

Mercodia Animal Insulin Control (Low, Medium, High)

Directions for Use

10-1221-01

For Research Use Only

Manufactured by

Mercodia AB Sylveniusgatan 8A SE-754 50 Uppsala Sweden

Intended use

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

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 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 expiry date is stated below. Store the complete package at 2-8°C. Reconstituted Controls are stable for 2 weeks 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.

Warnings and precautions

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 recomended 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, Control Medium and Control High contain <0.06% 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

The Controls are labeled:



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 - İF 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 concentrations of the control values were determined in 4 replicates per run, on a minimum of 10 occasions, performed by atleast 2 technicians.

The range is determined as: target value ±3 SD.

| Control Low | Lot No.: 33915 | | Exp.date: 2025-06-30 | | |
|----------------------------------|----------------|--------------|----------------------|-------|--|
| | | Target value | Range | Units | |
| Mercodia Porcine 10-1200-01 | Insulin ELISA | 5.30 | 4.51 - 6.10 | mU/L | |
| Mercodia Bovine II 10-1201-01 | nsulin ELISA | 0.435 | 0.344 - 0.526 | µg/L | |
| Mercodia Ovine In 10-1202-01 | sulin ELISA | 0.301 | 0.238 - 0.364 | µg/L | |
| Mercodia Canine I 10-1203-01 | nsulin ELISA | 5.30 | 4.51 - 6.10 | mU/L | |
| Mercodia Equine I 10-1205-01 | nsulin ELISA | 5.30 | 4.51 - 6.10 | mU/L | |
| | | | | | |

| Control Medium | Lot No.: 33916 | | Exp.date: 2025-06-30 | |
|--------------------------------------|----------------|-----------------|----------------------|-------|
| | | Target value | Range | Units |
| Mercodia Porcine Insu 10-1200-01 | lin ELISA | 17.1 | 14.5 - 19.7 | mU/L |
| Mercodia Bovine Insuli 10-1201-01 | n ELISA | 1.40 | 1.11 - 1.69 | μg/L |
| Mercodia Ovine Insulir 10-1202-01 | n ELISA | 0.830 | 0.706 - 0.955 | μg/L |
| Mercodia Canine Insul 10-1203-01 | in ELISA | 17.1 | 14.5 - 19.7 | mU/L |
| Mercodia Equine Insul 10-1205-01 | in ELISA | 17.1 | 14.5 - 19.7 | mU/L |
| | | | | |

| Control High | Lot No.: 33917 | | Exp.date: 2025-06-30 | |
|------------------------------------|----------------|-----------------|----------------------|-------|
| | | Target value | Range | Units |
| Mercodia Porcine Ins 10-1200-01 | ulin ELISA | 61.3 | 52.1 - 70.5 | mU/L |
| Mercodia Ovine Insul 10-1202-01 | in ELISA | 2.15 | 1.83 - 2.47 | μg/L |
| Mercodia Canine Inst 10-1203-01 | ulin ELISA | 61.3 | 52.1 - 70.5 | mU/L |
| Mercodia Equine Insu 10-1205-01 | ılin ELISA | 61.3 | 52.1 - 70.5 | mU/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.

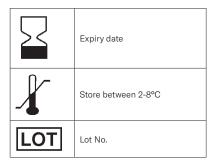
Good practice dictates that each laboratory establishes its own expected range of values.

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 expresed, implied or statutory, including the implied warranty of merchantability and fitness for use.

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Explanation of symbols used on labels



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