altona DIAGNOSTICS

# Instructions for use

# AltoStar®
# Purification Kit 1.5

05/2022 EN

AltoStar®

# AltoStar®

# Purification Kit 1.5

**For research use only!**

**(RUO)**

REF PK15-06

1152

05 2022

altona Diagnostics GmbH • Mörkenstr. 12 • D-22767 Hamburg

INS-PK1500-EN-S04

# Content

## 1. Application

The AltoStar® Purification Kit 1.5 is a reagent system that uses magnetic particle technology and, in conjunction with the AltoStar® Automation System AM16 (Hamilton; in the following summarized as AltoStar® AM16), allows the automated isolation and purification of nucleic acids from biological specimens.

**For research use only (RUO)! Not for use in diagnostic procedures.**

## 2. Kit content

The AltoStar® Purification Kit 1.5 is shipped in 2 separate boxes **Box 1** and **Box 2** (see tables 1 and 2).

**Table 1:** Kit components **Box 1**

| Component | Number per box | Volume per container [ml] |
|---|---|---|
| Lysis Buffer | 6 | 190 |
| Wash Buffer 1 | 6 | 175 |
| Wash Buffer 2 | 6 | 175 |
| Wash Buffer 3 | 6 | 175 |
| Container Re-Sealing Foil | 120 | n.a. |

**Table 2:** Kit components **Box 2**

| Component | Number of tubes | Volume per tube [ml] |
|---|---|---|
| Enhancer | 24 | 1.4 |
| Magnetic Beads | 24 | 1.6 |
| Elution Buffer | 12 | 8.3 |

The AltoStar® Purification Kit 1.5 contains reagents sufficient for 1,152 sample purifications when using 500 µl sample volume only or for 576 sample purifications when using 1,000 µl sample volume only.

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 10. Technical support).

# 3. Storage and handling

All reagents included in the AltoStar® Purification Kit 1.5 are ready-to-use solutions.

## 3.1 Storage

The AltoStar® Purification Kit 1.5 is shipped at room temperature. **Box 1** should be stored at +15 °C to +30 °C and **Box 2** should be stored at +2 °C to +8 °C upon receipt (see table 3). The reagent containers and tubes should be stored in an upright position.

**Table 3:** Storage conditions for **Box 1** and **Box 2**

| Storage conditions | |
|---|---|
| **Box 1** | **Box 2** |
| +15 °C to +30 °C | **+2 °C to +8 °C** |

## 3.2 Handling

The reagents of the AltoStar® Purification Kit 1.5 are stable after initial opening for 14 days, when closed after each use and stored as follows: Magnetic Beads, Enhancer and Elution Buffer should be closed with the original cap after use and stored at +2 °C to +8 °C. The Lysis Buffer and Wash Buffer 1, 2 and 3 should be resealed after use with unused Container Re-Sealing Foil and stored at +15 °C to +30 °C.

**NOTE**

Container Re-Sealing Foils should not be reused.

**NOTE**

Reagents should be always closed after use.

# 4. Product description

**Table 4:** Kit component description

| Kit component | Description |
|---|---|
| Lysis Buffer | The **Lysis Buffer** contains chaotropic salts and surfactants (guanidine thiocyanate, Octoxynol 9) to disrupt cells or virions chemically. It stabilizes nucleic acids and protects them against nucleases in solution. |
| Wash Buffer 1 | The **Wash Buffer 1** contains different salts and organic solvents (guanidine thiocyanate and ethanol) to remove proteins and other impurities. |
| Wash Buffer 2 | The **Wash Buffer 2** contains organic solvents (ethanol) to remove proteins and other impurities. |
| Wash Buffer 3 | The **Wash Buffer 3** contains different salts in order to purify the nucleic acids. |

| Kit component | Description |
|---|---|
| Enhancer | The **Enhancer** stabilizes and protects nucleic acids against nucleases in solution. |
| Magnetic Beads | The **Magnetic Beads** are coated with a thin layer of silica to bind free nucleic acids in solution. The magnetic characteristic allows the separation of beads from liquids in a magnetic field. |
| Elution Buffer | The **Elution Buffer** is a low salt buffer to release the nucleic acids from the Magnetic Beads for subsequent analysis. |
| Container Re-Sealing Foil | The **Container Re-Sealing Foil** is an adhesive tape seal to be used for resealing the containers of the AltoStar® Purification Kit 1.5 (Lysis Buffer and Wash Buffer 1, 2 and 3) after use. |

