



Complete Diabetes Mellitus Panel

- AUTOIMMUNITY
 - GAD-AB
 - IA2-AB
 - AIA
- C-PEPTIDE
- INSULIN



ENDOCRINOLOGY



AUTOIMMUNITY

GAD-AB p 5

IA2-AB p 6

AAI p 7



C-PEPTIDE

IRMA-C-PEP p 9



INSULIN

BI-INS-IRMA p 10

INSULIN-CT p 11

GAD-AB, IA2-AB, AAI

Clinical indications

Type 1 diabetes mellitus (T1DM) 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:

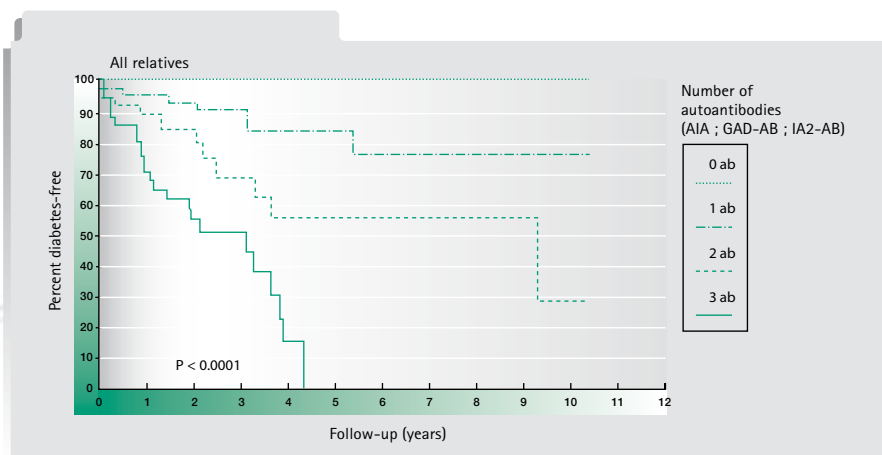
- Glutamic Acid Decarboxylase Autoantibodies: GAD-AB
- Tyrosine Phosphatase Autoantibodies: IA2-AB
- Insulin Autoantibodies: AIA.

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 AIAs, GAAs 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
Charles F. Verge, Roberto Gianini, Eiji Kawasaki, Liping Yu, Massimo Pietropaolo, Richard A. Jackson, H. Peter Chase and George S. Eisenbarth.

GAD-AB

GLUTAMIC ACID DECARBOXYLASE AUTOANTIBODIES

Kit characteristics

- Kit of 50 tubes.
- Sample volume: 20 μ L (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

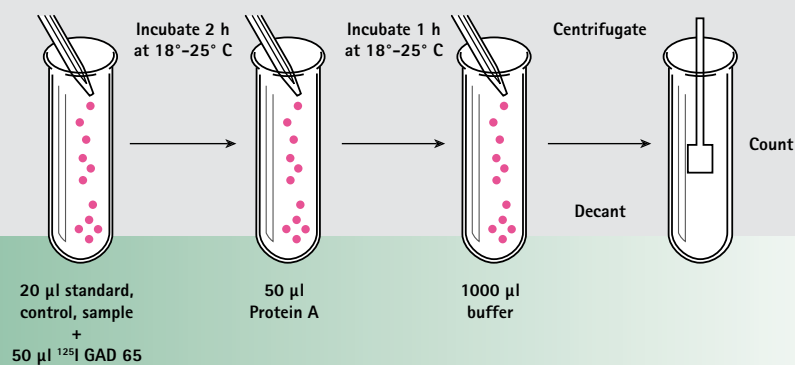
Specificity

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

Expected values

- 100% of healthy blood donors \leq 1 U/mL.
- Values $>$ 1 U/mL are considered as positive.

ASSAY PROCEDURE



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

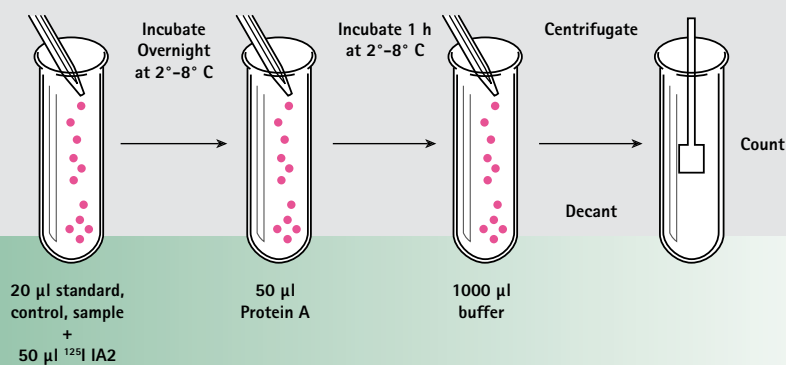
Specificity

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

Expected values

- 99% of healthy blood donors $\leq 1\text{U/mL}$
- Values $> 1\text{U/mL}$ are considered as positive

