

Hematology Devices (for in vitro diagnostic use)

Minipack AD60

(From lot #091210 and above)

09/12/09
A95A00255BEN

Exclusive use:

Advia 60

REF 0606051 (x4)

REAGENT 1 0,5L

REAGENT 2 0,3L

REAGENT 3 3,4L

IVD 

HORIBA ABX SAS

BP 7290 - 34184

Montpellier

cedex 4 - France

1. Functions

R1: Enzymatic solution with proteolytic action for the cleaning of blood cell counters.

R2: Erythrocyte lysing agent for white blood cell counting, and differentiation and hemoglobin determination on blood cell counters.

R3: Buffered isotonic solution for the determination and the differentiation of blood cells, and the measurement of hematocrit on blood cell counters.

Measurement procedure to be followed in using the device:

Principle of the method, specific analytical performance characteristics, analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility (including control of known relevant interference), limits of detection, limitations of the method and information about the use of available reference measurement procedures and materials by the user: see the appropriate section in the instrument User Manual.

2. Conservation & expiration

Storage conditions: Room temperature between 18°C (65°F) to 25°C (77°F).

Open stability:

Maximum 1 month after the pack has been opened.

Expiration date: refer to «expiration date» reagent packaging label.

3. Measurements, principles & results

Directions for use: see the appropriate section in the instrument User Manual. This reagent is for professional *in-vitro* diagnostic use only.

Measuring Principles : see the appropriate section in the instrument User Manual.

Results: Refer to the instrument User Manual

Performance data: see the appropriate section in the instrument User Manual.

Note: if performance changes, call your Horiba Medical representative.

4. Composition & Handling precautions^a

R1: Organic Buffer< 20%
Proteolytic enzyme.....< 1%
Detergent.....< 5%
Sodium Azide.....<0,1%
pH: 9,9 +/- 0,2 (T = 20°C)
Resistivity: 66,3 +/- 2,0 Ω (T = 20°C)
Description: Colorless liquid.

R2: Quaternary Ammonium salt < 20%
Potassium cyanide.<0,1%
pH: 10,0 +/- 0,5 (T = 20°C)
Resistivity: 213 +/- 10 Ω (T = 20°C)
Description: Colorless liquid.

R3: Sodium fluoride< 3%
Sodium Azide.< 0,1%
Sodium Hydroxyde.....< 1%
Dimethylolurea0,1%
pH: 7 +/- 0,1 (T = 20°C)
Resistivity: 60 +/- 6 Ω (T = 20°C)
Description: Limpid and odorless aqueous solution.

a.Modifications from index A to B: composition changed

Handling Precautions: The reagent contains Sodium Azide as preservative. Avoid contact with eyes, skin and clothing. Wear laboratory gloves when handling the product. The product may be harmful if ingested or inhaled. Keep the bottle closed when not in use. Please refer to the MSDS associated with the reagent.



Once the waste seal has been broken, the Minipack AD60 must be considered as potentially infectious! Use established, good laboratory working practices when handling the Minipack AD60.

Specimen Collection and Mixing: see the appropriate section in the instrument User Manual.

5. Limitations & waste disposal

Limitations: see the appropriate section in the instrument User Manual.

Safe Waste Disposal: Follow your laboratory's protocol when neutralizing and disposing of waste. Please refer to the MSDS associated with the reagent.