## 4.1 Principle of method

The AltoStar® Purification Kit 1.5 allows the automated isolation and purification of RNA and DNA from biological specimens (see chapter 5. Sample types) in conjunction with the AltoStar® AM16 (Order No. AM16). The AltoStar® Purification Kit 1.5 is based on magnetic bead technology, utilizing silica coated magnetic particles, which can bind and release nucleic acids under specific conditions.

The purification procedure comprises 3 automated steps on the AltoStar® AM16 (see figure 1).

1. In the first step nucleic acids are released by chemical and mechanical lysis under chaotropic high salt conditions. The conditions stabilize the nucleic acids in solution and enable their binding to the magnetic silica beads.
2. In the following washing steps different wash buffers are used to remove proteins and other impurities.
3. Finally, the nucleic acids are released from the magnetic beads with an elution buffer and transferred to the eluate plate.

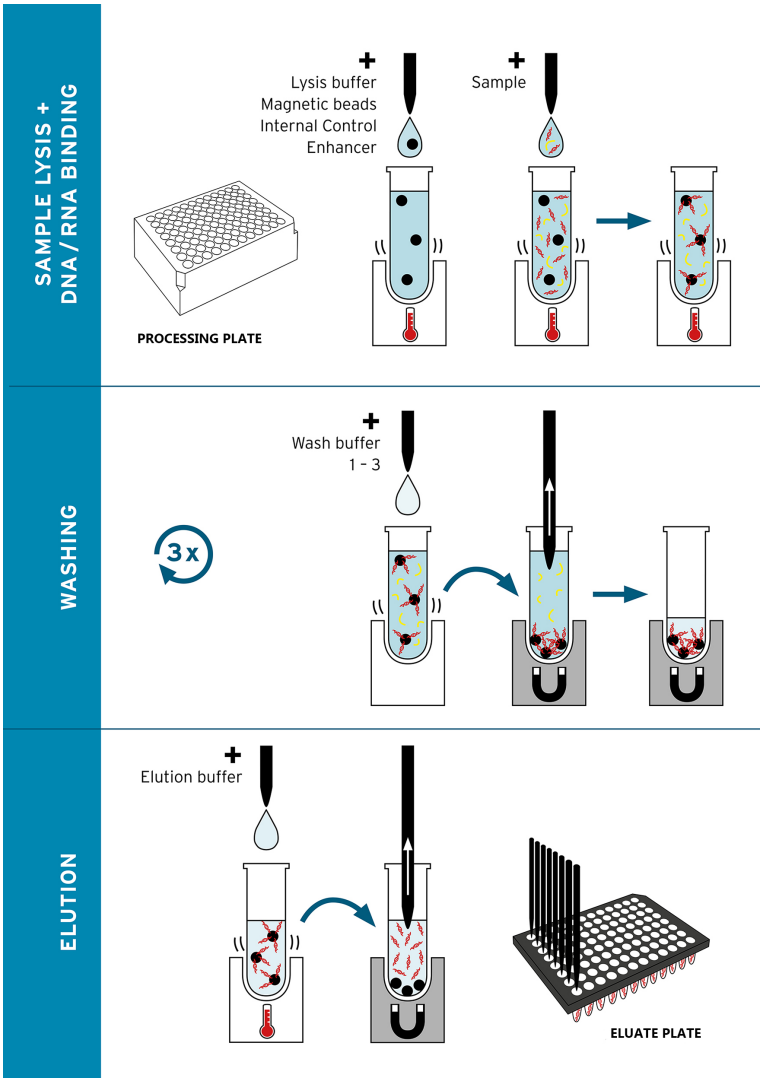


**Figure 1:** Illustration of the purification procedure

## 5. Sample types

The following sample types can be used with the AltoStar® Purification Kit 1.5:

- Whole blood
- Plasma
- Serum
- Urine
- Stool
- Cerebrospinal fluid (CSF)
- Swabs in viral transport medium
- Bronchoalveolar lavage (BAL)

**NOTE**

When working with frozen samples, make sure samples are completely thawed and properly mixed before use.

