

ABX Difftrol

- ABX Pentra 60 / 60C+
- Pentra ES60 / MS60 / MS CRP
- ABX Pentra XL80
- Pentra XLR
- Pentra DX Nexus / DF Nexus
- Yumizen H500 OT / CT / H550
- Yumizen H500E OT / CT / H550E
- Yumizen H1500 / H2500

1300136011 (L)
1300136015 (N)
1300136019 (H)
REF 2062207 (2L)
2062203 (2N)
2062208 (2H)

CONTROL 3 mL

IVD  2797

 **HORIBA ABX SAS**
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FRANCE

Hematology Devices (for *in vitro* diagnostic use)

Intended Use ^{a b c d}

ABX Difftrol is a tri-level multiparameter control intended for *in vitro* diagnostic use and designed for use in monitoring the accuracy and precision of HORIBA hematology blood cell counters for the following parameters in clinical laboratories: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, PLT-Ox, MPV, NEU%, NEU#, LYM%, LYM#, MON%, MON#, EOS%, EOS#, BAS%, BAS#, IMG%, IMG#, NRBC%, NRBC#, TNC, LPF.

Parameters can be different according to the instrument, please refer to the assay value data sheet for specific instrument models.

Warnings and Precautions

- **ABX Difftrol** is for professional *in vitro* diagnostic use only.
For laboratory use.
- It is the user's responsibility to verify that this document is applicable to the product use.
- This reagent is classified as non-hazardous in compliance with regulation (EC) N°.1272/2008.
- Human source material. Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found negative for the presence of HBsAg, HCV and antibody to HIV1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, the products should be treated like patient specimens as potentially infectious and handled with appropriate cautions in accordance with good laboratory practices (1, 2, 3).

- **Warning:** This reagent is obtained from substances of animal origin. Consequently, it should be treated as potentially infectious and handled with the appropriate cautions in accordance with good laboratory practices (2).
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- Please refer to the Safety Data Sheet (SDS) associated with **ABX Difftrol**.
- Do not use the product if the recommended storage conditions, including temperature, are not followed.
- User must be trained by a HORIBA representative before attempting to operate the device.
- 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.

Waste Management

Please refer to local legal requirements.

Microbiological State

Not applicable.

^aModification: new leaflet form.

^bModification: modification of intended use.

^cModification: modification of CE mark.

^dModification: reference modification.

ABX Difftrol

Description and Composition

Description

ABX Difftrol is similar in appearance to fresh whole blood. A light pink-tinted supernatant is normal.

Composition

ABX Difftrol contains leukocytes (WBCs), erythrocytes (RBCs) and thrombocytes (PLTs) of human or animal origin suspended in a plasma-like fluid

Storage and Stability

- **Storage condition (before opening):** 2-8°C (35-46°F). Do not freeze.
Store the tubes vertically in their original packages when not in use.
Storage in the door compartments of the refrigerator is not recommended.
- **Open stability:** **ABX Difftrol** is stable for 16 sampling events over a maximum of 16 days at 2-8°C (35-46°F) after opening and within the expiration limit.
ABX Difftrol must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

ABX Difftrol is ready to use.

An analysis of the control must be carried out on a daily basis at the same time as the patient samples, including each time a calibration or a maintenance is carried out. The frequency of the controls depends on the laboratory requirements. Each laboratory must establish the quality assurance procedures to be followed. These must conform to the current accreditation requirements and pertinent regulations.

1. Bring **ABX Difftrol** to room temperature by rolling the tube between the palms of your hands until the red blood cell sediment is completely suspended. Do not shake.

2. Refer to the user manual to identify **ABX Difftrol** using the barcode reader or manually.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX Difftrol** according to the procedure described in the user manual.
5. Wipe threads and cap of the tube after use with lint-free gauze.
6. Recap and refrigerate the tube promptly after use.

Refer to the **ABX Difftrol** assay value data sheet for specific instrument models.

Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

ABX Difftrol is a stable preparation used to monitor the accuracy and precision of blood cell counters. Reference values have been obtained from replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methods. **ABX Difftrol** is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements).

Performance Characteristics and Limitations

The mean assay values indicated for each **ABX Difftrol** parameter are obtained from replicated assays performed on analysers that have been calibrated using whole blood. The assays were performed using reagents recommended by HORIBA. The expected ranges are representative of estimates of the variation between different laboratories for each parameter.

Nevertheless, values stated on the assay sheets should only be indicative for control purposes and should not be used for calibration.

According to CLSI C24-A4 (4), the assay mean and standard deviation must be established by serial testing in the laboratory. For that, a new lot of **ABX Difftrol** should be analyzed in parallel with the lot of **ABX Difftrol** in current use.

Ideally, a minimum of 10 measurements should be made during at least 10 separate days and on a correctly calibrated analyser to establish the assay means. Standard Deviation must be defined over a longer period, to include long-term sources of variability.

See paragraph Traceability of Calibrators and Control Materials.

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Calculation and Interpretation of Results

Refer to the instrument user manual for control procedure and interpretation of results.

Changes in the Procedure and in the Performance

Packaging spoiling

In case of protective packaging spoiling, do not use **ABX Difftrol** 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 Difftrol** should be replaced.

Incorrect mixing

Incomplete mixing of the tube prior to use invalidates both the sample that is withdrawn and the remainder of **ABX Difftrol** in the tube.

Temperature limits

Do not use **ABX Difftrol** if it has been frozen or kept at excessive heat.

Before using **ABX Difftrol**, make sure it has reached the operating temperature conditions as described in the instrument user manual.

Internal Quality Control

ABX Difftrol 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 ^e

HORIBA controls and calibrators are traceable to standard reference methods.

Hematology analyzers in the Quality Assurance Laboratory are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cells (WBC)** and **Red Blood Cells (RBC)** are analyzed on a Coulter Counter Z series instrument*. All counts are corrected for coincidence (5).

Hemoglobin is measured using the Clinical Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (6). Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 (6).

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document (7). No correction is made for trapped plasma.

Platelets are assayed using a hemocytometer and phase contrast optics (8).

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Reference Intervals

Not applicable.

Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
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 - Third Edition. CLSI (NCCLS), document M29-A3 (2005) **25** (10).
4. Statistical Quality Control for quantitative Measurement Procedures: Principles and Definitions; Approved Guideline - Fourth Edition. CLSI C24-A4 (2016).

^eModification: bibliography evolution.

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5. Reference method for the enumeration of erythrocytes and leucocytes. International Council for Standardization in Haematology; prepared by the Expert Panel on Cytometry. Clin. Lab. Haemat. (1994) **16** (2): 131-138.
6. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. CLSI (NCCLS), document H15-A3 (2000) **20** (28).
7. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).
8. Platelet counting by the RBC/platelet ratio method: A reference method. International Council for Standardization in Haematology Expert Panel on Cytometry; International Society of Laboratory Hematology Task Force on Platelet Counting. American Journal of Clinical Pathology. (2001) **115** (3): 460-464.