

Instructions for use

AltoStar[®]

**Whole Blood Pretreatment
Buffer 1.5**

11/2021 EN

AltoStar[®]

Whole Blood Pretreatment Buffer 1.5

For use with

AltoStar[®] Purification Kit 1.5



WBPB15-46



576



11 2021



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1. About these instructions for use

These instructions for use guide the user in utilizing the AltoStar® Whole Blood Pretreatment Buffer 1.5 in combination with the AltoStar® Purification Kit 1.5.

The AltoStar® Whole Blood Pretreatment Buffer 1.5 is used for nucleic acid purification from human whole blood samples in combination with the AltoStar® Purification Kit 1.5. For detailed information on the use of that product, refer to the instructions for use of the AltoStar® Purification Kit 1.5.

Throughout this manual, the terms CAUTION and NOTE have the following meanings:

CAUTION



Highlights operating instructions or procedures which, if not followed correctly, may result in personal injury or impact product performance. Contact Altona Diagnostics technical support for assistance.

NOTE



Information is given to the user that is useful but not essential to the task at hand.

Read the instructions for use carefully before using the product.

2. Intended use

The AltoStar® Whole Blood Pretreatment Buffer 1.5 is intended for the stabilization and liquefaction of human whole blood samples for the subsequent isolation and purification of nucleic acids for *in vitro* diagnostic purposes.

The product is designed for use with Altona Diagnostics kits and reagents specified for use with the AltoStar® Whole Blood Pretreatment Buffer 1.5.

The AltoStar® Whole Blood Pretreatment Buffer 1.5 is intended for use by professional users trained in molecular biological techniques and *in vitro* diagnostic procedures.

3. Kit content

The AltoStar® Whole Blood Pretreatment Buffer 1.5 contains the following components:

Table 1: Kit components

Component	Number of tubes	Volume per tube [ml]
WBPB*	48	4.9

* Whole Blood Pretreatment Buffer

CAUTION



Before first use check the product and its components for completeness with respect to number, type and filling. Do not use a defective or incomplete product, product performance could be compromised.

The AltoStar® Whole Blood Pretreatment Buffer 1.5 contains enough reagents for the pretreatment of 576 human whole blood samples.

Upon receipt and before first use, check the product and its components for:

- Integrity
- Completeness with respect to number, type and filling
- Correct labeling
- Expiration date
- Clarity and absence of particles

If one or more tubes have been compromised during shipment or are missing, contact Altona Diagnostics technical support for assistance (see chapter 11. Technical support).

4. Storage and handling

The WBPB (Whole Blood Pretreatment Buffer) is a ready-to-use solution.

4.1 Storage

The WBPB must be stored at +15 °C to +30 °C upon arrival.

CAUTION



Improper storage conditions could compromise product performance.

CAUTION



Do not use products beyond the expiration date. The use of expired products could compromise product performance.

4.2 Handling

The WBPB is stable after initial opening for 14 days, when closed after each use and stored as follows: tubes shall be closed with the original cap after use and stored at +15 °C to +30 °C.

CAUTION



Do not leave reagents open in between use, as this could compromise product performance.

CAUTION



Improper handling of product components and samples may cause contamination and could compromise product performance:

- Do not interchange vial or bottle caps.
- Store positive and/or potentially positive material separated from the kit components.
- Use separated working areas for sample preparation/reaction setup and amplification/detection activities.
- Always dispose gloves after handling positive and/or potentially positive material.
- Do not open the PCR plates and/or tubes post amplification.

CAUTION



Do not exceed handling durations as specified in these instructions for use, as this could compromise product performance.

CAUTION



Do not mix components from different kit lots, as this could compromise product performance.

5. Product description

The AltoStar® Whole Blood Pretreatment Buffer 1.5 is intended for the stabilization and liquefaction of human whole blood samples for the subsequent isolation and purification of nucleic acids for *in vitro* diagnostic purposes.

Table 2: Kit component description

Kit component	Description
WBPB*	Contains surfactants and salts to stabilize and liquefy human whole blood samples for the subsequent isolation and purification of nucleic acids

* Whole Blood Pretreatment Buffer

5.1 Samples

5.1.1 Sample types

The following sample types are validated for use with the AltoStar® Whole Blood Pretreatment Buffer 1.5:

- Human EDTA whole blood
- Human citrate whole blood

CAUTION



Do not use other sample types! The use of other sample types could compromise product performance.