**NOTE**

All sample types can be processed simultaneously in one purification run with the AltoStar® Purification Kit 1.5.

# 6. Safety information

| Lysis Buffer | | |
|---|---|---|
|  GHS05  GHS07  GHS09 **Danger!** | H302+H312+H332 | Harmful in contact with skin or if inhaled or swallowed. |
| | H314 | Causes severe skin burns and eye damage. |
| | H318 | Causes serious eye damage. |
| | H411 | Toxic to aquatic life with long lasting effects. |
| | EUH032 | Contact with acids liberates very toxic gas. |
| | EUH071 | Corrosive to the respiratory tract. |
| | P260 | Do not breathe mist, vapours, spray. |
| | P264 | Wash hands thoroughly after handling. |
| | P270 | Do not eat, drink or smoke when using this product. |
| | P271 | Use only outdoors or in a well-ventilated area. |
| | P273 | Avoid release to the environment. |
| | 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. |
| | P362+P364 | Take off contaminated clothing and wash it before reuse. |
| | P405 | Store locked up. |
| | P501 | Dispose of contents/container to a hazardous or special waste collection point. |
| | **Contains:** | Guanidine thiocyanate (CAS 593-84-0) 50–70 %. |
| | | Octoxinol (CAS 9036-19-5) 2.5–5 %. |
| | | 2-Morpholinoethanesulfonic acid (CAS 4432-31-9) 1–2.5 %. |
| | | 4-Nonylphenol (CAS 127087-87-0) 0.1–1 %. |

| Wash Buffer 1 | | |
|---|---|---|
|  GHS02  GHS05 **Danger!** | H226 | Flammable liquid and vapour. |
| | H303 | May be harmful if swallowed. |
| | H313 | May be harmful in contact with skin. |
| | H314 | Causes severe skin burns and eye damage. |
| | H318 | Causes serious eye damage. |
| | H412 | Harmful to aquatic life with long lasting effect. |
| | EUH032 | Contact with acids liberates very toxic gas. |
| | EUH071 | Corrosive to the respiratory tract. |
| | P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| | P233 | Keep container tightly closed. |
| | P240 | Ground and bond container and receiving equipment. |
| | P241 | Use explosion-proof electrical/ventilating/lighting/…/equipment. |
| | P242 | Use non-sparking tools. |
| | P243 | Take action to prevent static discharges. |
| | P260 | Do not breathe mist, vapours, spray. |
| | P264 | Wash hands thoroughly after handling. |
| | P273 | Avoid release to the environment. |
| | P280 | Wear protective gloves, protective clothing, 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. |
| | P363 | Wash contaminated clothing before reuse. |
| | P370+P378 | In case of fire: Use media other than water to extinguish. |
| | P403+P235 | Store in a well-ventilated place. Keep cool. |
| | P405 | Store locked up. |
| | P501 | Dispose of contents/container to a hazardous or special waste collection point. |
| | **Contains:** | Guanidine thiocyanate (CAS 593-84-0) 25–50 %. |
| | | Ethanol (CAS 64-17-5) 25–50 %. |

| Wash Buffer 2 | | |
|---|---|---|
|  GHS02  GHS07 **Danger!** | H226 | Flammable liquid and vapour. |
| | H319 | Causes serious eye irritation. |
| | P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| | P233 | Keep container tightly closed. |
| | P240 | Ground and bond container and receiving equipment. |
| | P241 | Use explosion-proof electrical/ventilating/lighting/…/equipment. |
| | P242 | Use non-sparking tools. |
| | P243 | Take action to prevent static discharges. |
| | P280 | Wear protective gloves, protective clothing, eye protection, face protection. |
| | P303+P361+P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. |
| | P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| | P337+P313 | If eye irritation persists: Get medical advice/attention. |
| | P403+P235 | Store in a well-ventilated place. Keep cool. |
| | P501 | Dispose of contents/container to a hazardous or special waste collection point. |
| | **Contains:** | Ethanol (CAS 64-17-5) 50–70 %. |

| Enhancer | | |
|---|---|---|
|  GHS05 **Danger!** | H314 | Causes severe skin burns and eye damage. |
| | H318 | Causes serious eye damage. |
| | P260 | Do not breathe mist, vapours, spray. |
| | P264 | Wash hands thoroughly after handling. |
| | P280 | Wear protective gloves, protective clothing, 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. |
| | P363 | Wash contaminated clothing before reuse. |
| | P405 | Store locked up. |
| | P501 | Dispose of contents/container to a hazardous or special waste collection point. |
| | **Contains:** | Tris(2-carboxyethyl)phosphine (CAS 51805-45-9) 10–20 %. |

