

# Hemolysis Solution

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 Solution is intended for the dilution of whole blood samples for use with HA-8180V, HA-8180T or HA-8190V, which are intended for the quantitative measurement of HbA1c. For *in vitro* diagnostic use and professional use only.

## WARNINGS

- This product contains less than 0.02% mucosal-irritative sodium azide (NaN<sub>3</sub>) 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 Hemolysis Solution 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-8180V, HA-8180T or HA-8190V. DO NOT attempt to use it with other instruments. Please refer to the operating manual of the instrument.
- DO NOT use this set beyond its expiration date.
- The expiration date is written on both the box and bottle label.
- After opening, store the bottle at a temperature between 2°C and 8°C to prevent contamination by pathogenic microbes.
- Avoid mixing of reagents after opening the bottle.
- DO NOT use the prepared diluted whole blood sample if turbidity or foreign matter is present.
- Store the diluted whole blood sample at a temperature between 2°C and 8°C, and use it within 12 hours. Use beyond 12 hours may produce inaccurate measurement results.

## PROCEDURE

Whole blood samples (Preparing hemolysis samples)

- 1 tube contains 1.0 mL Hemolysis Solution - add 10 µL whole blood with an «end to end» capillary. Let the capillary fall directly into the Hemolysis Solution tube, close the tube and shake it to get the blood out from the capillary into the Hemolysis Solution. Then remove the cap and set the sample in the instrument. Alternatively, dispense it into a sample cup before setting it in the instrument.

## STORAGE

Unopened: Store it in a dark place at a temperature between 3°C and 30°C, avoiding direct sunlight.

Opened: Store it tightly capped at a temperature between 2°C and 8°C.

## MATERIALS PROVIDED

Hemolysis Solution: 1 mL × 100 bottles, phosphate buffer containing surfactant.  
Bottle materials: PS (Polystyrene) bottle with LDPE (Low-Density Polyethylene) outer 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.

## GLOSSARY OF SYMBOLS

	Use by
	Batch code
	Date of manufacture
	Catalogue number
	Manufacturer
	Authorised Representative in the European Community
	In vitro diagnostic medical device
	Temperature limitation
	Consult instructions for use
	This product conforms to Regulation (EU) 2017/746.
	Storage temperature limitation after opening



ARKRAY Factory, Inc.  
1480 Koji, Konan-cho, Koka-shi  
Shiga 520-3306, JAPAN  
[https://www.arkray.co.jp/script/mailform/afc-contact\\_eng](https://www.arkray.co.jp/script/mailform/afc-contact_eng)



ARKRAY Europe, B.V.  
Prof. J.H. Bavincklaan 2  
1183 AT Amstelveen, THE NETHERLANDS  
Contact for technical assistance  
[TEL: +31-20-545-24-50]



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