

# Technical Information

## Intact Proinsulin (TECO®)

CE

Cat. No.: TE1012 (RUO: TE1011)  
 Tests: 96  
 Method: **ELISA**  
 Range: ~ 3 - 100 pmol/l  
 Sensitivity: LLOD = 0.15 pmol/l  
 LLOQ = 0.49 pmol/L

Incubation time: 2.5 hours  
 Sample volume: 50 µl  
 Sample type: Serum, EDTA / Heparin plasma, cell culture  
 Sample preparation: Fasting blood sample collection.  
 Due to higher stability, EDTA or heparin plasma samples are preferred to serum samples.  
**Plasma:** the sample collection can take place in HbA<sub>1c</sub>-tubes. These samples are stable at room temperature and should be centrifuged within 48 hours. Plasma should be used in the assay or can be stored in aliquots, stable > 2 years at -20 °C.  
**Serum:** centrifuge whole blood within 4 hours. Proteases degrade intact proinsulin in serum, do not store longer *than* 1 day at 2-8 °C. Serum should be used in the assay or can be stored in aliquots at -20 °C. Avoid repeated freeze/thaw cycles.

Reference values: Fasting: 2.67 +/- 1.54 SD pmol/l SD  
 values ≤ 7 pmol/L are considered normal.  
 values > 7 pmol/L suggest progressive β-cell dysfunction, insulin resistance and possibly type 2 (pre)diabetes. It is also a high-risk indicator for cardiovascular disease.

**Species:** Human  
**Specificity:** No cross-reactivity has been observed:

Human Insulin	< 10 000 pmol/l
Human C-Peptide	50 000 pmol/l
Des (31,32) - Proinsulin	< 200 pmol/l
Split (32,33) - Proinsulin	5000 pmol/l
Des (64,65) - Proinsulin*	200 pmol/l
1000 pmol/l	Split (65,66) - Proinsulin

\* not present in Serum and Plasma samples

Intended use:

Proinsulin is produced in the pancreatic  $\beta$ -cells and is normally further processed to insulin and C-peptide. It is only seen in low concentrations in the plasma of healthy subjects. An increase in the insulin demand, as

provided by insulin resistance in later stages of type 2 diabetes mellitus, can result in increased expression of proinsulin into the blood. Intact proinsulin is rapidly degraded, but is considered to be an independent cardiovascular risk factor. The intact molecule and its degradation products are known to block fibrinolysis because of plasminogen-activator inhibitor (PAI-1) stimulation. In clinical practice, fasting morning intact proinsulin can be used as highly specific indicator of clinically relevant insulin resistance, to serve as the basis for the selection of an insulin resistance therapy, and to monitor the therapeutic effect on  $\beta$ -cell dysfunction.

Patients with type 2 diabetes mellitus and with elevated fasting intact proinsulin levels should be regarded and treated as insulin resistant, in order to reduce the risk for further cardiovascular damage. Elevated fasting intact proinsulin levels may also be seen in patients with insulinoma, a benign insulin producing tumor of the pancreas.

- Diabetes II
- Staging of insulin resistance and  $\beta$ -cell dysfunction
- Therapy selection
- Therapy monitoring
- Identification of high risk patients for CAD
- Polycystic ovary Syndrome (PCOS)
- Insulinoma

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[www.tecomedical.com](http://www.tecomedical.com)

A EUROBIO SCIENTIFIC COMPANY

Switzerland / Headquarters

**TECOmedical AG**

Gewerbestrasse 10

4450 Sissach

Phone +41 61 985 81 00

Fax +41 61 985 81 09

Mail [info@tecomedical.com](mailto:info@tecomedical.com)

Germany

**TECOmedical GmbH**

Marie-Curiestr. 1

53359 Rheinbach

Hotline 0800 985 99 99

Phone +49 2226 87 24 55

Fax +49 2226 87 24 58

Mail [info@tecomedical.com](mailto:info@tecomedical.com)



