2015/01/12
A95A00012OEN

ABX Cleaner (1L)

REF 0903010

REAGENT 1L

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

- ABX Pentra 60 / 60C+
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- Pentra ES60 / MS60 / MS CRP
- Pentra DX Nexus / DF Nexus
- ABX Pentra 80 / XL80
- Pentra XLR
- Yumizen H500 OT / CT

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a]

ABX Cleaner is an enzymatic solution intended for *in vitro* diagnostic use with proteolytic action for the cleaning of HORIBA Medical blood cell counters.

Warnings and Precautions [b]

- **ABX Cleaner** is for professional *in vitro* diagnostic use only.
- It is the user's responsability 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.
- 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.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Cleaner**.
- This reagent is destined for use with HORIBA Medical blood cell counters specified above. HORIBA Medical cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.

Waste Management

Please refer to local legal requirements.

This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

Microbiological State

Not applicable.

Description and Composition

Description:

Limpid and colourless to light yellowish aqueous solution.

Composition:

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

Storage and Stability [c]

- **Storage condition (before opening):** 18-25°C (65-77°F).
  Do not freeze.
- **Open stability:** 3 months maximum at 18-25°C (65-77°F) after opening and within the expiration limit.
- **Expiration date:** refer to "expiration date" reagent packaging label.

[a]Modification: new instrument added.
[b]Modification: CLP classification.
[c]Modification: modification of Storage and Stability.

ABX Cleaner (1L)

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 blood samples should be collected using proper technique! Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious and follow biosafety practices (1, 2). When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric collection tubes (3, 4). The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself to avoid variations in the results.

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 normal conditions. Otherwise, blood clots may be possible.

Blood sample stability:

Sample stability at low temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at 4°C. Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters

Sample stability at room temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at room temperature (25°C). Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters

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 [a]

This reagent is ready to use.

Procedure for reagent with stopper and straw

Reagent with stopper and straw is used on:

- ABX Pentra 60
- ABX Pentra 60 C+
- Pentra ES 60
- Pentra MS 60
- Pentra MS CRP
- ABX Pentra 80
- ABX Pentra XL 80
- Pentra XLR
- Yumizen H500 OT / CT

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

[a]Modification: new instrument added.

ABX Cleaner (1L)

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

Procedure for plugged-in reagent

Plugged-in reagent is used on:

- ABX Pentra 120
- ABX Pentra 120 Retic
- ABX Pentra DF 120
- ABX Pentra DX 120
- Pentra DX Nexus
- Pentra DF Nexus

1. If necessary, remove the empty **ABX Cleaner** from the reagent compartment.
2. Refer to the user manual to identify **ABX Cleaner** using the barcode reader or manuallly.
3. Install **ABX Cleaner** into the reagent compartment of the instrument.
4. Gently push it down in order to plug it correctly into the male connectors.

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

Methodology

ABX Cleaner: 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 Cleaner** 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 Cleaner** should be replaced.

Temperature limits

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

Internal Quality Control

HORIBA Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA Medical 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.

ABX Cleaner (1L)

Reference

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).
3. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) **27** (26).
4. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4-A6 (2008) **28** (25).

2015/01/12
A95A00005KEN

REF 0901020

REAGENT 20 L

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducé
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

ABX Diluent (20L)

- ABX Pentra 60 / 60C+
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- Pentra ES60 / MS60 / MS CRP
- Pentra DX Nexus / DF Nexus
- ABX Pentra 80 / XL80
- Pentra XLR
- Yumizen H500 OT / CT

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a]

ABX Diluent is a buffered isotonic solution intended for *in vitro* diagnostic use and designed for sheathing and diluting leucocytes (WBC), and for the determination and differentiation of blood cells, and the measurement of hematocrit on HORIBA Medical blood cell counters.

Warnings and Precautions [b]

- **ABX Diluent** is for professional *in vitro* diagnostic use only.
- It is the user's responsability 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.
- 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.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Diluent**.
- This reagent is destined for use with HORIBA Medical blood cell counters specified above. HORIBA Medical cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.

Waste Management

Please refer to local legal requirements.

This reagent contains less than 0.1% of sodium azide as a preservative. Sodium azide may react with lead and copper to form explosive metal azides.

Microbiological State

Not applicable.

Description and Composition

Description:

Limpid and colourless aqueous solution.

