

DILUENT 90

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

DILUENT 90 is intended for the dilution of commercially available control materials for use with HA-8190V, which is intended for the quantitative measurement of HbA1c. DILUENT 90 is also intended for the dilution of whole blood samples. For *in vitro* diagnostic use and professional use only.

WARNINGS

- If DILUENT 90 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-8190V. DO NOT attempt to use 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.
- Read the package insert that comes with commercially available controls carefully before use.
- Avoid mixing of reagents after opening the bottle.
- DO NOT use the prepared control if turbidity or foreign matter is present.
- Store the diluted whole blood sample and control at a temperature between 2°C and 8°C, and use within 8 hours. Use beyond 8 hours may produce inaccurate measurement results.

PROCEDURE

Whole blood samples (Preparing hemolysis samples)

- Add appropriate volume of DILUENT 90 to whole blood samples.
- The measurable hemoglobin concentration of a diluted hemolysis sample of HA-8190V is 75 - 225 mg/dL (standard 150 mg/dL).
- If the concentration does not fall within this range, an error message may be displayed or the reproducibility may become poor.
- If this happens, change the dilution ratio appropriately to adjust the concentration before performing the measurement again. (HA-8190V uses whole blood diluted 101 times.)

STORAGE

Unopened: Store it in a dark place at a temperature between 2°C and 30°C, avoiding direct sunlight.

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

MATERIALS PROVIDED

DILUENT 90: 250 mL X 1 bottle, phosphate buffer containing surfactant.

Bottle materials:

Polyethylene (PE) bottle with PE inner cap and polypropylene (PP) outer cap.



ARKRAY Factory, Inc.
1480 Koji, Konan-cho, Koka-shi
Shiga 520-3306, JAPAN
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]



UK RESPONSIBLE PERSON
ARKRAY Ltd.
Beacon House Stokenchurch Business Park, Ibstone Road
Stokenchurch, High Wycombe HP14 3FE, UK
<http://Arkray.co.uk>

