

COLUMN UNIT 80

ALWAYS KEEP THIS PACKAGE INSERT ON HAND AND CAREFULLY READ IT BEFORE USE. IF YOU HAVE HAD OR COULD HAVE HAD ANY SERIOUS INCIDENT RELATED TO THE DEVICE, PLEASE REPORT IT DIRECTLY TO THE MANUFACTURER OR THROUGH THE AUTHORISED REPRESENTATIVE AND TO YOUR LOCAL REGULATORY AUTHORITY.

INTENDED PURPOSE

The COLUMN UNIT 80 is intended for the quantitative and automated measurement of HbA1c when used with HA-8180V or HA-8380V in whole blood and hemolysis samples. HbA1c measurements are used for screening, monitoring and as an aid to diagnosis of diabetes and prediabetes, for individuals diagnosed with or at risk of developing diabetes or prediabetes. For *in vitro* diagnostic use and professional use only.

SUMMARY AND PRINCIPLE

The measurement of stable HbA1c is very useful in the diagnosis and treatment of diabetes and observations of diabetic conditions. HA-8180V and HA-8380V measure HbA1c in blood using reversed-phase cation exchange chromatography. Blood sample diluted with the hemolysis washing solution is sent to the column, which fractionates the sample into several hemoglobin components based on high performance liquid chromatography (HPLC).

WARNINGS



- Wear protective gloves to prevent exposure to pathogenic microbes when replacing the column.
- Discard used columns in accordance with local regulations for biohazardous waste.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- This product is only for HA-8180V or HA-8380V. DO NOT attempt to use with other instruments. Please refer to the operating manual of the instrument.
- It is recommended to use the instrument at a temperature between 10°C and 30°C, and avoid rapid temperature variation.
- DO NOT use columns beyond their expiration date.
- The expiration date is written on both the box and the label attached to the OUT side of the column.
- Check the IN and OUT sides of the column when installing it in the instrument.
- Make sure that the column is installed with the arrow to the top.
- NEVER install the column upside-down.
- Keep the sealing screws removed from new columns in the accessory case. These screws should be reused if the instrument is not to be used for extended periods of time.
- Column proper functioning is guaranteed for, at least, 2500 measurements.
- DO NOT introduce anything other than eluents into the column.
- DO NOT subject the column to shocks or vibrations.
- DO NOT disassemble the column.
- DO NOT attempt to loosen or tighten either of the end fittings.
- DO NOT attempt to loosen or tighten either of the tube fitting adapters of the column.

MEASUREMENT PROCEDURE

Refer to the operating manual of the instrument.

STORAGE

- Store unopened column unit at a temperature between 3°C and 25°C. It is recommended to keep the column refrigerated. Do not freeze.
- If the instrument is not to be used for one week or more, remove the column from the instrument and then store the removed column with both ends sealed at a temperature between 3°C and 25°C. It is recommended to keep the column refrigerated. Do not freeze.

MATERIALS PROVIDED

COLUMN UNIT 80: 1 unit / box

Filler: Hydrophilic polymer of methacrylate esters copolymer (Approx 0.35 mL).

The column is made of SUS (stainless steel) and the sealing screws are made of PEEK (polyether ether ketone).

MATERIALS REQUIRED BUT NOT PROVIDED

Refer to the operating manual of the instrument.

SAMPLE COLLECTION

Refer to the operating manual of the instrument.

QUALITY CONTROL

Refer to the operating manual of the instrument.



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