

Mercodia Animal Insulin Control (Low, Medium, High)

Direction for Use

10-1221-01

Manufactured by
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Mercodia 

INTENDED USE

Mercodia Animal Insulin Control (Low, Medium, High) is designed to be used as a three-level control for Mercodia Porcine, Bovine, Ovine, Canine and Equine Insulin ELISA kits. 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
Mercodia Porcine Insulin ELISA 10-1200-01	x	x	x
Mercodia Bovine Insulin ELISA 10-1201-01	x	x	
Mercodia Ovine Insulin ELISA 10-1202-01	x	x	x
Mercodia Canine Insulin ELISA 10-1203-01	x	x	x
Mercodia Equine Insulin ELISA 10-1205-01	x	x	x

REAGENTS

Each Mercodia Animal Insulin Control 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 Animal Insulin Control (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. 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 (Porcine, Bovine, Ovine, Canine and Equine) according to the "Directions for Use", handling Mercodia Animal Insulin Control 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 twelve occasions in three days by four different technicians.

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

Control Low Batch No./Lot No.: 15960		Exp.date: 2011-12-11	
	Target value	Range	Units
Mercodia Porcine Insulin ELISA 10-1200-01	0,05	0,04 - 0,07	$\mu\text{g/l}$
Mercodia Bovine Insulin ELISA 10-1201-01	0,53	0,43 - 0,64	$\mu\text{g/l}$
Mercodia Ovine Insulin ELISA 10-1202-01	0,33	0,29 - 0,36	$\mu\text{g/l}$
Mercodia Canine Insulin ELISA 10-1203-01	0,05	0,04 - 0,07	$\mu\text{g/l}$
Mercodia Equine Insulin ELISA 10-1205-01	0,05	0,04 - 0,07	$\mu\text{g/l}$

Control Medium Batch No./Lot No.: 15961		Exp. date: 2011-12-11	
	Target value	Range	Units
Mercodia Porcine Insulin ELISA 10-1200-01	0,15	0,14 - 0,17	$\mu\text{g/l}$
Mercodia Bovine Insulin ELISA 10-1201-01	1,44	1,24 - 1,64	$\mu\text{g/l}$
Mercodia Ovine Insulin ELISA 10-1202-01	0,85	0,78 - 0,93	$\mu\text{g/l}$
Mercodia Canine Insulin ELISA 10-1203-01	0,15	0,14 - 0,17	$\mu\text{g/l}$
Mercodia Equine Insulin ELISA 10-1205-01	0,15	0,14 - 0,17	$\mu\text{g/l}$

Control High Batch No./Lot No.: 15962	Exp. date: 2011-12-11		
	Target value	Range	Units
Mercodia Porcine Insulin ELISA 10-1200-01	0,42	0.37 - 0,47	µg/l
Mercodia Ovine Insulin ELISA 10-1202-01	1,90	1,68 - 2,13	µg/l
Mercodia Canine Insulin ELISA 10-1203-01	0,42	0,37 - 0.47	µg/l
Mercodia Equine Insulin ELISA 10-1205-01	0,42	0,37 - 0.47	µg/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.