altona DIAGNOSTICS

Instructions for use

AltoStar®
Purification Kit 1.5

04/2022 EN

AltoStar®

AltoStar®

Purification Kit 1.5

For use with

AltoStar® Automation System AM16

PK15-46

1152

04 2022

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MAN-PK1540-EN-S02

Content

1. About these instructions for use

These instructions for use guide the user in utilizing the AltoStar® Purification Kit 1.5 in combination with the AltoStar® Internal Control 1.5 on the AltoStar® Automation System AM16 (Hamilton; in the following summarized as AltoStar® AM16) with the AltoStar® Connect software (Hamilton).

The main operation steps of the AltoStar® AM16, the AltoStar® Connect software and the AltoStar® Internal Control 1.5 during the purification procedure are described for comprehensibility.

For more detailed information about these products, refer to the respective instructions for use listed below:

- AltoStar® Automation System AM16 Operator's Manual IVD (Hamilton)
- AltoStar® Connect Software Manual IVD (Hamilton)
- Instructions for use AltoStar® Internal Control 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® Purification Kit 1.5 uses magnetic particle technology and is intended to be used for the automated isolation and purification of nucleic acids from specified human specimens for *in vitro* diagnostic purposes.

The product is designed for use with the AltoStar® Automation System AM16, the AltoStar® Internal Control 1.5 and altona Diagnostics kits and reagents specified for use with the AltoStar® Purification Kit 1.5.

The AltoStar® Purification Kit 1.5 is intended for use by professional users trained in molecular biological techniques and *in vitro* diagnostic procedures.

3. 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

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, as product performance could be compromised.

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 any kit component has been compromised during shipment or is missing, contact altona Diagnostics technical support for assistance (see chapter 13. Technical support).

4. Storage and handling

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

4.1 Storage

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

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 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 shall 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 shall be resealed after use with unused Container Re-Sealing Foil and stored at +15 °C to +30 °C.

CAUTION

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

CAUTION

Do not reuse Container Re-Sealing Foils to avoid contamination of the reagents, which 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

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.
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.

5.1 Principle of method

The AltoStar® Purification Kit 1.5 is intended for the automated isolation and purification of RNA and DNA from specified human specimens (see chapter 6. Sample types) for *in vitro* diagnostic purposes in conjunction with the AltoStar® AM16, the AltoStar® Internal Control 1.5 and altona Diagnostics kits and reagents specified for use with the AltoStar® Purification Kit 1.5. 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 [1,2,3].

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. The AltoStar® Internal Control 1.5 is automatically added by the AltoStar® AM16.
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.

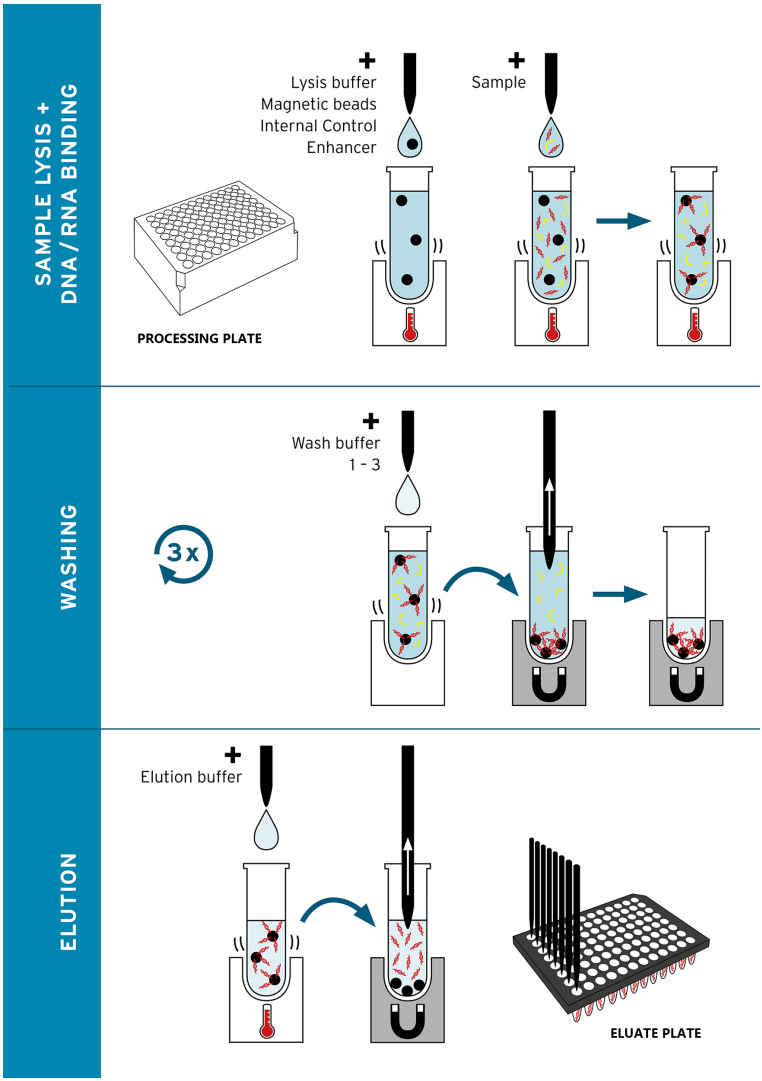


Figure 1: Illustration of the purification procedure using the AltoStar® Purification Kit 1.5 on the AltoStar® AM16

6. Sample types

The following sample types are validated for use with the AltoStar® Purification Kit 1.5:

- Human EDTA and citrate whole blood
- Human EDTA and citrate plasma
- Human serum
- Human urine
- Human stool
- Human cerebrospinal fluid (CSF)
- Human swabs in viral transport medium

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.

