Mercodia Diabetes Antigen Control (Low, High)/Human

Directions for Use

REF 10-1164-03

For Research Use Only
Not for Use in Diagnostic Procedures

Mercodia AB
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31-3208
Version 1.0
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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. Values are found below.

Preparation of reagent

Reconstitute each Mercodia Diabetes Antigen Control by adding 500 µL 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 expire date is stated below. 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

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.

- Dispose of used components according to local regulations for biohazardous waste.

For safety information, please consult the safety data sheets (SDS) available at our website https://www.mercodia.com/technical-library/.

Table of values

The concentrations of the control values were determined by 4 replicates per run, on a minimum of 10 occasions, performed by at least 2 technicians.
The range is determined as: target value ±20%.
The following values only apply to the lot number and expiry date mentioned below.

Control Low Lot No.: 36489 Exp. date: 2028-02-17

Method	Mean value	Range	Units
Mercodia Insulin ELISA	10.7	7.81-13.6	mU/L
Mercodia C-peptide ELISA	477	363-591	pmol/L
Mercodia Proinsulin ELISA	9.63	7.90-11.4	pmol/L
Mercodia Iso-Insulin ELISA	11.5	9.78-13.2	mU/L

Control High Lot No.: 36490 Exp. date: 2028-02-17

Method	Mean value	Range	Units
Mercodia Insulin ELISA	59.1	48.5-69.7	mU/L
Mercodia C-peptide ELISA	1760	1500-2020	pmol/L
Mercodia Proinsulin ELISA	40.6	35.7-45.5	pmol/L
Mercodia Iso-Insulin ELISA	57.2	50.3-64.1	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

	Use-by date
	Temperature limit
	Batch code
	Catalogue number
	Consult electronic Instructions for Use
	Manufacturer

For technical support please contact: support@mercodia.com

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