Composition:

Organic buffer	< 5%
Preservative	< 0.1%
Surfactant	< 0.1%

Storage and Stability [c]

- **Storage condition (before opening):** 18-25°C (65-77°F).
  Do not freeze.
- **Open stability:** 6 months maximum at 18-25°C (65-77°F) after opening and within the expiration limit.
- **Expiration date:** refer to "expiration date" reagent packaging label.

[a]Modification: new instrument added.
[b]Modification: CLP classification.
[c]Modification: modification of Storage and Stability.

ABX Diluent (20L)

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 blood samples should be collected using proper technique! Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious and follow biosafety practices (1, 2). When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric collection tubes (3, 4). The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself to avoid variations in the results.

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 normal conditions. Otherwise, blood clots may be possible.

Blood sample stability:

Sample stability at low temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at 4°C. Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters

Sample stability at room temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at room temperature (25°C). Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters

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 **ABX Diluent** using the barcode reader or manuallly.
2. Uncap the new reagent container.
3. Insert the stopper assembly straw into the container.
4. Tighten the stopper assembly to ensure an adequate seal.
5. Install the **ABX Diluent** container below the instrument as described in the user manual.

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

Methodology

ABX Diluent is a saline and buffered electrolytic solution which allows the dilution and the preparation of blood sample for analysis. The presence of non-ionic surfactant ensures an optimal dynamic of flow in the whole hydraulic systems of the instrument. The electrolytic action supports the counting of the cells by impedance.
This reagent is also used to stop the chemical reactions of some other reagents. This reagent is also used in the rinsing and cleaning cycles of the hydraulic systems of the instrument.

ABX Diluent (20L)

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 Diluent** 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 Diluent** should be replaced.

Temperature limits

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

Internal Quality Control

HORIBA Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA Medical 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. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).
3. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) **27** (26).
4. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4-A6 (2008) **28** (25).

2013/02/13
A95A00029NEN

REF 0401005

REAGENT 0.5 L

IVD CE 0120

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

ABX Minoclair (0.5L)

- ABX Micros / Advia 60
- ABX Micros 60 / ABC Vet
- ABX Micros ES60 / ESV60
- ABX Micros CRP / CRP200
- ABX Pentra 60 / 60C+
- ABX Pentra 80 / XL80
- Pentra XLR
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- Pentra DX Nexus / DF Nexus
- Pentra ES60 / MS60 / MS CRP
- Micros Care ST
- Microsemi CRP

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a] [b]

ABX Minoclair is a chemical solution intended for *in vitro* diagnostic use and designed for the cleaning of HORIBA Medical blood cell counters.
ABX Minoclair can be used for self-testing on Micros Care ST only.

Warnings and Precautions

- It is the user's responsability to verify that this document is applicable to the product use.
- **ABX Minoclair** is classified as non-hazardous in compliance with regulations 67/548/EEC - 1999/45/EC.
- 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.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Minoclair**.
- This reagent is destined for use with HORIBA Medical blood cell counters specified above. HORIBA Medical cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.

Waste Management

Please refer to local legal requirements.

Microbiological State

Not applicable.

Description and Composition

Description:

Basic, limpid and yellowish aqueous solution. Smells of bleach.

Composition:

Chemical cleaning agent	< 5%
Stabilizer	< 1%

Storage and Shelf Life after First Opening

- **Storage condition:** 18-25°C (65-77°F). Do not freeze.
- **Open stability:** 6 months maximum at 18-25°C (65-77°F) after opening.
- **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.

[a] Modification: new instrument added.
[b] Modification: new reagent leaflet form.

ABX Minoclair (0.5L)

Specimen

Sample collection:

All blood samples should be collected using proper technique! Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious and follow biosafety practices (1, 2). When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric collection tubes (3, 4). The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself to avoid variations in the results.

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 normal conditions. Otherwise, blood clots may be possible.

Blood sample stability:

Sample stability at low temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at 4°C. Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters

Sample stability at room temperature: Ten "normal" and ten "pathological" specimens were collected from the routine laboratory workload and stored at room temperature (25°C). Sample stability was assessed over a period of 72 hours. The results (mean of ten tests) conclude with a relative sample stability claim of:

- 48 hours for the CBC parameters
- 24 hours for the DIFF parameters

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.
ABX Minoclair is used during auto-concentrated cleaning procedure. Refer to the instrument user manual for running auto-concentrated cleaning.