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.

NOTE

For information regarding collection, handling and storage of samples refer to the instructions for use of altona Diagnostics kits and reagents specified for use with the AltoStar® Purification Kit 1.5.

NOTE

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

7. Warnings, precautions and limitations

Lysis Buffer		
 GHS05	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.
 GHS07	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.
 GHS09	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.
Danger!	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	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.
 GHS05	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.
Danger!	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).

- 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, as 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.
- Do not reuse Container Re-Sealing Foils to avoid contamination of the reagents, which 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 sample types! The use of other sample types could compromise product performance.
- The presence of PCR inhibitors (e.g. heparin) could cause false negative or invalid results.

- Always use the correct "**Sample Type**" and "**Sample Volume**" when programming an AltoStar® run, otherwise the product performance could be compromised.
- Do not use samples which contain solids and high-viscosity constituents, as this could compromise product performance.
- Always provide at least 500 µl or 1,000 µl sample volume, plus the required dead volume in a suitable sample tube. Insufficient volume will lead to sample exclusion.
- 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.
- Improper preparation of reagents (e.g. lysis buffer and magnetic beads) may cause invalid or false negative results.
- Do not interchange tube caps when closing product components after use to avoid contamination of reagents, which could compromise product performance.
- 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.
- Storage of eluates under wrong conditions may lead to loss of eluate volume and/or degradation of the pathogen specific target sequence and could compromise product performance.
- Disposal of hazardous and biological waste shall comply with local and national regulations to avoid environmental contamination.

8. Using the AltoStar® Purification Kit 1.5

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

8.1 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 8.2 Sample tubes).

8.2 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.

Fill an ample number of sample tubes with the suitable sample material free of solids and high-viscosity constituents at the volume specified in the table. Use these filled sample tubes in a test purification run. If the transfer procedure fails for one or more samples, repeat the test purification run with increased filling volume.

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

For further information and assistance, contact altona Diagnostics technical support (see chapter 13. Technical support).

8.3 Sample barcodes

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

For general barcode specifications, refer to the instructions for use of the AltoStar® Automation System AM16.

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. Additional sample volume has to be provided to account for the dead volume of the sample tube used (see chapter 8.2 Sample tubes).

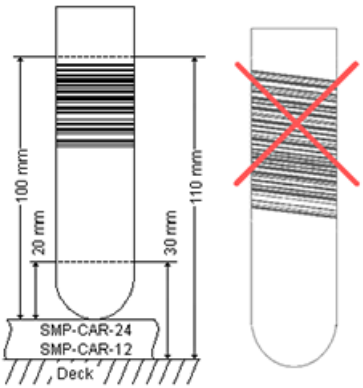


Figure 2: Placement of barcode on the sample tube

8.4 Material and devices required but not provided

The material and devices shown in table 6 must be ordered from altona Diagnostics.

Table 6: 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® Internal Control 1.5	Nucleic acid extraction and PCR amplification and detection control	IC15-16/ IC15-46
AltoStar® Whole Blood Pretreatment Buffer 1.5	Buffer for the pretreatment of whole blood samples	WBPB15-46
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

8.5 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

8.6 Procedure

8.6.1 Overview of the AltoStar® Workflow

The steps of the purification procedure using the AltoStar® Purification Kit 1.5 on the AltoStar® AM16 are summarized in table 8.

Table 8: Overview of the purification procedure

Step	Action
1. Start the AltoStar® AM16	• Switch on the AltoStar® AM16. • Switch on the computer and the monitor. • Start the AltoStar® Connect software.

Step	Action
2. Perform maintenance	• In the menu bar click **Application** → **Instrument Maintenance**. ◦ If weekly maintenance is due, click **Start Weekly Maintenance**. ◦ If daily maintenance is due, click **Start Daily Maintenance**. • 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. • Enter samples or import from the LIMS. • Select assays for the sample unless already imported from the LIMS. • Click the **Create Run** button in the tool bar to create the AltoStar® run.
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. • Select the purification run to be started to display the samples included in the selected purification run. • Prepare the purification reagents: ◦ Ensure that the purification reagents to be used have the same loading number (except AltoStar® Internal Control 1.5) and are not expired. ◦ If precipitates are visible in the Lysis Buffer, heat it (≤ +50 °C) until completely dissolved. ◦ Thaw the IC (AltoStar® Internal Control 1.5) and vortex for 5 seconds. ◦ Vortex the Magnetic Beads for 5 seconds without wetting the lid. • Prepare the samples for the purification run to be started as described in chapter 8.6.6.1 Sample preparation. • Click the **Start Run** button in the tool bar. • Follow the loading dialogs and load the instrument accordingly. • Confirm the Loading complete message with **OK** or wait 10 seconds. The system will now perform the purification run automatically.