CAUTION



The presence of PCR inhibitors (e.g. heparin) could cause false negative or invalid results.

5.1.2 Sample collection and handling

Blood has to be collected with commercially available standard blood collection systems (e.g. Sarstedt, Becton Dickinson, Greiner or equivalent). Tube contents should be mixed directly after sample collection. The blood samples should be shipped cooled at +2 °C to +8 °C. Transport should occur following the local and national instructions for the transport of biological material.

CAUTION




Always treat samples as infectious and (bio-)hazardous material in accordance with safety and laboratory procedures. For sample material spills promptly use an appropriate disinfectant. Handle contaminated materials as biohazardous.

NOTE



Frozen storage of samples does not compromise kit performance. When working with frozen samples, make sure samples are completely thawed and properly mixed before use.

6. Warnings, precautions and limitations

Whole Blood Pretreatment Buffer		
 GHS05	H314	Causes severe skin burns and eye damage.
	H318	Causes serious eye damage.
	H412	Harmful to aquatic life with long lasting effects.
	P260	Do not breathe mist, vapours, spray.
	P264	Wash hands thoroughly after handling.
	P273	Avoid release to the environment.
Danger!	P280	Wear protective gloves, eye protection, face protection.
	P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
	P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER, a doctor.
	Contains:	Sodium hydroxide (CAS 50-01-1) 1–2.5 %

NOTE



For more information, please consult the safety data sheet (SDS).

- Before first use check the product and its components for completeness with respect to number, type and filling. Do not use a defective or incomplete product, product performance could be compromised.
- Improper storage conditions could compromise product performance.
- Do not use products beyond the expiration date. The use of expired products could compromise product performance.
- Do not leave reagents open in between use, as this could compromise product performance.
- Improper handling of product components and samples may cause contamination and could compromise product performance:
 - Do not interchange vial or bottle caps.
 - Store positive and/or potentially positive material separated from the kit components.

- Use separated working areas for sample preparation/reaction setup and amplification/detection activities.
- Always dispose gloves after handling positive and/or potentially positive material.
- Do not open the PCR plates and/or tubes post amplification.
- Do not exceed handling durations as specified in these instructions for use, as this could compromise product performance.
- Do not mix components from different kit lots, as this could compromise product performance.
- Do not use other samples types! The use of other sample types could compromise the product performance.
- The presence of PCR inhibitors (e.g. heparin) could cause false negative or invalid results.
- Always treat samples as infectious and (bio)hazardous material in accordance with safety and laboratory procedures. For sample material spills promptly use an appropriate disinfectant. Handle contaminated materials as biohazardous.
- Do not use samples which contain solids and high-viscosity constituents, as this could compromise product performance.
- Improper mixing of whole blood samples during preparation may cause invalid or false negative results.
- Do not exceed the incubation time for the pretreatment of whole blood samples, as this could compromise product performance.
- Disposal of hazardous and biological waste shall comply with local and national regulations to avoid environmental contamination.

7. Using the AltoStar® Whole Blood Pretreatment Buffer 1.5

The following chapters describe the use of the AltoStar® Whole Blood Pretreatment Buffer 1.5.

7.1 Sample volume

The AltoStar® Automation System AM16 (Hamilton; in the following summarized as AltoStar® AM16) allows purification of 500 µl of pretreated sample. Additional pretreated sample volume has to be provided to account for the dead volume of the sample tube used. When using the sample tubes purchased from Altona Diagnostics (see chapter 7.2 Sample tubes), provide at least 700 µl pretreated sample volume in total.

7.2 Sample tubes

Sample tubes suitable for use on the AltoStar® AM16 can be purchased from Altona Diagnostics (7 ml tube with cap, 82 x 13 mm, VK000010). Other sample tubes can be tested for applicability by the user. For details, refer to the instructions for use of the AltoStar® Purification Kit 1.5.

7.3 Sample barcodes

For automated sample identification by the AltoStar® AM16 all sample tubes must be labeled with a suitable barcode. For details, refer to the instructions for use of the AltoStar® Purification Kit 1.5.

7.4 Material and devices required but not provided

The material and devices shown in table 3 must be ordered from Altona Diagnostics.