**NOTE**

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

# 7. Using the AltoStar® Purification Kit 1.5

The following chapters describe the use of the AltoStar® Purification Kit 1.5.

## 7.1 Sample volume

The AltoStar® Purification Kit 1.5 allows purification of either 500 µl or 1,000 µl of a sample. Additional sample volume has to be provided to account for the dead volume of the sample tube used (see chapter 7.2 Sample tubes).

**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.

## 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, Order No. VK000010).

Sample tubes that fulfill the following requirements can be tested for applicability by the user:

- Height below 100 mm
- Inner diameter greater than 9 mm
- Outer diameter within 11–14 mm when using the tube carrier 32
- Outer diameter within 14.5–18 mm when using the tube carrier 24

Depending on the chosen sample volume, 500 µl or 1,000 µl of the sample are automatically transferred from the sample tube to the purification process. To account for the dead volume of the sample tube additional sample volume has to be provided. The necessary excess volume depends on the tube geometry.

The volumes specified in table 5 serve as a starting point for testing sample tube and dead volume suitability.

**Table 5:** Suggested total sample volumes for different tube types

| Outer tube diameter [mm] | Total volume [µl] needed for 500 µl / 1,000 µl processing volume | | |
|---|---|---|---|
| | Round bottom | Flat bottom | Conical bottom |
| 11 | Not suitable | 900 / 1,400 | Not suitable |
| 11.5 | 700 / 1,300 | 900 / 1,400 | 700 / 1,300 |
| 12 | 700 / 1,300 | 900 / 1,400 | 900 / 1,400 |
| 13 | 700 / 1,300 | 900 / 1,400 | 1,000 / 1,500 |
| 14 | 800 / 1,300 | 900 / 1,400 | 1,000 / 1,500 |
| 15 | 1,300 / 1,900 | 900 / 1,400 | 1,000 / 1,500 |
| 15.3 | 1,300 / 1,900 | 1,600 / 2,200 | 1,000 / 1,500 |
| 16 | 1,300 / 1,900 | 1,600 / 2,200 | 1,000 / 1,500 |
| 16.5 | 1,400 / 1,900 | 1,700 / 2,200 | 1,000 / 1,500 |
| 16.8 | 1,500 / 1,900 | Not tested | 1,000 / 1,500 |
| 17 | 1,500 / 1,900 | Not tested | 1,000 / 1,500 |
| 18 | 1,500 / 1,900 | Not tested | Not tested |

## 7.3 Sample barcodes

For automated sample identification by the AltoStar® AM16 sample tubes must be labeled with a suitable barcode (see figure 2).

For a given purification run, ensure that each sample barcode is unique. The sample barcode must contain between 1 and 20 characters. It is possible to use numbers (0–9) and letters (A–Z, a–z). The barcode label must be fixed to the tube within a range of 20 mm to 100 mm from the bottom of the tube.

The label must fit tightly at an angle of approximately 90° to the tube. The label must fit tightly over its whole length.