Step	Action
5. Finish the purification run	• Make sure the loading tray is empty and confirm the Run finished dialog with **OK**. • Follow the instructions in the Maintenance dialog and confirm with **OK**. • Seal and store the components of the AltoStar® Purification Kit 1.5 that can be reused. • 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. • View the purification run results to confirm successful processing of each sample.
6. Start a PCR setup run	Refer to the instructions for use of the respective altona Diagnostics kits and reagents specified for use with the AltoStar® Purification Kit 1.5.

8.6.2 Starting the AltoStar® AM16

1. Turn on the AltoStar® AM16 with the front left green switch and start the computer by pressing the power button.
2. Wait until Windows has booted.
3. Start the AltoStar® Connect software using the **a*** icon on the Windows desktop, the Windows task bar or in the Windows start menu.

The Start screen of the AltoStar® Connect software is displayed (see figure 3) showing 3 buttons representing the AltoStar® Workflow steps to be performed on the AltoStar® AM16:

- **Program Run**: Sample data are entered and if using an automated PCR setup run, assays are assigned to the samples. The programmed samples are then assigned to an AltoStar® run (see chapter 8.6.5 Creating an AltoStar® run), which includes one purification run and if assays were assigned, one or more PCR setup runs. Several AltoStar® runs can be programmed in advance.
- **Start Purification**: A programmed purification run is selected and started as described in chapter 8.6.6 Starting a purification run.
- **Start PCR Setup**: A programmed PCR setup run is selected and started as described in the instructions for use of the respective altona Diagnostics kits and reagents specified for use with the AltoStar® Purification Kit 1.5.

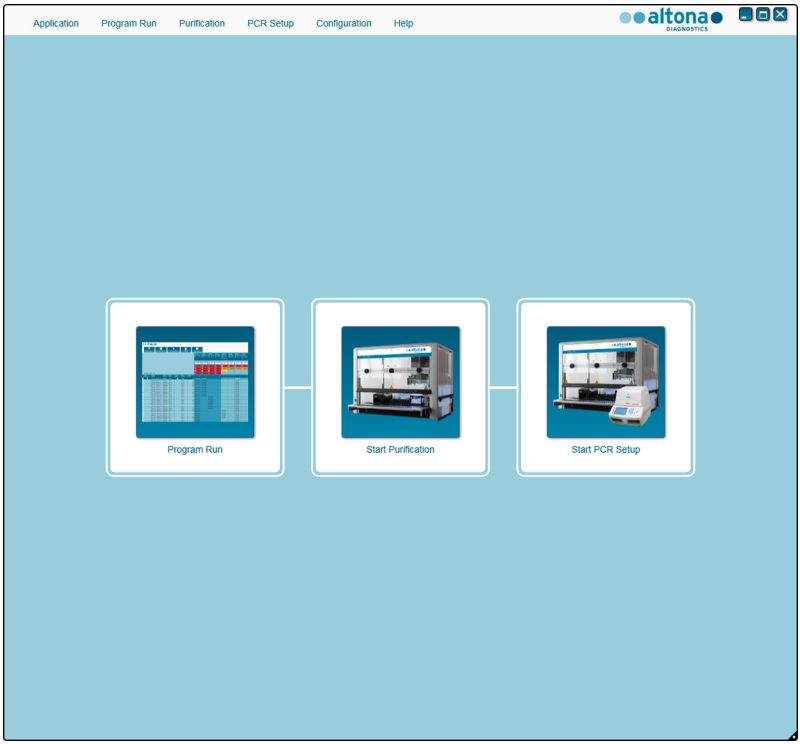


Figure 3: Start screen of the AltoStar® Connect software

8.6.3 Performing maintenance

1. Access the Maintenance screen (see figure 4) by clicking **Application** → **Instrument Maintenance** in the menu bar.

A valid status of the **Daily Maintenance** and **Weekly Maintenance** is depicted by a green check mark in the column **Status** (see figure 4). If a red crossed circle is displayed, the respective maintenance procedure has to be performed.

If the daily or weekly maintenance has to be performed:

1. Click the corresponding button in the tool bar.
2. Follow the on-screen instructions to complete the maintenance procedure. Refer to the instructions for use of the AltoStar® Automation System AM16 and the AltoStar® Connect software for detailed information.

The maintenance routines verify the correct functionality of the instrument and will prompt all necessary user actions including cleaning of the instrument.

NOTE

Verification refers to the semi-annual maintenance procedure that is performed by Hamilton trained field service engineers. The **Verification** row must show a green check mark in the column **Status** as well. Otherwise the instrument will not process any samples or reagents.

