

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

Direction for Use

**10-1220-01**

Manufactured by  
Mercodia AB  
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Mercodia 

## INTENDED USE

Mercodia Diabetes Antigen Control (Low, Medium, High) Rat/Mouse is designed to be used as a three-level control for Mercodia Ultrasensitive Mouse, Ultrasensitive Rat, Mouse, 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	Low	Control Medium	High
Ultrasensitive Mouse Insulin ELISA 10-1150-01, 10-1150-10	Only 50 $\mu$ l assay	x	Only 5 $\mu$ l assay
Ultrasensitive Rat Insulin ELISA 10-1137-01, 10-1137-10	Only 50 $\mu$ l assay	x	Only 5 $\mu$ l assay
Mouse Insulin ELISA 10-1149-01, 10-1149-10		x	x
Rat Insulin ELISA 10-1124-01, 10-1124-10		x	x
Rat C-peptide ELISA 10-1172-01	x	x	x

## REAGENTS

Each Mercodia Diabetes Antigen Control (Low, Medium, High) Rat/Mouse 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 (Low, Medium, High) Rat/Mouse by adding 500  $\mu$ 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. Reconstituted 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, Ultrasensitive Rat, Mouse, Rat and Rat C-peptide ELISA) according to the "Directions for Use", handling Mercodia Diabetes Antigen Control (Low, Medium, High) Rat/ Mouse 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 twelve occasions, performed in three days by four different technicians.

The range is determined as: target value  $\pm 3$  SD (obtained from the twelve analysis)

<b>Control Low</b>	Batch No./Lot No.: 15954	Exp.date: 2011-12-04	
	Target value	Range	Units
Ultrasensitive Mouse Insulin ELISA			
10-1150-01/10-1150-10, 50 $\mu$ l	0,12	0,10-0,15	$\mu$ g/l
Ultrasensitive Rat Insulin ELISA			
10-1137-01/10-1137-10, 50 $\mu$ l	0,08	0,05-0,11	$\mu$ g/l
Rat C-peptide ELISA			
10-1172-01	307	237-377	pmol/l

<b>Control Medium</b>	Batch No./Lot No.: 15955	Exp.date: 2011-12-04	
	Target value	Range	Units
Ultrasensitive Mouse Insulin ELISA			
10-1150-01/10-1150-10, 5 $\mu$ l	0,72	0,61-0,83	$\mu$ g/l
Ultrasensitive Mouse Insulin ELISA			
10-1150-01/10-1150-10, 50 $\mu$ l	0,71	0,66-0,76	$\mu$ g/l
Ultrasensitive Rat Insulin ELISA			
10-1137-01/10-1137-10, 5 $\mu$ l	0,58	0,51-0,64	$\mu$ g/l
Ultrasensitive Rat Insulin ELISA			
10-1137-01/10-1137-10, 50 $\mu$ l	0,55	0,46-0,63	$\mu$ g/l
Mouse Insulin ELISA			
10-1149-01/10-1149-10	0,72	0,61-0,83	$\mu$ g/l
Rat Insulin ELISA			
10-1124-01/10-1124-10	0,58	0,51-0,64	$\mu$ g/l
Rat C-peptide ELISA			
10-1172-01	1244	1087-1401	pmol/l

<b>Control High</b>	Batch No./Lot.: 15956	Exp.date: 2011-12-04	
	Target value	Range	Units
Mouse Insulin ELISA			
10-1149-01/10-1149-10	3,67	3,07-4,28	µg/l
Ultrasensitive Mouse Insulin ELISA			
10-1150-01/10-1150-10, 5 µl	3,67	3,07-4,28	µg/l
Rat Insulin ELISA			
10-1124-01/10-1124-10	3,28	3,04-3,51	µg/l
Ultrasensitive Rat Insulin ELISA			
10-1137-01/10-1137-10, 5 µl	3,28	3,04-3,51	µg/l
Rat C-peptide ELISA			
10-1172-01	2204	1881-2526	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

	Expiry date
	Store between 2–8 °C
	Lot No.