Methodology

ABX Minoclair has an oxydizing action to clean up the hydraulic parts of the instrument.

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 Minoclair** if the damages might have an effect on the product performance.

ABX Minoclair (0.5L)

Signs of deterioration

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

Temperature limits

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

Internal Quality Control

HORIBA Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA Medical 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. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Third Edition. CLSI (NCCLS), document M29-A3 (2005) **25** (10).
3. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) **27** (26).
4. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4-A6 (2008) **28** (25).

2015/01/21
A95A00273BEN

REF 1210906022

REAGENT 1 L

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

Whitediff (1L)

- Yumizen H500 OT / CT

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 Medical blood cell counters.

Warnings and Precautions

- **Whitediff 1L** is for professional *in vitro* diagnostic use only.
- It is the user's responsability 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.
- 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.
- In the event of a malaise following skin contact, ingestion, or inhalation, consult a doctor.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **Whitediff 1L**.
- This reagent is destined for use with HORIBA Medical blood cell counters specified above. HORIBA Medical cannot guarantee the correct functionning of this reagent with instruments other than those specified above, or with instruments not manufactured by HORIBA Medical.

Waste Management

Please refer to local legal requirements.

Microbiological State

Not applicable.

Description and Composition

Description:

Limpid and pale yellow aqueous solution.

Composition:

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

Storage and Stability [a]

- **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.

[a]Modification: modification of Storage and Stability.

Whitediff (1L)

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 blood samples should be collected using proper technique! Consider all specimens, reagents, calibrators, controls, etc. that contain human specimen extracts as potentially infectious and follow biosafety practices (1, 2).
When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric collection tubes (3, 4). The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself to avoid variations in the results.

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.

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 5 populations (lymphocytes, monocytes, neutrophils, eosinophils and basophils).
Whitediff 1L also allows detection of atypical lymphocytes and large immature cells.

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.

Whitediff (1L)

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 Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
HORIBA Medical 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. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR 1910. 1030). Federal Register July 1, 1998; **6**: 267-280.
2. Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline - Fourth Edition. CLSI (NCCLS), document M29-A4 (2014) **34** (18).
3. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard - Sixth Edition. CLSI (NCCLS), document H3-A6 (2007) **27** (26).
4. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard - Sixth Edition. CLSI (NCCLS), document H4-A6 (2008) **28** (25).

2013/02/15
A01A00053JEN

ABX Difftrol

REF 2062011 (1L)
2062012 (1N)
2062013 (1H)
2062203 (Twin Pack: 2N)
2062207 (Twin Pack: 2L)
2062208 (Twin Pack: 2H)

CONTROL 3 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

- ABX Pentra 60 / 60C+
- ABX Pentra 80 / XL80
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- Pentra ES60 / MS60 / MS CRP
- Pentra DX Nexus / DF Nexus
- Pentra XLR

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a] [b]

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 Medical hematology blood cell counters.
Refer to the **ABX Difftrol** assay value data sheet for specific instrument models.

Warnings and Precautions

- **ABX Difftrol** is for professional *in vitro* diagnostic use only.
- It is the user's responsability to verify that this document is applicable to the product use.
- 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).
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Difftrol**.

Waste Management

Please refer to local legal requirements.

Microbiological State

Not applicable.

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 mammalian leucocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid.

Storage and Shelf Life after First Opening

- **Storage condition:** 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.
  ABX Difftrol must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

[a] Modification: new instrument added.
[b] Modification: new reagent leaflet form.

ABX Difftrol

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 manuallly.
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 methodes. **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 of 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 Medical. Values obtained with **ABX Difftrol** (if used before its expiry date) should fall within the expected range. The expected ranges are representative of estimates of the variation between different laboratories for each parameter. Inter-laboratory variations are the consequence of instrument calibration, maintenance, and operating technique. The reference results are therefore only indicative for control purposes and should not be used for calibration. At least five consecutive analyses, on a correctly calibrated analyser, are needed to establish the assay means and standard deviations for each **ABX Difftrol** parameter.
See paragraph Traceability of Calibrators and Control Materials.

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.