ASSAY PROCEDURE



AAI

ANTI-INSULIN ANTIBODIES

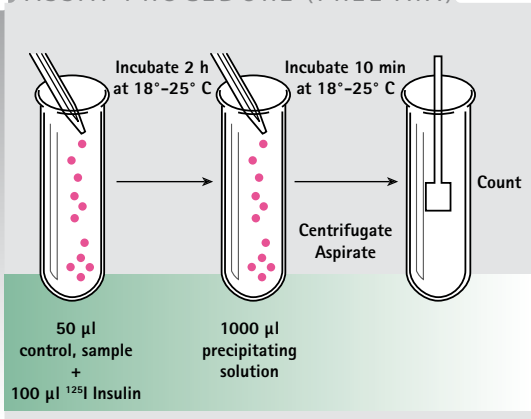
Kit characteristics

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

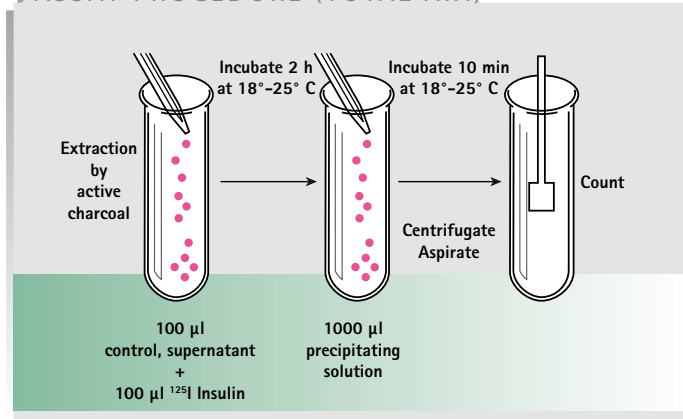
Specificity

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

ASSAY PROCEDURE (FREE AIA)



ASSAY PROCEDURE (TOTAL AIA)





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

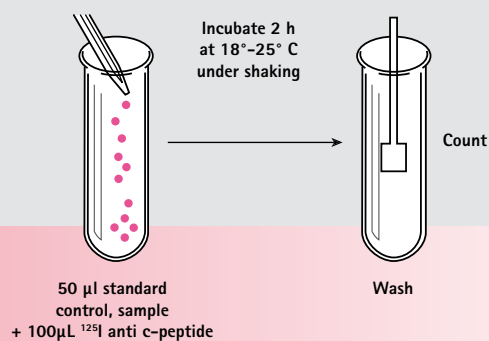
Cross reactivity %

- 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



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 $\mu\text{IU/mL}$ (WHO 66/304).
- Detection limit: 0.2 $\mu\text{IU/mL}$.

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

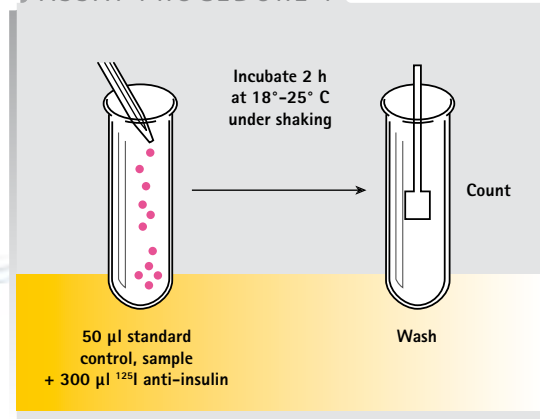
Cross reactivity %

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

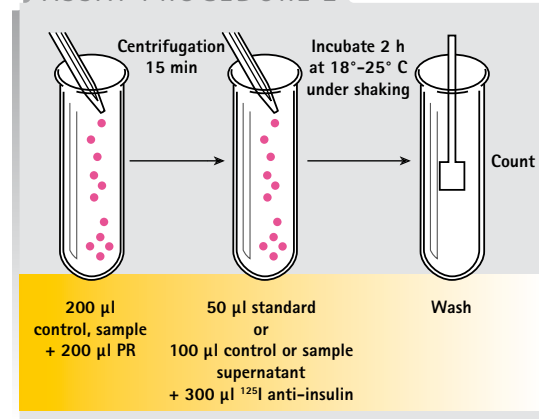
Expected values

- Serum, plasma: 2 – 17 $\mu\text{IU/mL}$.

ASSAY PROCEDURE 1



ASSAY PROCEDURE 2



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 $\mu\text{IU/mL}$.
- Detection limit: 4.6 $\mu\text{IU/mL}$.

Specificity

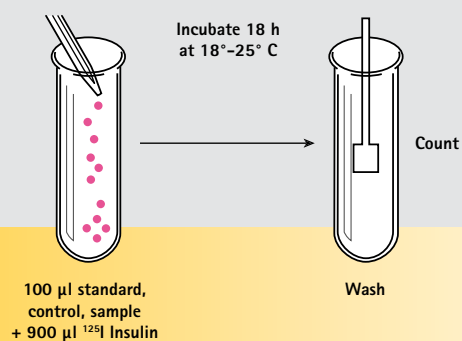
Cross reactivity %

- Porcine insulin: 119
- Bovine insulin: 122
- Rat insulin: 89.5
- Dog insulin > 90.

Expected values

- Serum, plasma: 4.3 – 19.9 $\mu\text{IU/mL}$.

ASSAY PROCEDURE



Bibliography

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This is a comprehensive list.

However these products are not all available in every country.

Please contact Cisbio Bioassays for further details.