

**Mercodia Diabetes
Antigen Control
Rat/Mouse
(Low, Medium, High)**

Direction for Use

10-1220-01

Manufactured by
Mercodia AB
Sylveniusgatan 8A
SE-754 50 Uppsala
Sweden

INTENDED USE

Mercodia Diabetes Antigen Control Rat/Mouse (Low, Medium, High) is designed to be used as a three-level control for Mercodia Ultrasensitive Mouse, Ultrasensitive Rat, Mouse and Rat Insulin ELISA kits and Mercodia Rat C-peptide.

It is manufactured from human serum and insulin.

For Mercodia assays the control levels are suitable in each method as stated in the table below.

Method	Control		
	Low	Medium	High
Ultrasensitive Mouse Insulin ELISA 10-1249-01/10-1249-10	x	x	-
Ultrasensitive Rat Insulin ELISA 10-1251-01/10-1251-10	x	x	-
Mouse Insulin ELISA 10-1247-01/10-1247-10	-	x	x
Rat Insulin ELISA 10-1250-01/10-1250-10	-	x	x
Rat C-peptide ELISA 10-1172-01	x	x	x

REAGENTS

Each Mercodia Diabetes Antigen Control Rat/Mouse (Low, Medium, High) contains 3 vials of lyophilized serum, each containing 0.5 mL after reconstitution. Values are found below.

PREPARATION OF REAGENTS

Reconstitute each Mercodia Diabetes Antigen Control Rat/Mouse (Low, Medium, High) 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 expiry date is stated below. Store the complete package at 2-8°C. Re-constituted Controls are stable for 2 week at 2-8°C or three months at -20°C. Avoid repeated freezing and thawing.

PROCEDURE

Perform the Mercodia Insulin ELISA assays (Ultrasensitive Mouse, Ultra-sensitive Rat, Mouse and Rat Insulin ELISA) and Rat C-peptide ELISA according to the "Directions for Use", handling Mercodia Diabetes Antigen Control Rat/Mouse (Low, Medium, High) as samples.

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 derivatives should be observed. Please refer to HHS Publication No. (CDC) 88-8395 or corresponding local/national guidelines on laboratory safety procedures.

TABLE OF VALUES

The concentrations of the control values were determined in 4 replicates on 12 occasions, performed in 7 days by 3 different technicians.

The range is determined as: target value ± 3 SD (obtained from the 12 analysis).

Control Low	Lot No.: 20300	Exp.date: 2014-06-14		
	Target value	Range	Units	
Ultrasensitive Mouse Insulin ELISA 10-1249-01/10-1249-10	0.218	0.172-0.264	$\mu\text{g/L}$	
Ultrasensitive Rat Insulin ELISA 10-1251-01/10-1251-10	0.155	0.123-0.188	$\mu\text{g/L}$	
Rat C-peptide ELISA 10-1172-01	280	204-356	pmol/L	

Control Medium	Lot No.: 20302	Exp.date: 2014-06-14		
	Target value	Range	Units	
Ultrasensitive Mouse Insulin ELISA 10-1249-01/10-1249-10	0.743	0.587-0.899	$\mu\text{g/L}$	
Ultrasensitive Rat Insulin ELISA 10-1251-01/10-1251-10	0.527	0.416-0.638	$\mu\text{g/L}$	
Mouse Insulin ELISA 10-1247-01/10-1247-10	0.790	0.624-0.956	$\mu\text{g/L}$	
Rat Insulin ELISA 10-1250-01/10-1250-10	0.594	0.469-0.719	$\mu\text{g/L}$	
Rat C-peptide ELISA 10-1172-01	1303	951-1655	pmol/L	

Control High	Lot No.: 20301	Exp.date: 2014-06-14	
	Target value	Range	Units
Mouse Insulin ELISA 10-1247-01/10-1247-10	4.218	3.332-5.104	µg/L
Rat Insulin ELISA 10-1250-01/10-1250-10	3.318	2.621-4.015	µg/L
Rat C-peptide ELISA 10-1172-01	1759	1548-1970	pmol/L

Determinations performed at Mercodia AB.

The values given are only applicable to the lot number and the expiry date mentioned in the table and 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

 An icon of an hourglass with a black fill in the bottom bulb, representing an expiry date.	Expiry date
 An icon of a thermometer with a black fill in the bulb and a line indicating a temperature level, representing storage temperature.	Store between 2-8°C
 The word "LOT" in a bold, sans-serif font, enclosed in a rectangular border, representing a lot number.	Lot No.