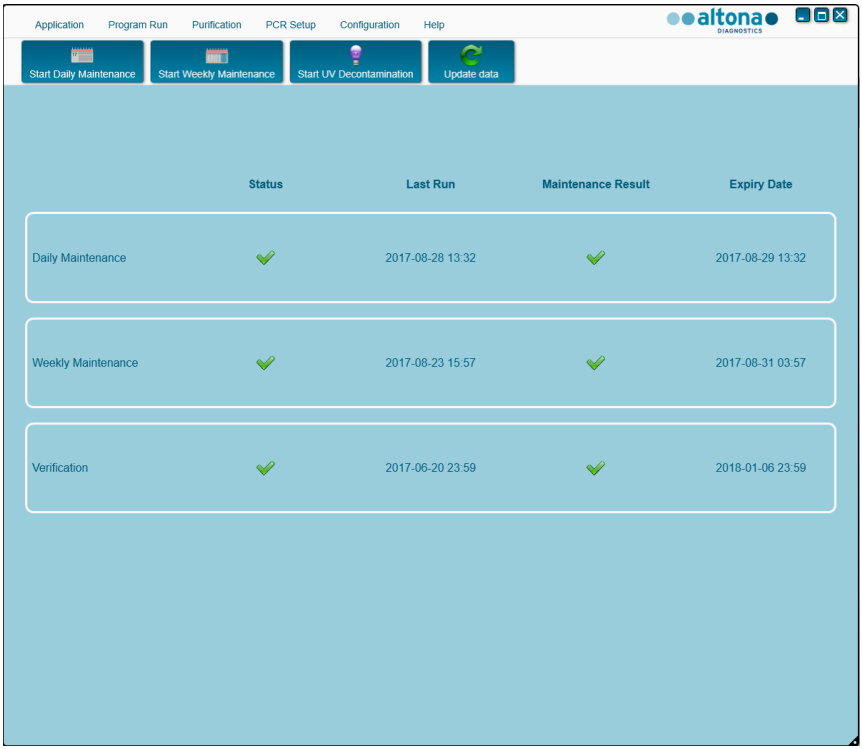


Figure 4: Maintenance screen with valid maintenance status

8.6.4 Programming an AltoStar® run

Input of sample data and assay assignments can be done manually (see chapter 8.6.4.1 Manual programming) or by import from a connected Laboratory Information Management System (LIMS). If no manual programming is necessary, continue with chapter 8.6.4.2 Importing from LIMS.

8.6.4.1 Manual programming

1. Click **Program Run → Program Run (AltoStar® Purification)** in the menu bar. Alternatively, go back to the Start screen of the AltoStar® Connect software and select the **Program Run** button.

The Programming screen is displayed (see figure 5) showing the sample table at the bottom of the screen with columns for:

- Sample properties: **Sample Name** (optional), **Sample Barcode**, **Sample Type** and **Predilution**
- Sample settings: **Process Sample, Sample Priority**
- Sample information: required **Sample Volume** for the purification run (dead volume not factored in), **Eluate left** (determined by assay assignment)
- Assay assignment to the samples: **Programming**

NOTE

The sample settings **Process Sample** and **Sample Priority** are selected manually while the sample information **Sample Volume** and **Eluate left** are set automatically when assigning PCR assays to the samples.

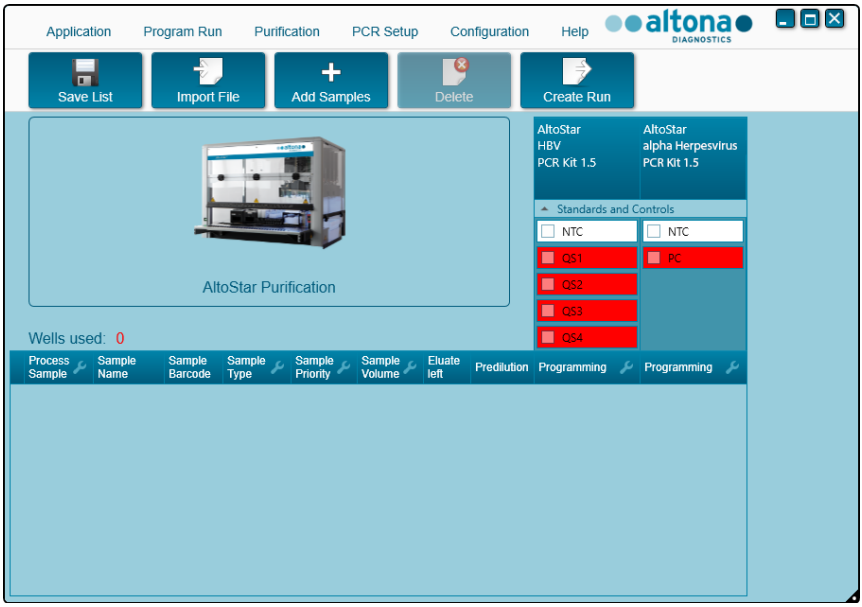


Figure 5: Programming screen

2. Click the **Add Samples** button to manually add samples to the sample table. The Add Samples dialog will appear (see figure 6).

