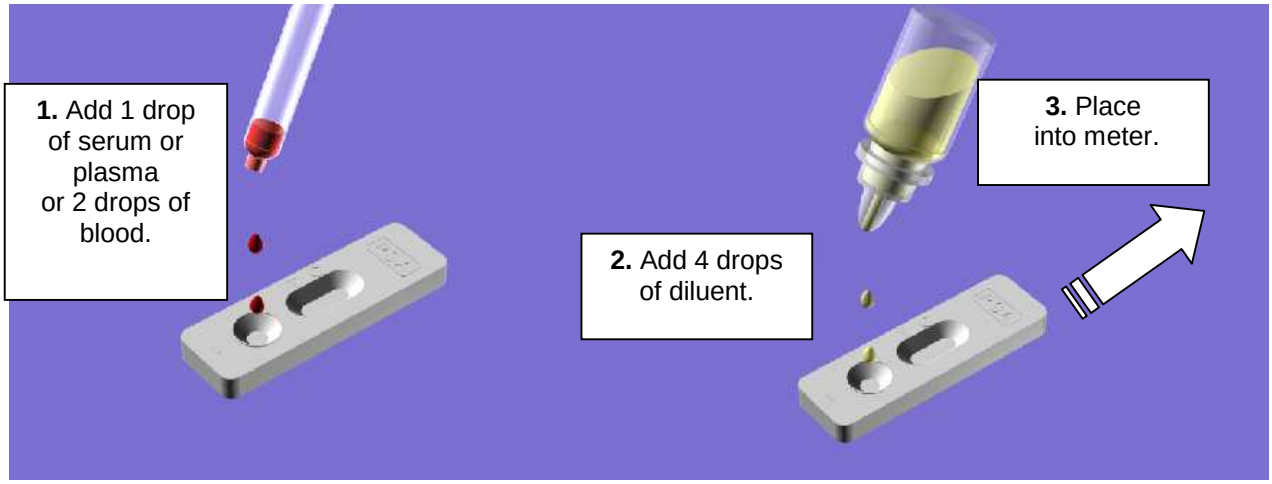
VI- ASSAY PROCEDURE

<u>IMPORTANT</u>: Switch the reader on and allow it to warm up for at least 30 minutes before performing any measurements.

<u>Follow the below instructions or refer to the picture n°1</u>

1– Allow samples and INSULIN-CHECK-1 test devices to come to room temperature prior to testing.
2– Remove the reaction device from its protective wrapper by tearing along the split.
3– Label device with the patient's name or control number
4– Fill the plastic pipette with specimen (serum, plasma or whole blood) and by holding it vertically, dispense one drop (25 µL) into sample well. (If whole blood is used, dispense 2 drops (50 µL) into the well (▷) **<u>and wait for the blood sample to be completely absorbed before adding diluent</u>**.
5– Add exactly 4 drops of diluent (150 µL) in the sample well (▷).
6– Read the result **(in µIU/mL**) after 15 minutes either using the immediate or countdown reading mode (see corresponding leaflet).

For general instructions describing how to use the EASY READER® or EASY READER+® meter, refer to the corresponding leaflet.



Picture n°1

VII- PERFORMANCES CHARACTERISTICS

a) Linearity

The measuring range is 5 -200 µIU/mL.
For Insulin concentration below 5 µIU/mL, the result will be given as "< 5 µIU/mL".
For Insulin concentration over 200 µIU/mL, the result will be given as "> 200 µIU/mL".
For samples whose concentration is higher than 200 µIU/mL, dilute with saline and repeat the assay as per instructions of Part VI.

b) Accuracy

A study has been performed using serum samples obtained from dilutions of Insulin international reference material WHO (83/500) covering a range of 5 to 200 µIU/mL. Optical densities expressed as a function of Insulin concentrations are described by following linear curve:

$$Y = - 2.24 + 3.26\ x - 4.10^{-3}\ x^2 \ (r = 0.995).$$

The results show a good correlation (r = 0.97) of the values obtained with INSULIN-CHECK-1 on VEDALAB's readers.

c) Sensitivity

Concentrations close to 2 µIU/mL are detected by INSULIN-CHECK-1 test. In these cases, results will be rendered as "< 5 µIU/mL". Levels over 20 µIU/mL are considered as abnormal.

d) Precision

A correlation study was performed on 32 known serum samples preassayed on Beckman Dxi analyser. The results show an overall correlation of 97.2 % between VEDA.LAB INSULIN-CHECK-1 test and Beckman Dxi analyser.

e) Hook effect

There was no observed hook effect up to an insulin concentration of 9,335 µIU/mL.

f) Intra assay reproducibility

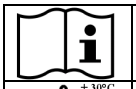
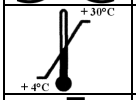
Within run reproducibility was evaluated using 25 replicates of three sera containing 40.7, 87.1 and 168.1 µIU/mL of insulin. The obtained CV (coefficient of variation) are 11.8%, 10.8% and 10.3 % respectively.

VIII- LIMITATIONS

1- As for any diagnostic procedure, the physician should confirm the data obtained using this test by other clinical methods.
2- Some serum specimens with high rheumatoid factor concentration (RF) may yield non specific positive results during testing. Such cases should be discriminated before testing.
3- The test is designed to eliminate the potential interference of human antibodies to murine IgG (HAMA). However high level of HAMA could give falsely positive results.
4- <u>Use only fresh whole blood samples (< 4 hours) when test is performed with blood samples. Finger prick samples should be assayed just after collection</u>.
5- This format of test is to be only used with VEDALAB's rapid test readers (EASY READER® or EASY READER+®).
6- If the reading time (15 minutes) is not strictly respected, wrong results will be obtained.
7- This format of test should not be used for visual reading.
8- As with any diagnostic method or for any measurements through analysers, there is a variability of the obtained result. Therefore, a confidence range of +/- 25% should be considered for the final value and for the clinical significance of the result.
9- It is recommended that each laboratory establish its own references ranges based on representative patient population in order to test the validity of the supplied data. Therefore, the data given should only be intended as orientational guidelines.
10- Do not use the reader for measurements before at least 30 minutes warm-up after having switched it on.

IX- BIBLIOGRAPHY

1- Turkington RW, Estkowkski A, Link M. Secretion of insulin or connecting peptide; a predictor of insulin dependence of obese diabetics. Archives of Internal Med.1982: 142:1102-1105.
2- Kahn CR, Rosenthal AS, Immunologic reactions to insulin, insulin allergy, insulin resistance and autoimmune insulin syndrome.diabetes Care 1979; 2.283-295
3- Steiner DF, Oyer PE (february 1967). The biosynthesis of insulin and a probable precursor of insulin by a human islet cell adenoma. Proc. Natl.Acad. Sci.USA. 57 (2):473-480.
4- Maria A.G. Reid, Martin G. Latour and al. Comparison of the rapid insulin sensitivity test (RIST), the insulin tolerance test (ITT), and the hyperinsulinemic euglycemic clamp (HIEC) to measure insulin action in rats. Can. J. Physiol. Pharmacol (2002) 80: 811-818.

	Read the instructions before use		For *in vitro* diagnostic use
	Temperature limitations		Do not reuse
	Manufacturer		

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