

Mercodia

Diabetes Antigen Control (Low, High)/Human

Directions for Use

10-1164-01



Gebrauchsanweisung in deutsch finden Sie unter folgenden Link:

Veuillez trouver le mode d'emploi en français à:

Podrá encontrar las instrucciones de uso en español en:

Le istruzioni per l'uso sono reperibili in italiano all'indirizzo:

For danske brugsanvisning gå til:

För svensk bruksanvisning gå till:

<http://www.mercodia.se/products/directions-for-use.html>

oder/ou/o/o/eller/eller **Fax No +46 18 57 00 80**

Manufactured by

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Sweden

INTENDED USE

Mercodia Diabetes Antigen Control is designed to be used as a two-level control for human insulin, C-peptide and proinsulin. 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 μ L re-distilled 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 expire date is stated below. Store the complete package at 2-8°C. Reconstituted Controls are stable for 1 week at 2-8°C or 3 months at -20°C. Avoid repeated freezing and thawing.

PROCEDURE

Perform the Insulin, C-peptide and Proinsulin assays according to the "Directions for Use", handling Mercodia Diabetes Antigen Controls 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 derivates 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 following values only apply to the lot number and the expiry date mentioned below.

| | | | |
|----------------------------|----------------|------------|------------|
| Control L | Lot No.: 22093 | Exp. date: | 2016-04-22 |
| Method | Mean value | Range | Units |
| Mercodia Insulin ELISA | 8.36 | 6.10-10.6 | mU/L |
| Mercodia C-peptide ELISA | 324 | 246-402 | pmol/L |
| Mercodia Proinsulin ELISA | 7.06 | 5.79-8.33 | pmol/L |
| Mercodia Iso-Insulin ELISA | 8.98 | 7.63-10.3 | mU/L |

| Control H | Lot No.: 22094 | Exp. date: | 2016-04-22 |
|----------------------------|----------------|------------|------------|
| Method | Mean value | Range | Units |
| Mercodia Insulin ELISA | 40.7 | 33.4-48.0 | mU/L |
| Mercodia C-peptide ELISA | 1844 | 1567-2121 | pmol/L |
| Mercodia Proinsulin ELISA | 33.5 | 29.5-37.5 | pmol/L |
| Mercodia Iso-Insulin ELISA | 43.4 | 38.2-48.6 | 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.

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. |
|  | For <i>in vitro</i> diagnostic use |