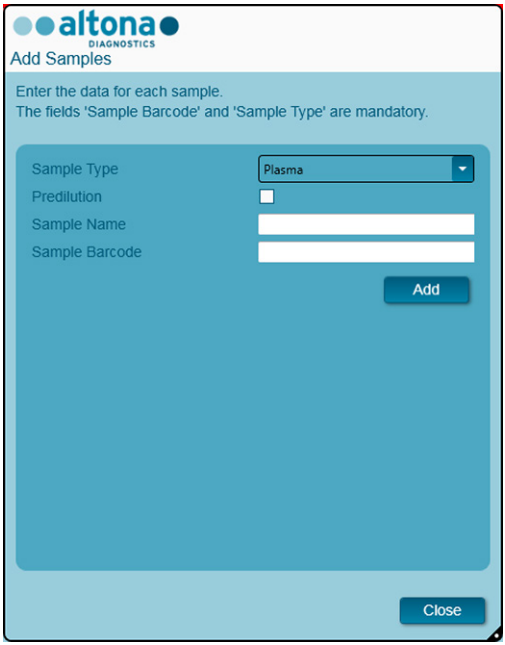


Figure 6: Add Samples dialog

3. Select the requested sample type in the **Sample Type** field.

For both human plasma and serum samples select the sample type “Plasma”.

CAUTION

Always use the correct "**Sample Type**" and "**Sample Volume**" when programming an AltoStar® run, otherwise the product performance could be compromised.

4. *Optional*: Enter a sample name in the **Sample Name** field.
5. Enter a barcode via the handheld barcode scanner in the **Sample Barcode** field. A unique barcode for each sample tube is required.
6. Check for each sample if the required sample volume of 500 µl or 1,000 µl plus dead volume of the sample tube used is available.

NOTE

When calculating the required sample volume for whole blood samples, consider that the sample volume of whole blood samples will always already be doubled by the addition of AltoStar® Whole Blood Pretreatment Buffer 1.5 during the specified sample preparation procedure (see section Whole blood in chapter 8.6.6.1 Sample preparation).

NOTE

Insufficient sample volume (e.g. due to lack of the required dead volume of the sample tube) will lead to the exclusion of the sample in the purification run.

7. Tick the **Predilution** checkbox if the sample needs to be prediluted during the sample preparation procedure (see chapter 8.6.6.1 Sample preparation) to provide the required sample volume.

   - The **Sample Volume** field and **Added Diluent** field will appear (see figure 7), each with 1,000 µl as preset volumes.
   - Change the preset volumes of 1,000 µl in the **Sample Volume** field and **Added Diluent** field to match the volumes that will be used during the sample preparation.
   - For whole blood samples, the **Predilution** checkbox is automatically ticked to reflect the dilution step with AltoStar® Whole Blood Pretreatment Buffer 1.5 during the sample preparation procedure. Change the preset volumes of 1,000 µl in the **Sample Volume** field and **Added Diluent** field to match the volumes that will be used during the sample preparation, while maintaining the ratio of 1 volumetric part whole blood to 1 volumetric part diluent (AltoStar® Whole Blood Pretreatment Buffer 1.5).

CAUTION

Always use the correct "**Sample Type**" and "**Sample Volume**" when programming an AltoStar® run, otherwise the product performance could be compromised.

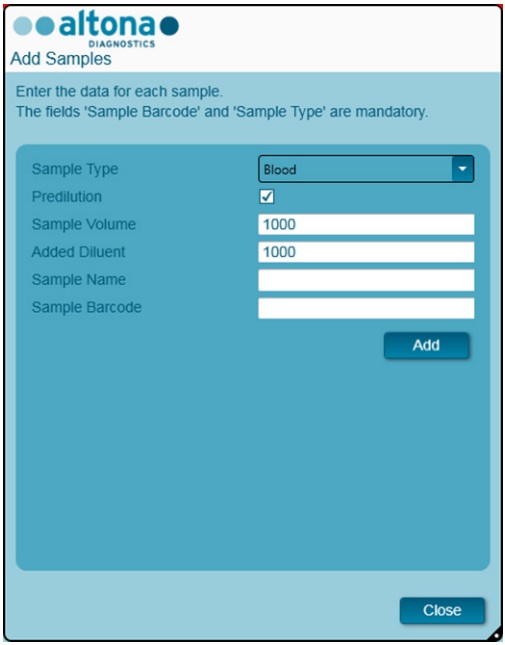


Figure 7: Add Samples dialog: Ticked Predilution checkbox

NOTE

The predilution will be included in the *Concentration factor*, which accounts for the change in concentration from the original sample to the eluate during the purification process. It is reported in the purification run report.

NOTE

The predilution property of a sample can be edited after closing the Add Samples dialog by ticking the checkbox in the column **Predilution** of the sample table.

8. Click the **Add** button to add the sample to the sample table.
9. Repeat the steps above until all samples are added to the sample table.
10. When all samples are added, click the **Close** button to close the Add Samples dialog. The added samples are displayed in the sample table of the Programming screen (see figure 8).

