

HSi Hemolysis & Wash Solution

Instructions for Use

Intended Use

The HSi Hemolysis & Wash Solution is intended for in vitro diagnostic use exclusively with the Automated Glycohemoglobin Analyzer HLC-723 series. This is not designed for and should not be used with any other system.

Summary and Explanation

The Tosoh Automated Glycohemoglobin Analyzer HLC-723 series uses non-porous ion- exchange high performance liquid chromatography (HPLC) for rapid, accurate and precise separation of the stable form of HbA1c from other hemoglobin fractions. Analysis is carried out without off-line specimen pretreatment or interference from Schiff base. HSi Hemolysis & Wash Solution is used to dilute and rupture the red blood cell exposing hemoglobin for further separation. The separated hemoglobin components pass through the LED photometer flow cell where the analyzer measures changes in absorbance at 415 nm. The analyzer integrates and reduces the raw data, and then calculates the relative percentages of each hemoglobin fraction.

Material Supplied

Catalogue No.	Description	Package contents	Applicable analyzers
018431US	HSi Hemolysis & Wash Solution (L)	2000 mL per bottle	Automated Glycohemoglobin Analyzer HLC-723 Series

Warning and Precautions

- Rx Only - US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- This product is for in vitro diagnostic use only.
- This product is intended exclusively for use on the Tosoh Automated Glycohemoglobin Analyzers and not for use on any other analyzer.
- Do not use this product beyond the expiration date.
- Hemolysis & Wash Solution contain sodium azide that may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
- Avoid refilling or combining leftover Hemolysis & Wash Solution HSi into open packs as this combination can produce unreliable assay results.
- For complete details on safe handling, refer to the SAFETY DATA SHEET (SDS) available at <http://www.diagnostics.us.tosohbioscience.com/msds>

Storage and Stability

Unopened Hemolysis & Wash Solution is stable until the expiration date printed on the label when store at 4° to 30°C. After opening, Hemolysis & Wash Solution is stable for three months when stored at 4° to 25°C.

Prior to Use

Inspect the packaging and the exterior of the bottle for any signs of damage prior to use. If any damages are visible, contact your local Tosoh Technical Support.

Hemolysis & Wash Solution is provided ready to use.

Be sure HSi Hemolysis & Wash Solution is at room temperature prior use.

Procedure

For installation of HSi Hemolysis & Wash Solution

- Press the STOP key on the system operation panel to enable the STAND-BY state.
- Remove the cap from the bottle and place the cap in the designated location.
- Ensure that the suction tube is inserted into the HSi Hemolysis & Wash Solution and tighten on the cap. The weighted end of the tube should be at the bottom of the bottle.
- Perform priming of the HSi Hemolysis & Wash Solution line as necessary.
- Refer to the Automated Glycohemoglobin Analyzer HLC-723 Series Operator's Manuals for detailed instructions.