Complete Diabetes Mellitus Panel, Brochure

Interest in any of the products, request or order them at Bio-Connect Diagnostics.
Complete Diabetes Mellitus Panel

- AUTOIMMUNITY
  - GAD-AB
  - IA2-AB
  - AIA

- C-PEPTIDE
- INSULIN
Type 1 diabetes mellitus (TIDM) is the consequence of the destruction of β cells of the Langerhans islets, eventually leading to absolute insulin deficiency in most cases.

The majority of them undergoes a destructive process controlled by an immune mediation. Interaction between genetic and environmental factors induces secretion of diabetes autoantibodies:

- Glutamic Acid Decarboxylase Autoantibodies: GAD-AB
- Tyrosine Phosphatase Autoantibodies: IA2-AB
- Insulin Autoantibodies: AIA.

These antibodies can be used as:
- Diagnostic markers to help to define the aetiology and to classify the disease origin (immune or not).
- Monitoring markers
- Prognosis factor.

They are potentially valuable to predict the disease through population screening (the presence of two or more autoantibodies is highly predictive of the development of type 1 diabetes among relatives).

"We conclude that the presence of two or more autoantibodies (out of AIA, GAA and ICA512bdcAAs) is highly predictive of the development of type 1 diabetes among relatives"[1]

(1) "Prediction of Type 1 Diabetes in First-Degree Relatives Using a Combination of Insulin, GAD and ICA512bdc/IA-2 Autoantibodies". Diabetes, 1996, 45: 926-933

GLUTAMIC ACID DECARBOXYLASE AUTOANTIBODIES

**Kit characteristics**
- Kit of 50 tubes.
- Sample volume: 20 µL (allows pediatric determination).
- Working range: 0-300 U/mL.*
- Detection limit: 0.11 U/mL.*
- Objective quantification in opposition to IHC techniques: results are measured on a standard curve with a good reproducibility.

* : 1 U/mL = 25 U/mL of 97/550

**Specificity**
- No cross reactivity with AIA, IA2-AB, TPO-AB, TR-AB, 21-OH-AB.

**Expected values**
- 100% of healthy blood donors ≤ 1 U/mL.
- Values > 1 U/mL are considered as positive.

**ASSAY PROCEDURE**

1. Incubate 2 h at 18°-25° C
2. Incubate 1 h at 18°-25° C
3. Centrifuge
4. Count

- 20 µl standard, control, sample
- 50 µl Protein A
- 50 µl Protein A
- 1000 µl buffer
- 50 µl && GAD 65
IA2-AB

ANTI-TYROSINE PHOSPHATASE AUTOANTIBODIES

**Kit characteristics**
- Kit of 50 tubes.
- Sample volume: 20 µL.
  (allows pediatric determination).
- Working range: 0-50 U/mL.*
- Detection limit: 0.19 U/mL.*
- Objective quantification in opposition to IHC techniques: results are measured on a standard curve with a good reproducibility.

* : 1 U/mL = 125 U/mL of 97/550

**Specificity**
- No cross reactivity
  with TG-AB, TPO-AB, TR-AB, GAD-AB.

**Expected values**
- 99% of healthy blood donors ≤ 1U/mL.
- Values > 1U/mL are considered as positive.

**Assay procedure**

1. **Incubate Overnight** at 2°-8° C
2. **Incubate 1 h** at 2°-8° C
3. **Centrifugate**
4. **Decant**
5. **Count**

20 µl standard, control, sample

50 µl Protein A

50 µl ^125I IA2

1000 µl buffer
**Anti-Insulin Antibodies (IA-2-AB)**

### Kit Characteristics
- Kit of 100 tubes.
- Semi-quantitative measurement.
- Two alternative protocols:
  - Free AIA
  - Total AIA: (free AIA + AIA complexed with insulin).

### Specificity
- Positivity threshold > 5.5% B/T indicates the presence of anti-insulin antibodies.

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**Assay Procedure (Free AIA)**
- Incubate 2 h at 18°-25° C
- Incubate 10 min at 18°-25° C
- Centrifuge
- Aspirate
- Count

50 µl control, sample + 100 µl [125I] Insulin
1000 µl precipitating solution

**Assay Procedure (Total AIA)**
- Incubate 2 h at 18°-25° C
- Incubate 10 min at 18°-25° C
- Centrifuge
- Aspirate
- Count

100 µl control, supernatant + 100 µl [125I] Insulin
1000 µl precipitating solution

Extraction by active charcoal
IRMA-C-PEP

Clinical indications
- Differential diagnosis between type 1 (T1DM) and type 2 (T2DM) diabetes.
- Assessment of residual β-cell function in diabetes under insulin therapy.
- Detection and monitoring of remission period in type 1.
- Diagnosis of insulin induced factitious hypoglycemia.
- Contribution to insulinoma diagnosis.

Kit characteristics
- Immunoradiometric assay: two monoclonal antibodies.
- Coated tube (100).
- Sample: serum, plasma, urine.
- Working range: 0-6 nmol/L
  WHO 1st IRP 1986 (NIBSC 84/510)
- Detection limit: 0.012 nmol/L.

Specificity
Cross reactivity %
- Human Insulin < 0.12
- Human Glucagon < 0.0004
- Human Proinsulin < 12.8

Expected values
- Serum, plasma: 0.35 – 1.17 nmol/L.
- Urine: 5.7 - 39.2 nmol/24h.

ASSAY PROCEDURE

Incubate 2 h at 18°-25° C under shaking

Wash

50 µl standard control, sample + 100µL 125I anti c-peptide

Count
BI-INS-IRMA

Clinical indications
- Diagnosis of diabetes mellitus.
- Early detection of diabetes before clinical signs.
- Monitoring of metabolic control in diabetic patients.
- Prognosis factor for the risk of coronary incident.
- Diagnosis of insulinoma.

Kit characteristics
- Immunoradiometric assay: two monoclonal antibodies.
- Coated tube (100).
- Working range: 0–500 µIU/mL (WHO 66/304).
- Detection limit: 0.2 µIU/mL.

Two alternative procedures
- BI-INS-IRMA kit will enable the measure of:
  - Immunoreactive insulin (assay procedure 1) (free insulin + insulin bound to anti-insulin antibodies)
  - Free insulin (assay procedure 2).

Specificity
Cross reactivity %
- Porcine insulin: 100
- Bovine insulin: 100
- Rat insulin < 0.03
- Human proinsulin < 0.0001
- Des 31, 32 proinsulin < 0.0004

Expected values
- Serum, plasma: 2 – 17 µIU/mL.
INSULIN-CT

Clinical indications
- Diagnosis of diabetes mellitus.
- Early detection of diabetes before clinical signs.
- Monitoring of metabolic control in diabetic patients.
- Prognosis factor for the risk of coronary incident.
- Diagnosis of insulinoma.

Kit characteristics
- Competition assay: one polyclonal antibody.
- Coated tube (100).
- Working range (WHO 66/304): 0-300 µIU/mL.
- Detection limit: 4.6 µIU/mL.

Specificity
Cross reactivity %
- Porcine insulin: 119
- Bovine insulin: 122
- Rat insulin: 89.5
- Dog insulin > 90.

Expected values
- Serum, plasma: 4.3 – 19.9 µIU/mL.

ASSAY PROCEDURE

Incubate 18 h at 18°-25° C

Wash

Count

100 µl standard, control, sample + 900 µl 125I insulin
This is a comprehensive list.

However these products are not all available in every country.

Please contact Cisbio Bioassays for further details.