Table 3: Required material and devices

Material	Description	Order No.
AltoStar® Molecular Diagnostic Workflow	Product bundle containing the AltoStar® Automation System AM16, the AltoStar® Connect software (Version 1.7.4 or higher) and IT hardware	AM16
AltoStar® Purification Kit 1.5	Nucleic acid isolation and purification chemistry for use with the AltoStar® Automation System AM16	PK15-46

Table 4: Additional laboratory material

Material	Description	Order No.
Sample tubes	e.g. 7ml tube with cap, 82 x 13mm	VK000010
Sample tube caps	e.g. ribbed plug for sample tubes	VK000011

7.5 General material and devices

- Vortex mixer
- Powder-free gloves (disposable)
- Pipettes (adjustable, for sample preparation)
- Pipette tips with filters (disposable, for sample preparation)

7.6 Procedure

7.6.1 Whole blood pretreatment procedure

1. Transfer the required volume of whole blood free of solids and high-viscosity constituents from the primary tube to a suitable barcode-labeled sample tube and add the same volume of WBPB to the sample to achieve a volumetric ratio of 1:1 (e.g. 500 µl of whole blood and 500 µl of WBPB).
2. Immediately and thoroughly mix by vortexing for 10 seconds. Insufficient mixing may render the sample unsuitable for processing due to increased viscosity or clotting.
3. Avoid formation of bubbles. If bubbles have formed during mixing they can be removed after 2–3 minutes by carefully tapping the sample tube. Do not centrifuge the sample.
4. Start the purification run on the AltoStar® AM16 for the pretreated whole blood samples within 60 minutes from the beginning of the pretreatment.

CAUTION



Do not use samples which contain solids and high-viscosity constituents, as this could compromise product performance.

CAUTION



Improper mixing of whole blood samples during preparation may cause invalid or false negative results.

CAUTION



Do not exceed the incubation time for the pretreatment of whole blood samples, as this could compromise product performance.

NOTE



The sample volume is not checked by the system prior to processing. Samples with insufficient volume will not be processed and error flagged during the sample transfer step in the AltoStar® AM16 purification run.

NOTE



If the samples must be prediluted: predilution diluent, which is not compatible with this application may affect nucleic acid stability, sample transfer and purification performance.

8. Performance data

The performance of the AltoStar® Whole Blood Pretreatment Buffer 1.5 is verified in conjunction with each altona Diagnostics real-time PCR kit or reagent specified for use with the AltoStar® Whole Blood Pretreatment Buffer 1.5. For information on performance data, refer to the instructions for use of the respective altona Diagnostics real-time PCR kit or reagent.

9. Disposal

Dispose of hazardous and biological waste in compliance with local and national regulations. Leftover product components and waste should not be allowed to enter sewage, water courses or the soil.

CAUTION



Always treat samples as infectious and (bio-)hazardous material in accordance with safety and laboratory procedures. For sample material spills promptly use an appropriate disinfectant. Handle contaminated materials as biohazardous.

CAUTION



Disposal of hazardous and biological waste shall comply with local and national regulations to avoid environmental contamination.

10. Quality control

In accordance with the altona Diagnostics GmbH EN ISO 13485-certified Quality Management System, each lot of AltoStar® Whole Blood Pretreatment Buffer 1.5 is tested against predetermined specifications to ensure consistent product quality.

11. Technical support

For customer support, contact altona Diagnostics technical support:

e-mail: **support@altona-diagnostics.com**

phone: **+49-(0)40-5480676-0**

NOTE



Any serious incident that has occurred in relation to this product shall be reported to altona Diagnostics and the competent authority of your country.

12. Trademarks and disclaimers

AltoStar® (altona Diagnostics).

Registered names, trademarks, etc. used in this document, even if not specifically marked as such, are not to be considered unprotected by law.















The AltoStar® Whole Blood Pretreatment Buffer 1.5 is a CE-marked diagnostic kit according to the European *in vitro* diagnostic directive 98/79/EC.

Product not licensed with Health Canada and not FDA cleared or approved.

Not available in all countries.

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13. Symbols

Symbol	Explanation
	<i>In vitro</i> diagnostic medical device
	Global Trade Item Number
	Batch code
	Content
	Catalogue number
	Consult instructions for use
	Contains sufficient for "n" tests/reactions (rxns)
	Temperature limit
	Use-by date
	Manufacturer
	Caution
	Version
	Note
	Unique formula identifier

14. Revision history

Table 5: Revision history

Identifier	Date of issue [month/year]	Modifications
MAN-WBPB1540-EN-S01	11/2021	Initial release

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