

HEMOLYSIS WASHING SOLUTION Lite H

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

HEMOLYSIS WASHING SOLUTION Lite H is a washing solution for use with HA-8380V, which is intended for the quantitative measurement of HbA1c. 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-8380V measures 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

- This product contains less than 0.02% mucosal-irritative sodium azide (NaN₃) as a preservative.
- Sodium azide may react with copper or lead whereby potentially generating explosive metal azide.
- Sodium azide may also react with acid leading to the generation of toxic explosive hydrogen azide.
- Therefore, when these materials are disposed of, you should flush them with an adequate volume of water in order to prevent any residual reagent in the water service pipe.
- If this product makes contact with eyes or mouth, immediately wash with plenty of water and consult a doctor.
- If it makes contact with skin, wash with plenty of water.
- Discard liquid waste that contains blood sample in accordance with local regulations for biohazardous waste.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- This product is only for HA-8380V. DO NOT attempt to use with other instruments. Please refer to the operating manual of the instrument.
- If this product is stored in a cold place, such as a refrigerator, allow it to adjust to the same environment as the instrument for at least one hour before placing it on the instrument.
- DO NOT use hemolysis washing solution bottle beyond its expiration date.
- The expiration date is written on both the box and bottle label.
- Place the hemolysis washing solution bottle in the specified position on the bottle tray and correctly attach the bottle cap with nozzle for the hemolysis washing solution.
- Replace the hemolysis washing solution bottle with a new one even if a small volume of solution remains.
- Adding new solution to the old bottle may cause inaccurate measurement results.
- Always handle this product with care.
- Avoid physical shock.

MEASUREMENT PROCEDURE

Refer to the operating manual of the instrument.

STORAGE

- Store unopened hemolysis washing solution bottles at a temperature between 3°C and 30°C, avoiding direct sunlight.
- Once opened, use the hemolysis washing solution within one month, even if it is before expiration date.
- If the instrument is not to be used for one week or more, remove the hemolysis washing solution bottle from the instrument. Then cap them tightly and store them at a temperature between 3°C and 30°C in order to prevent liquid degradation and/or concentration.

MATERIALS PROVIDED

HEMOLYSIS WASHING SOLUTION Lite H: 3 bottles X 2 L / box, phosphate buffer containing surfactant.

Materials of the bottle:

Polyethylene (PE) bottle with polypropylene (PP) cap

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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