



MercoDia Diabetes Antigen Control (Low/High)/Human

Unassayed

Directions for Use

10-1134-01

**Important changes made in
this version**

Page 2 Shelf life and storage

For *in vitro* diagnostic use



Manufactured by

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Intended use

Mercodia Diabetes Antigen Control is designed to be used as a two-level control for human insulin, C-peptide, proinsulin and iso-insulin. It is manufactured from human serum and human insulin, C-peptide and proinsulin.

Reagents

Each Mercodia Diabetes Antigen Control contains 2 vials of lyophilized serum, each containing 0.5 mL after reconstitution.

Preparation of reagents

Reconstitute each Mercodia Diabetes Antigen Control by adding 500 μ L redistilled water. Replace the rubber stopper and wait 5 minutes before vortexing to ensure that the content is thoroughly dissolved.

Shelf life and storage

The expiry date is stated on the vial label. Store the complete package at 2-8°C. Reconstituted Controls of Insulin, Proinsulin and Iso-Insulin are stable for 1 week at 2-8°C or 3 months at -20°C. Reconstituted Controls of C-peptide are stable for 1 week at 2-8°C or 3 months at -80°C. Avoid repeated freezing and thawing for all controls.

Procedure

Perform the Insulin, C-peptide, Proinsulin and Iso-Insulin ELISAs according to the Directions for Use, handling Mercodia Diabetes Antigen Controls as samples.

Warnings and precautions

Warning! This kit contains reagents that may be infectious!

This kit contains reagents manufactured from human blood components. The source of material have been tested by immunoassay for hepatitis B surface antigen, antibodies for hepatitis C virus and for antibodies for HIV virus and found to be negative. Nevertheless, all recommended precautions for the handling of blood derivates should be observed. Please refer to HHS Publication no. (CDC) 88-8395 or corresponding local/national guidelines on laboratory safety procedures.

- Control Low (L) and Control High (H) contain <0.06% 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

The controls are labelled:



Warning

H317 – May cause an allergic skin reaction.

P280 – Wear protective gloves.

P261 – Avoid breathing vapour.

P272 – Contaminated work clothing should not be allowed out of the workplace.

P302 + P352 – IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 – If skin irritation or rash occurs: Get medical attention.





P501 – Dispose of contents and container in accordance with all local, regional, national and international regulations.

Warranty

The performance data presented here was obtained using the procedure indicated. Any change or modification in the procedure not recommended by Mercodia AB may affect the results, in which event Mercodia AB disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and fitness for use.

Mercodia AB and its authorized distributors, in such event, shall not be liable for damages indirect or consequential.

Explanation of symbols used on labels

	Expiry date
	Store between 2-8°C
	Lot No.
	For <i>in vitro</i> diagnostic use

For technical support please contact: support@mercodia.com