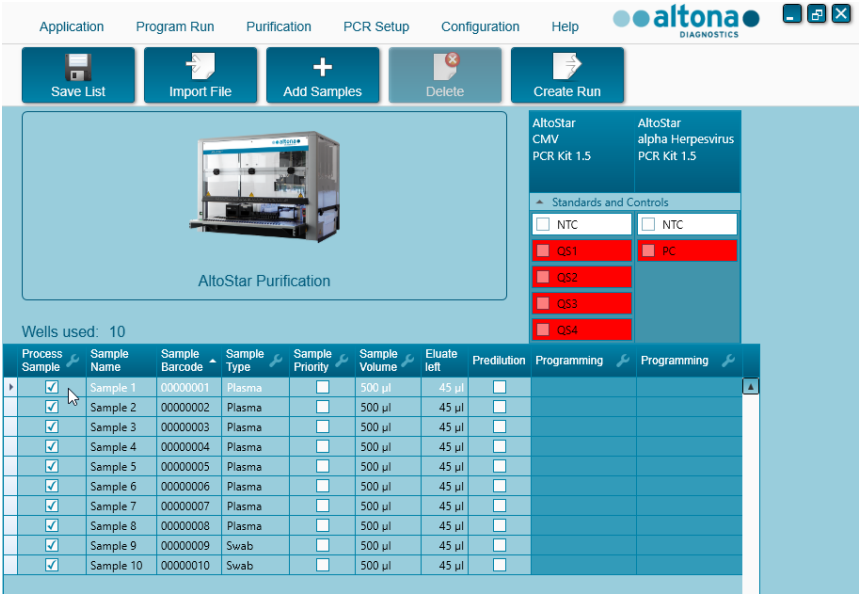


Figure 8: Programming screen with added samples

NOTE

The sample list can be sorted by individual columns by clicking the column header. Multiple samples can be selected by holding down the **Shift-Key** or **Ctrl-Key** while clicking on sample lines. The selected samples can be modified collectively by clicking the wrench symbol in the appropriate column header. Samples can be removed from the list by selecting them and clicking the **Delete** button in the tool bar.

11. If using an automated PCR setup run, assign the appropriate assay(s) to specific samples by clicking in the cell which is in the row of the respective sample and in the column of the respective assay (see figure 9). For more details refer to the respective instructions for use of altona Diagnostics kits and reagents specified for use with the AltoStar® Purification Kit 1.5.

12. Select **quantitative** or **qualitative** in the appearing menu.

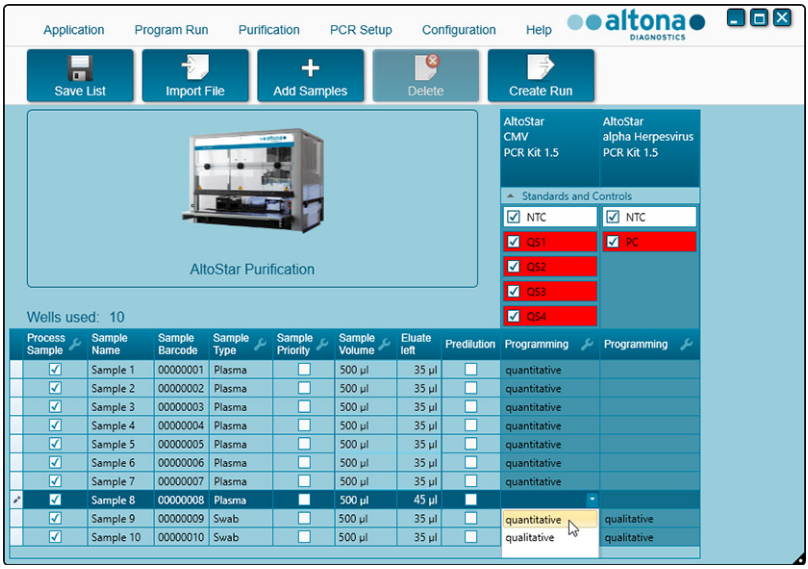


Figure 9: Programming screen: PCR Assay Assignment

The correct set of **Standards** and **Controls** is automatically selected for qualitative and quantitative assay application.

Additionally, the required sample volume for the purification run (dead volume not factored in) and the eluate volume that remains available for assignment to other assays are automatically adjusted in the sample list columns **Sample Volume** and **Eluate left**, respectively.

NOTE

If it is not possible to select a PCR assay for a sample, check in the **Eluate left** column of the sample table, whether the eluate volume required for this assay is still available.

8.6.4.2 Importing from LIMS

Both the sample properties as well as the assay assignment can be imported from the LIMS. To do so, click the **Import File** button in the tool bar. In the dialog that opens, select the Import File (.psv) that contains the required information.

For information regarding the LIMS integration, contact altona Diagnostics technical support (see chapter 13. Technical support).

8.6.5 Creating an AltoStar® run

For processing the samples in the sample table must be assigned to an AltoStar® run which includes one purification run and – if assays are assigned to the samples – one or more PCR setup and PCR runs.

All sample types specified in chapter 6. Sample types can be processed simultaneously in one purification run.

1. Tick the **Sample Priority** checkbox for samples that should be sorted to the same PCR plate for fastest processing.
   - Initially, all samples are ticked in the column **Process Sample** indicating that the respective samples are to be included in the AltoStar® run generated next.
   - Above the sample table in the Programming screen (see figure 9), **Wells used** is displayed (showing the number of the Processing Plate wells needed for processing of the samples currently ticked in the column **Process Sample**).
   - Up to 96 wells can be used in one purification run.