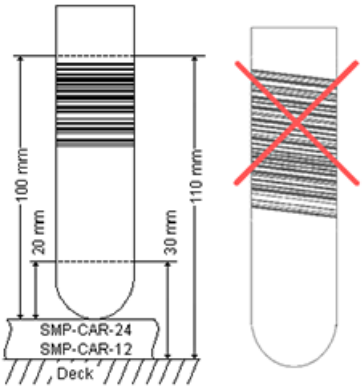


**Figure 2:** Placement of barcode on the sample tube

## 7.4 Equipment and reagents to be supplied by the user

**Table 6:** Equipment and consumables

| Material | Description | Order No. |
|---|---|---|
| AltoStar® AM16 Workflow | Product bundle containing the AltoStar® Automation System AM16, the AltoStar® Connect software and IT hardware | AM16 |
| AltoStar® Internal Control 1.5 | Nucleic acid extraction and PCR amplification and detection control | IC15-06 |
| AltoStar® Whole Blood Pretreatment Buffer 1.5 | Buffer for the pretreatment of whole blood samples | WBPB15-06 |
| AltoStar® Respiratory Sample Pretreatment Buffer 1.5 | Buffer for the pretreatment of respiratory samples | RSPB15-04 |
| Processing Plate | Fully-skirted, barcoded 96 deep-well plate | VK000001 |
| Eluate Plate | Semi-skirted, barcoded 96 multi-well plate | VK000003 |
| Eluate Plate Sealing Foil | Sealing foil for the eluate plate | VK000004 |
| 1,000 µl CO-RE Tips | 1,000 µl filter tips for use with the AltoStar® Automation System AM16 | VK000007 |
| 300 µl CO-RE Tips | 300 µl filter tips for use with the AltoStar® Automation System AM16 | VK000008 |
| Waste Bag | Autoclavable sterile bag for use with the AltoStar® Automation System AM16 | VK000009 |
| Container Re-Sealing Foil | Re-sealing foil for the AltoStar® Purification Kit 1.5 Lysis Buffer, Wash Buffer 1, 2 and 3 containers | VK000021 |

**Table 7:** Additional laboratory material and devices

| Material | Description | Order No. |
|---|---|---|
| Sample Tubes | e.g. 7 ml tube with cap, 82 x 13 mm | VK000010 |
| Sample Tube Caps | e.g. ribbed plug for sample tubes | VK000011 |
| Plate Sealer | e.g. AltoStar® Plate Sealer | VK000023 |
| | e.g. PX1 Plate Sealer (Bio-Rad) | VK000033 |

## 7.5 General material and devices

- Vortex mixer
- Powder-free gloves (disposable)
- Centrifuge for pretreatment of samples
- Pipettes (adjustable, for sample preparation)
- Pipette tips with filters (disposable, for sample preparation)
- Sodium chloride solution (0.9 %)*

* For purification of stool samples

## 7.6 Procedure

### 7.6.1 Overview of the AltoStar® Workflow

The steps of the purification procedure are summarized in table 8. For details refer to the instructions for use of the AltoStar® AM16 and the AltoStar® Connect software (Hamilton).

**Table 8:** Overview of the purification procedure

| Step | Action |
|---|---|
| **1. Start the AltoStar® AM16** | • Switch on the AltoStar® AM16.<br>• Switch on the computer and the monitor.<br>• Start the AltoStar® Connect software. |
| **2. Perform maintenance** | • In the menu bar click **Application** → **Instrument Maintenance**.<br>◦ If weekly maintenance is due, click **Start Weekly Maintenance**.<br>◦ If daily maintenance is due, click **Start Daily Maintenance**.<br>• Follow the on-screen instructions for the maintenance process. |
| **3. Program an AltoStar® run** | • In the menu bar click **Program Run** → **Program Run** (**AltoStar® Purification**). Alternatively, go back to the Start screen and click the **Program Run** button.<br>• Enter samples or import from the LIMS.<br>• Select assays for the sample unless already imported from the LIMS.<br>• Click the **Create Run** button in the tool bar to create the AltoStar® run. |

| Step | Action |
|---|---|
| **4. Start a purification run** | • In the menu bar click **Purification** → **Start Purification**. Alternatively, go back to the Start screen and click the **Start Purification** button.<br>• Select the purification run to be started to display the samples included in the selected purification run.<br>• Prepare the purification reagents:<br>◦ Ensure that the purification reagents to be used have the same loading number (except AltoStar® Internal Control 1.5) and are not expired.<br>◦ If precipitates are visible in the Lysis Buffer, heat it (≤ +50 °C) until completely dissolved.<br>◦ Thaw the IC (AltoStar® Internal Control 1.5) and vortex for 5 seconds.<br>◦ Vortex the Magnetic Beads for 5 seconds without wetting the lid.<br>• Prepare the samples for the purification run to be started as described in chapter 7.6.2 Sample preparation.<br>• Click the **Start Run** button in the tool bar.<br>• Follow the loading dialogs and load the instrument accordingly.<br>• Confirm the Loading complete message with **OK** or wait 10 seconds.<br>The system will now perform the purification run automatically. |
| **5. Finish the purification run** | • Make sure the loading tray is empty and confirm the Run finished dialog with **OK**.<br>• Follow the instructions in the Maintenance dialog and confirm with **OK**.<br>• Seal and store the components of the AltoStar® Purification Kit 1.5 that can be reused.<br>• If the associated PCR setup run is not started right away, seal the eluate plate with an Eluate Plate Sealing Foil and store at +2 °C to +8 °C for up to 24 hours.<br>• View the purification run results to confirm successful processing of each sample. |

