

Mercodia Diabetes Antigen Control (Low, High)/Human

Unassayed

Directions for Use

10-1134-01

For *in vitro* diagnostic use



Manufactured by

Mercodia AB

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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.

PREPARATION OF REAGENTS

Reconstitute each Mercodia Diabetes Antigen Control 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 on the vial label. 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 derivatives should be observed. Please refer to HHS Publication no. (CDC) 88-8395 or corresponding local/national guide-lines on laboratory safety procedures.

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