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REAGENT 1 L

IVD CE

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée
BP 7290
34184 Montpellier Cedex 4
FRANCE

Whitediff 1L

- Yumizen H500 OT / CT / H550
- Yumizen H500 CRP
- Yumizen H500E OT / CT / H550E

Hematology Devices (for *in vitro* diagnostic use)

Intended Use

Whitediff 1L is a lysing solution intended for *in vitro* diagnostic use and designed for lysing erythrocytes (RBC) for leucocytes (WBC) counting and differentiation and for hemoglobin determination on HORIBA blood cell counters.
Clinical laboratories use.

Warnings and Precautions [a]

- **Whitediff 1L** is for professional *in vitro* diagnostic use only.
  For 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.
- **Warning**
  H317: May cause an allergic skin reaction.
  P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
  P272: Contaminated work clothing should not be allowed out of the workplace.
  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.
  P362 + P364: Take off contaminated clothing and wash it before reuse.
  P501: Dispose of contents and container in accordance with all local, regional, national and international regulations.
  Contains: Glutaral
- 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 **Whitediff 1L**.
- 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.
- 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.

[a]Modification: modification of warnings and precautions.

Whitediff 1L

Microbiological State

Not applicable.

Description and Composition

Description:

Limpid and pale yellow aqueous solution.
Cyanide free reagent.

Composition:

Lysing agent	< 5%
Surfactant	< 5%
Preservative	< 1%
Buffer	
Diluent	qs 100%

Storage and Stability

- **Storage condition (before opening):** 2-25°C (36-77°F).
  Do not freeze.
- **Open stability:** 2 months maximum at 15-30°C (59-86°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

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).
Specimen collection must be placed in vacuum or atmospheric collection tubes (4, 5, 6).
Please refer to the user manual for sample collection.

Recommended anti-coagulant:

The recommended anticoagulants are K_3-EDTA and K_2-EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer. 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 for pediatrics and geriatrics (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

This reagent is ready to use.

1. Refer to the user manual to identify **Whitediff 1L** using the barcode reader or manuallly.
2. If necessary, remove the empty **Whitediff 1L** from the reagent compartment.
3. Uncap the new reagent bottle.
4. Insert the stopper assembly straw into the bottle.
5. Tighten the stopper assembly to ensure an adequate seal.
6. Install **Whitediff 1L** into the reagent compartment of the instrument.

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

Whitediff 1L

Methodology

Whitediff 1L breaks down the erythrocyte (RBC) cell membrane allowing the release of hemoglobin which is measured by spectrophotometry.
Whitediff 1L is a selective lysing agent which allows total leucocytes count and leucocyte differential count of the 6 populations (lymphocytes, monocytes, neutrophils, eosinophils, basophils and large immature cells).
Whitediff 1L also allows detection of atypical lymphocytes.

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 **Whitediff 1L** 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.) **Whitediff 1L** should be replaced.

Temperature limits

Do not use **Whitediff 1L** if it has been frozen or kept at a temperature above 25°C.
Before using **Whitediff 1L**, 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).
4. Collection of Diagnostic Venous Blood Specimens - Seventh Edition. CLSI (NCCLS), document GP41 (2017).
5. Collection of Capillary Blood Specimens; Approved Standard - Seventh Edition. CLSI (NCCLS), document GP42 (2020).
6. Body Fluid Analysis for Cellular Composition; Approved Guideline - Fifth Edition. CLSI (NCCLS), document H56-A (2006) **26** (26).