## 7.6.2 Sample preparation

### Whole blood

Whole blood samples must be pretreated to generate a solids-free, low viscosity liquid suitable for liquid handling on the AltoStar® AM16.

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 AltoStar® Whole Blood Pretreatment Buffer 1.5 (Order No. WBPB15-06) to the sample to achieve a volumetric ratio of 1:1.
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. Take care to 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.

### Plasma and serum

Plasma and serum samples that are free of solids and high-viscosity constituents can be processed without pretreatment on the AltoStar® AM16.

### Urine

Urine samples that are free of solids and high-viscosity constituents can be processed without pretreatment on the AltoStar® AM16.

### Stool

Stool samples must be pretreated to generate a solids-free, low viscosity liquid suitable for liquid handling on the AltoStar® AM16.

1. Add 1 volumetric part stool to 25 volumetric parts 0.9 % sodium chloride solution (not provided).
2. Thoroughly mix by vortexing to achieve a homogenous suspension.
3. Centrifuge at 500 x *g* for 1 minute. Transfer the solids-free supernatant to a suitable barcode-labeled sample tube (see chapter 7.2 Sample tubes).

### Cerebrospinal fluid (CSF)

Cerebrospinal fluid samples that are free of solids and high-viscosity constituents can be processed without pretreatment on the AltoStar® AM16.

### Swabs in viral transport medium

Viral transport medium samples that are free of solids and high-viscosity constituents can be processed without pretreatment on the AltoStar® AM16.

**NOTE**

Remove the swab before loading the sample tube on the AltoStar® AM16.

### Bronchoalveolar lavage (BAL)

BAL samples must be pretreated to generate a solids-free, low viscosity liquid suitable for liquid handling on the AltoStar® AM16.

1. Transfer the required volume of BAL sample from the primary tube to a suitable barcode-labeled sample tube and add the same volume of AltoStar® Respiratory Sample Pretreatment Buffer 1.5 (Order No. RSPB15-04) to the sample to achieve a volumetric ratio of 1:1 [e.g. 400 µl of BAL sample and 400 µl of Respiratory Sample Pretreatment Buffer (RSPB)].
2. Immediately and thoroughly mix by vortexing for 10 seconds.
3. Incubate the sample/RSPB mixture at +60 °C for 15 min (e.g. with a block heater or water bath).
4. After incubation, mix again thoroughly (e.g. by vortexing) for 10 seconds.
5. The BAL sample/RSPB mixture shall be free of solids and high viscosity constituents. If this is not the case, transfer only the liquid fraction of the mixture and discard the solid fraction. If the liquid fraction is not enough for the purification process, repeat the pretreatment procedure with the sample material and combine the liquid fractions until enough liquid is reached.
6. Start the purification run on the AltoStar® AM16 for the pretreated BAL samples.

### 7.6.3 Sealing of the eluate plate

In case the eluates in the eluate plate are to be stored, the eluate plate should be heat sealed with Eluate Plate Sealing Foil using a suitable plate sealer [e.g. AltoStar® Plate Sealer (170 °C and 2 seconds)].

### 7.6.4 Unsealing of the eluate plate

1. Briefly centrifuge the eluate plate in a plate centrifuge to remove any liquid from the inside of the sealing foil.
2. Press the eluate plate onto a table to avoid sudden plate movements during the removal of the sealing foil.
3. Start peeling in one corner and slowly and steadily pull the sealing foil towards the diagonally opposite corner until it is removed.

## 8. 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.

**NOTE**

Liquid waste and any liquids containing Lysis Buffer or Wash Buffer 1 contain guanidine thiocyanate, which can form toxic, highly reactive and volatile compounds when combined with bleach or strong acids.

