Hematology

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REF 0604052
REAGENT 1 0.5 L
REAGENT 2 0.3 L
REAGENT 3 3.4 L

HORIBA ABX SAS
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BP 7290
34184 Montpellier Cedex 4
FRANCE

ABX VET Pack

- ABX Micros ESV60

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

ABX VET Pack is constituted of 3 reagents (R1, R2, R3) and a waste container intended for use on blood cell counters.

- R1 is an enzymatic solution with proteolytic action for the cleaning of blood cell counters.
- R2 is a lysing solution for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation and for hemoglobin determination.
- R3 is a buffered isotonic solution designed for the determination of blood cells counting, and the measurement of hematocrit.

Warnings and Precautions [a]

- **ABX VET Pack** is for professional *in vitro* diagnostic use only.
  For veterinary laboratory use.
- It is the user's responsability to verify that this document is applicable to the product use.
- This reagent is classified as hazardous in compliance with regulation (EC) N°.1272/2008.
- **Reagent 1 (R1):**
  Warning
  H317: May cause an allergic skin reaction.
  H412: Harmful to aquatic life with long lasting effects.
  P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
  P280: Wear protective gloves or clothing and eye or face protection.
  P302 + P352: IF ON SKIN: Wash with plenty of soap and water.
  P333 + P313: If skin irritation or rash occurs: Get medical advice/attention.
  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
  Contains: 2-methyl-(2H)-isothiazol-3-one
  Contains: Octhilinone (ISO)
- **Reagent 2 (R2):**
  Warning
  H410: Very toxic to aquatic life with long lasting effects.
  P273: Avoid release to the environment.
  P391: Collect spillage.
  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Users are advised to wear approved protective clothing when handling chemical products: lab coat, gloves, and eye protection.
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- User must be trained by a HORIBA representative before attempting to operate the device.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Please refer to the Safety Data Sheet (SDS) associated with **ABX VET Pack**.

[a]Modification: recommendation added.

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- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the user and/or the patient is established.
- Very toxic to the environment.
  It is strongly recommended not to release the product into the environment.
- The reagent containers are disposable and should be disposed of in accordance with the local legal requirements.
- For technical assistance, you can call +33 (0)4 67 14 15 16.
- This reagent is destined for use with HORIBA blood cell counters specified above. HORIBA cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA.

Waste Management

Please refer to local legal requirements.
This reagent contains less than 0.1% of sodium azide as a preservative.

Microbiological State

Not applicable.

Description and Composition

Description:

R1:	Limpid and colourless to light yellowish aqueous solution.
R2:	Limpid and yellowish aqueous solution.
R3:	Limpid and colourless aqueous solution.

Composition:

R1	
Organic buffer	< 5%
Proteolytic enzyme	< 1%
Preservative	< 1%

R2	
Preservative	< 0.1%
Detergent	< 2.5%
Organic buffer	< 5%

R3	
Organic buffer	< 5%
Preservative	< 0.1%

Storage and Stability

- **Storage condition (before opening):** 5-25°C (41-77°F).
  Do not freeze.
- **Open stability:** 3 months maximum at 5-25°C (41-77°F) after opening and within the expiration limit.
- **Expiration date:** refer to "expiration date" reagent packaging label.

Materials Required but not Provided

- Automated hematology analyzer.
- Calibrator: **ABX Minocal**.
- Control: refer to the user manual for the specific control used with your instrument.
- Standard laboratory equipment.

Specimen [b] [c]

Sample collection:

All specimen samples should be collected using proper technique. Consider all specimens, reagents, calibrators, controls, etc. that contain biological specimen extracts as potentially infectious and follow biosafety practices (1, 2, 3).
Sample collection is species dependent.
Specimen collection must be placed in vacuum or atmospheric collection tubes.
Please refer to the user manual for sample collection.

Recommended anti-coagulant:

The recommended anticoagulant is K_3-EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer. K_2-EDTA is an acceptable alternative, as long as the sample collection is made in

[b]Modification: bibliographic reference updated.
[c]Modification: correction.

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normal conditions. Otherwise, blood clots may be possible.

Blood sample stability:

Please refer to the user manual.

Microsampling:

Instrument sampling mode enables the user to work with microsamples (refer to the instrument user manual for the minimum blood sample volume). These microsamples can only be used in the following conditions:

- The tube must always be held in vertical position.
- Blood mixing must be obtained by slight tapping on the tube. Do not rotate the tube for mixing, otherwise the blood will be spread on the tube side, and the minimum required level will be lost.

Mixing:

Blood samples must be gently and thoroughly mixed just before sampling. This ensures a homogeneous mixture for measurement.

Procedure

These reagents are ready to use.

1. Open the door of the reagent compartment.
2. If necessary, remove the empty **ABX VET Pack** from the reagent compartment.
3. Remove the three reagent output protections from the new pack.
4. Refer to the user manual to identify **ABX VET Pack** using the barcode reader or manuallly.
5. Install **ABX VET Pack** into the reagent compartment of the instrument.
6. Gently push it down in order to plug it correctly into the male connectors.
7. Cut the seal of the waste input protection.
8. Remove the waste input protection.
9. Plug the free male connector onto the pack waste connector input (upper valve).

Follow instructions displayed on your instrument software.
Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

- **ABX VET Pack, R3** is a saline and buffered electrolytic solution which allows the dilution and the preparation of blood sample for analysis. The electrolytic action supports the counting of the cells by impedance.
  This reagent also participates in the differentiation of leucocytes (WBC). It is also used in the rinsing and cleaning cycles of the hydraulic systems of the instrument.
- **ABX VET Pack, R2** breaks down the erythrocyte (RBC) cell membrane. By addition of surfacting agent, hemoglobin is released. All the heme iron is oxidized and resulting complexes are quantified by spectrophotometry at a wavelenght of 530 nm.
  Detergent present in the solution differentiates also morphological populations of leucocytes (WBC).
- **ABX VET Pack, R1**: the combined action of a proteolytic enzyme with a detergent eliminates protein residues and prevents the hydraulic tubes from clogging and / or blocking. It is used also to break down the protein build-ups in the counting chambers and apertures.

Performance Characteristics and Limitations of the Method

Refer to the user manual for the performance characteristics of the instrument and the limitations of the analyses on instrument parameters.

Calculation and Interpretation of Analytical Results

Refer to the instrument user manual for calculation and interpretation of analytical results.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ABX VET Pack** if the damages might have an effect on the product performance.

Signs of deterioration

In the event of any signs of physical or chemical deterioration (turbidity, change in colour etc.) **ABX VET Pack** should be replaced.

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Temperature limits

Do not use **ABX VET Pack** if it has been frozen or kept at excessive heat.
Before using **ABX VET Pack**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

Internal Quality Control

HORIBA control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA offers an Online Interlaboratory Comparison Program (QCP) which provides internet access to:

- Submit Internal Quality Control results online.
- Monitor analytical performances and compare directly with hundreds of laboratories worldwide.
- Obtain real time peer group statistical reports from QCP

More informations are available at:
http://qcp.horiba-abx.com

Traceability of Calibrators and Control Materials

Not applicable.

Reference Intervals

Not applicable.

Reference

1. US Department of labor, Occupational Safety and Health Administration. 29 CFR 1910. 1030: Occupational Safety and Health Standards: Bloodborne pathogens.
2. Council Directive (2000/54/EC). Official Journal of the European Communities. No. L262 from October 17, 2000: 21-45.
3. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).