



Mercodia Diabetes Antigen Control (Low, High)/Human

Directions for Use

10-1164-01

For *in vitro* diagnostic use in EU/EEA, UK and Canada



Gebrauchsanweisung auf Deutsch finden Sie unter folgendem Link:
Veuillez trouver le mode d'emploi en français à:

Podrá encontrar las instrucciones de uso en español en:

Le istruzioni per l'uso sono reperibili in italiano all'indirizzo:

For danske brugsanvisning gå til:

För svensk bruksanvisning gå till:

For norsk oversettelse gå til:

Ga voor de Nederlandse vertaling naar:

Para tradução em português, vá para:

<https://www.mercodia.com/product/diabetes-antigen-control-human-low-and-high/>

oder/ou/o/eller/of email: info-global@mercodia.com

Regulatory status in the rest of the world:

For research use only. Not for use in diagnostic procedures.

Manufactured by

Mercodia AB

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Sweden

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. Values are found below.

Preparation of reagent

Reconstitute each Mercodia Diabetes Antigen Control by adding 500 μ L redistilled water to each vial. Replace the rubber stopper and allow to stand for 5 minutes. Gently swirl until contents are thoroughly mixed. Avoid foaming.

Shelf life and storage

The expire date is stated below. Store the complete package at 2-8°C. Reconstituted Controls are stable for 1 week at 2-8°C or 3 months at -20°C. Avoid repeated freezing and thawing.

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

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.

- The 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.

Table of values

The following concentrations apply to Kit Lot No: 31207.

The concentrations of the control values were determined by 4 replicates per run, on a minimum of 10 occasions, performed on at least 2 days by at least 2 technicians.

The ranges are determined as: target value \pm 3 SD.

The following values only apply to the lot number and expiry date mentioned below.

Control Low	Lot No.: 30951	Exp. date: 2023-04-30		
Method	Mean value	Range	Units	
Mercodia Insulin ELISA	8.65	6.31-11.0	mU/L	
Mercodia C-peptide ELISA	417	317-517	pmol/L	
Mercodia Proinsulin ELISA	6.63	5.44-7.82	pmol/L	
Mercodia Iso-Insulin ELISA	10.5	8.93-12.1	mU/L	

Control High	Lot No.: 30952	Exp. date: 2023-04-30		
Method	Mean value	Range	Units	
Mercodia Insulin ELISA	50.2	41.2-59.2	mU/L	
Mercodia C-peptide ELISA	1530	1300-1760	pmol/L	
Mercodia Proinsulin ELISA	33.0	29.0-37.0	pmol/L	
Mercodia Iso-Insulin ELISA	50.3	44.3-56.3	mU/L	

Determinations performed at Mercodia AB.





The values given are only applicable to assays manufactured by Mercodia AB. If used with other methods, different values may be obtained. Good practice dictates that each laboratory establishes its own expected range of values.

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