NOTE

The Processing Plate is a consumable for purification runs and contains 96 wells that can be used for processing of samples. Samples with a processing volume of 1,000 µl need 2 wells of the Processing Plate. Thus, the maximum number of samples that can be processed in one purification run varies and depends on the number of samples with a processing volume of 1,000 µl.

   - If the number of 96 wells is exceeded, the AltoStar® run cannot be created and **Wells used** is displayed in red.

2. In this case, deselect samples in the column **Process Sample** until **Wells used** displays 96 or less. The remaining samples still ticked in the column **Process Sample** will be assigned to the next AltoStar® run.
3. Click the **Create Run** button in the tool bar of the Programming screen. The Save Run Definition dialog is displayed (see figure 10).

NOTE

No further modifications to samples are possible after clicking the **Create Run** button. If changes to a created AltoStar® run are necessary, the created AltoStar® run has to be deleted and manual programming or the import from LIMS has to be repeated.

4. Enter a unique **Run Name** and optionally a **Description** for identification of the AltoStar® run later on.
5. Click the **OK** button to save the AltoStar® run.

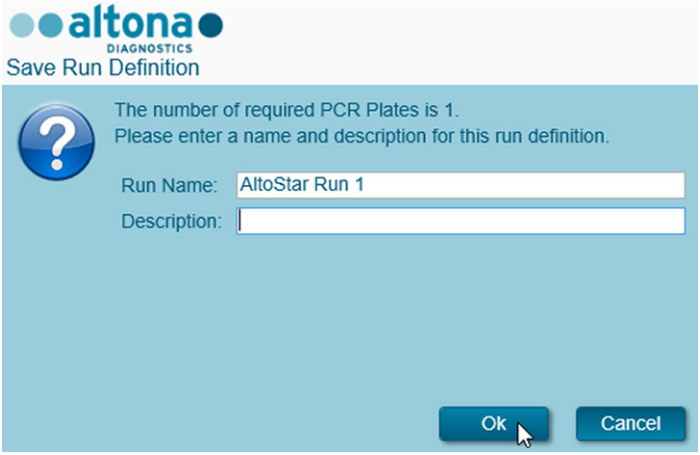


Figure 10: Save Run Definition dialog

Samples that have been assigned to an AltoStar® run are removed from the sample table of the Programming screen. To create further AltoStar® runs for the remaining samples in the sample table:

6. Select up to 96 of the remaining samples in the column **Process Sample**.
7. Click the **Create Run** button and repeat the steps 4 and 5.

8.6.6 Starting a purification run

1. Select **Purification** → **Start Purification** in the menu bar. Alternatively, go back to the Start screen of the AltoStar® Connect software and select the **Start Purification** button.
   - The Start Purification Run screen is displayed (see figure 11). Each programmed AltoStar® run includes one purification run.
   - The pending purification runs are displayed in the **Programmed Purification Runs** table on the left side of the screen.

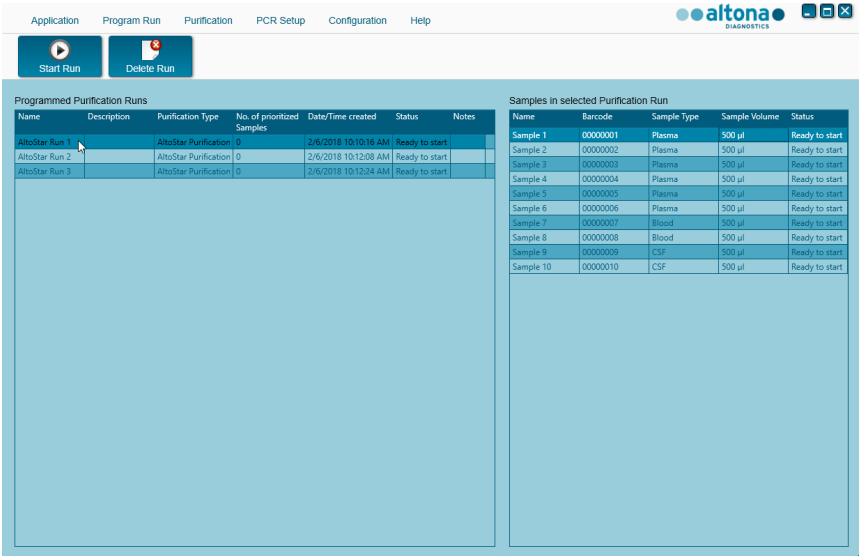


Figure 11: Start Purification Run screen

2. Select the purification run to be started in the **Programmed Purification Runs** table. The samples included in the selected purification run are displayed in the table on the right side of the screen (Samples in selected Purification Run).

Before clicking the **Start Run** button in the tool bar, prepare the samples of the selected purification run and the reagents as described in chapters 8.6.6.1 Sample preparation and 8.6.6.2 Preparing reagents for a purification run.