ABX Difftrol

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 Medical 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

HORIBA Medical 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.
Hemoglobin is measured using the Clinical Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method (4). Readings are made at 540 nm in a colorimeter/ spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations (4).
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 (5). No correction is made for trapped plasma.
Platelets are assayed using a hemocytometer and phase contrast optics.
** All brands and products are trademarks or registered trademarks of their respective companies.*

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. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition. CLSI (NCCLS), document H15-A3 (2000) **20** (28).
5. Procedure for Determining Packed Cell Volume by Microhematocrit Method; Approved Standard - Third Edition. CLSI (NCCLS), document H7-A3 (2001) **20** (18).

2013/02/15
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REF 2032002

CAL 2 mL

IVD CE

HORIBA ABX SAS
Parc Euromédecine - Rue du Caducée
B.P. 7290
34184 MONTPELLIER Cedex 4
FRANCE

ABX Minocal

- ABX Micros / Advia 60
- ABX Micros 60 / ABC Vet
- ABX Micros ES60 / ESV60
- ABX Micros CRP / CRP200
- ABX Pentra 60 / 60C+
- ABX Pentra 80 / XL80
- Pentra XLR
- Microsemi CRP
- ABX Pentra 120 / 120 Retic
- ABX Pentra DX120 / DF120
- scil Vet abc Plus+
- Pentra ES60 / MS60 / MS CRP
- Micros Care ST
- Pentra DX Nexus / DF Nexus

Hematology Devices (for *in vitro* diagnostic use)

Intended Use [a] [b]

ABX Minocal is a multiparameter blood calibrator intended for *in vitro* diagnostic use and designed for use in calibration of hematology blood cell counters.
Refer to the **ABX Minocal** assay value data sheet for specific instrument models.

Warnings and Precautions

- **ABX Minocal** is for professional *in vitro* diagnostic use only.
- It is the user's responsability to verify that this document is applicable to the product use.
- 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).
- Observe the standard laboratory precautions for use and follow national or local health and safety guidelines.
- Please refer to the Material Safety Data Sheet (MSDS) associated with **ABX Minocal**.

Waste Management

Please refer to local legal requirements.

Microbiological State

Not applicable.

Description and Composition

Description:

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

Composition:

ABX Minocal contains mammalian leucocytes (WBC), erythrocytes (RBC) and thrombocytes (PLT) suspended in a plasma-like fluid.

Storage and Shelf Life after First Opening

- **Storage condition:** 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 Minocal** is stable for 1 day after the tube has been opened if it is properly handled and promptly refrigerated at 2-8°C (35-46°F) after use.
  ABX Minocal must be tightly capped after use.
- **Expiration date:** refer to "expiration date" reagent packaging label.

[a] Modification: new instrument added.
[b] Modification: new reagent leaflet form.

ABX Minocal

Materials Required but not Provided

- Automated hematology analyzer.
- Standard laboratory equipment.

Specimen

Not applicable.

Procedure

ABX Minocal is ready to use.
The calibration on HORIBA Medical instruments is an important procedure, which may need to be performed during certain technical situations such as installation, maintenance and service interventions. Calibration should not be performed to compensate for a drift in results due to a blockage on the instrument.
Frequent re-calibration needs to be reported to HORIBA Medical Technical Support to determine the actual cause and appropriate remedy. After calibration, ensure the values for MCV, MCH and MCHC on patient samples agree with usual population means for these parameters.

1. Bring **ABX Minocal** 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 Minocal** using the barcode reader or manuallly.
3. Gently invert the tube 8 to 10 times immediately before sampling.
4. Run **ABX Minocal** 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 Minocal** assay value data sheet for specific instrument models.
Refer to the instrument user manual for detailed analysis and control procedures.

Methodology

ABX Minocal is a stable preparation used to calibrate blood cell counters. Calibration values have been obtained from replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methodes. **ABX Minocal** is run on the instrument in the same way as a patient blood sample (resistivity, absorbance and spectrophotometry measurements) and is used to calibrate leucocytes (WBC), erythrocytes (RBC), hemoglobin, hematocrit and thrombocytes (PLT) values.

Performance Characteristics and Limitations

Refer to the assay value data sheet for the target values and their tolerances regarding the instrument used.
See paragraph Traceability of Calibrators and Control Materials.

Calculation and Interpretation of Results

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

Changes in the Procedure and in the Performance

Packaging spoiling

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Signs of deterioration

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Incorrect mixing

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

Temperature limits

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

ABX Minocal

Internal Quality Control

HORIBA Medical control bloods must be used to periodically assess the integrity of the reagents and the instrument in the specified ranges.
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