# 9. Troubleshooting guide

## Problem: Precipitate in reagent

| Possible cause | Suggestions |
|---|---|
| Storage of the Lysis Buffer container at low temperature or prolonged storage | If the Lysis Buffer container is already opened, make sure to reseal it with Container Re-Sealing Foil. Heat the Lysis Buffer container (≤ +50 °C, e.g. in a water bath) with careful intermittent pivoting until the precipitates are completely dissolved. |
| Excessive evaporation due to improper use and/or sealing may lead to increased salt concentration in reagents | Discard the reagent. Make sure to immediately close the reagent containers with Container Re-Sealing Foil and reagent tubes with lids after use. |

## Problem: Low yield or purity of nucleic acids

| Possible cause | Suggestions |
|---|---|
| Storage of reagents under wrong conditions | Discard reagents. Make sure to store the product components under defined storage conditions (see chapter 3. Storage and handling). |
| Reagents were not closed and/or stored properly in between use | Discard reagents. Make sure to store the product components under defined storage conditions (see chapter 3. Storage and handling). Make sure to immediately close the reagent containers with Container Re-Sealing Foil and reagent tubes with lids after use. |
| Improper pretreatment of samples | Make sure to prepare samples according to the instructions in chapter 7.6.2 Sample preparation. |
| Frozen samples were not thawed or mixed properly | Make sure samples are completely thawed and properly mixed before use. |
| Incomplete sample lysis | Before use, check that the Lysis Buffer does not contain precipitates. If the Lysis Buffer container is already opened, make sure to reseal it with Container Re-Sealing Foil. Heat the Lysis Buffer container (≤ +50 °C, e.g. in a water bath) with careful intermittent pivoting until the precipitates are completely dissolved. |

### Problem: Un-processed sample

| Possible cause | Suggestions |
|---|---|
| High sample viscosity or solids in the sample | Make sure to prepare samples according to chapter 7.6.2 Sample preparation. |
| Insufficient sample volume | Short samples will not be processed and error flagged during the sample transfer step. Make sure to provide the processing volume plus the required dead volume suitable for the sample tube used (see chapter 7.2 Sample tubes). |

### Problem: Un-processed whole blood sample

| Possible cause | Suggestions |
|---|---|
| High sample viscosity due to prolonged incubation with AltoStar® Whole Blood Pretreatment Buffer 1.5 | Make sure to comply with the mixing requirements and to start the purification run on the AltoStar® AM16 within 60 minutes from the beginning of the pretreatment (see section Whole blood in chapter 7.6.2 Sample preparation). |

## 10. Technical support

For customer support, contact altona Diagnostics technical support:

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

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

## 11. Trademarks and disclaimers

AltoStar® (altona Diagnostics GmbH).

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

**For research use only (RUO)! Not for use in diagnostic procedures.**

## 12. Symbols

| Symbol | Explanation |
|---|---|
| RUO | Research use only |
| LOT | Batch code |
| CONT | Content |
| REF | Catalogue number |
| NUM | Number |
| COMP | Component |
|  | Consult instructions for use |
|  | Contains sufficient for "n" tests/reactions (rxns) |
|  | Temperature limit |
|  | Use-by date |
|  | Manufacturer |
| MAT | Material number |
|  | Version |
|  | Note |
| UFI | Unique formula identifier |

# 13. Revision history

**Table 9:** Revision history

| Identifier | Date of issue [month/year] | Modifications |
|---|---|---|
| INS-PK1500-EN-S04 | 04/2022 | • Modification of the document structure<br>• Chapter 1: adaption of the application<br>• Chapter 5: addition of BAL as sample type<br>• Chapter 7.4: adaption of table 6 "Equipment and consumables" and addition of table 7 "Additional laboratory material and devices"<br>• Chapter 7.6.2: addition of instructions for sample pretreatment of BAL<br>• Chapter 13: addition of revision history |

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altona Diagnostics GmbH
Mörkenstr. 12
22767 Hamburg, Germany

phone +49 40 548 0676 0
fax +49 40 548 0676 10
e-mail info@altona-diagnostics.com

**www.altona-diagnostics.com**