8.6.6.1 Sample preparation

For correct results the specifications regarding sample type, sample collection, sample volume, sample tube and sample barcode (see chapters 6. Sample types and 8.1 Sample volume to 8.3 Sample barcodes) as well as with respect to sample preparation have to be followed carefully.

1. Prepare all samples that shall be used in the next purification run. The samples required for the selected purification run are listed in the table (Samples in selected Purification Run) on the right side of the Start Purification Run screen.
2. Provide at least 500 µl or 1,000 µl sample volume plus the required dead volume in a suitable sample tube.

CAUTION

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

CAUTION

Always provide at least 500 µl or 1,000 µl sample volume, plus the required dead volume in a suitable sample tube. Insufficient volume will lead to sample exclusion.

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.

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.

Whole blood

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 (see chapter 8.2 Sample tubes) and add the same volume of AltoStar® Whole Blood Pretreatment Buffer 1.5 (Order No. WBPB15-46) 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.

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.

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 8.2 Sample tubes).

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.

Cerebrospinal fluid (CSF)

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

8.6.6.2 Preparing reagents for a purification run

1. Ensure to prepare sufficient amounts of non-expired reagents which all have to have the same loading number.

The loading number consists of the last 4 lot number digits of the Lysis Buffer and Wash Buffer containers and the Magnetic Bead, Enhancer and Elution Buffer tubes.

NOTE

For your convenience, the 4-digit loading number (see figure 12) is displayed on the outside of each component box.

Figure 12: Loading number

NOTE

Before processing starts the AltoStar® AM16 automatically verifies

- that sufficient reagent volume of the AltoStar® Purification Kit 1.5 components and of the AltoStar® Internal Control 1.5 is present.
- that the loading numbers of the loaded AltoStar® Purification Kit 1.5 components are congruent.

2. Visibly inspect the Lysis Buffer for precipitates. In case precipitates are visible, heat it to below +50 °C. Intermittently pivot the container gently without wetting the seal until precipitates are completely dissolved. Slight color changes may occur to the Lysis Buffer. These slight changes in color do not indicate a change in the quality of the buffer.
3. Vortex the Magnetic Bead tubes for 5 seconds. Avoid wetting the lid. Do not centrifuge the Magnetic Beads.
4. Thaw the required number of IC tubes (AltoStar® Internal Control 1.5) completely and vortex for 5 seconds.

CAUTION

Improper preparation of reagents (e.g. lysis buffer and magnetic beads) may cause invalid or false negative results.

CAUTION

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

8.6.6.3 Loading the AltoStar® AM16 for a purification run

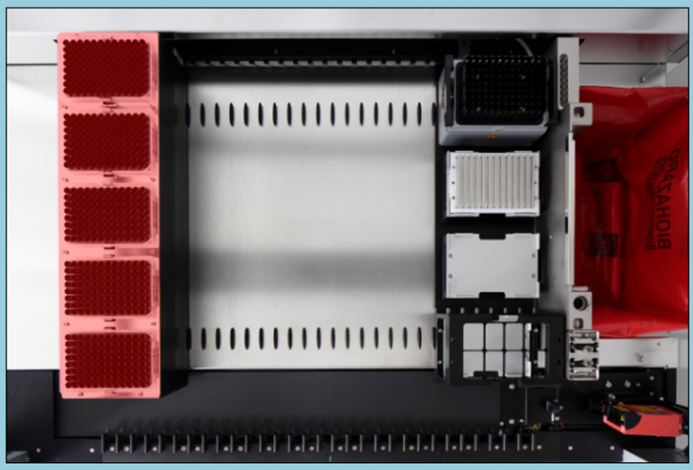
1. Click the **Start Run** button in the tool bar of the Start Purification Run screen to display the Loading dialog (see figure 13).

The Loading dialog consists of a visual representation of the AltoStar® AM16 deck at the top and a table specifying the carrier, the respective tracks on the AltoStar® AM16 deck for each carrier, the material for each carrier and comments with respect to the carrier loading.

altona DIAGNOSTICS

Loading

Please load the following labware:



Carrier	Track	Material	Comment
1	1 - 6	Tips 1000 µl	Replace empty Tip Racks with completely filled new ones
2	7 - 12	Tips 300 µl	Replace empty Tip Racks with completely filled new ones
2	7 - 12	Eluate Plate	New Eluate Plate
3 - 4	13 - 16	Lysis Buffer Wash Buffer 1 Wash Buffer 2 Wash Buffer 3	One or several containers of each buffer anywhere on these carriers
5	17	Enhancer Internal Control Magnetic Beads Elution Buffer	One or several tubes of each component anywhere on this carrier
6 - 11	18 - 23	Samples	10 samples on up to 6 carriers
12	24 - 30	Processing Plate	One new Processing Plate
12	24 - 30	Tip Park Plate	One new Processing Plate
12	24 - 30	Tip Park Rack	Empty unused Tip Rack

☐ Reset 1000µl tip counter

☐ Reset 300µl tip counter

Ok Cancel

Figure 13: Loading dialog

NOTE

To visualize the position of an item on a carrier and the position of the carrier on the AltoStar® AM16 deck, select the respective row of the table in the Loading dialog. The position of the item and its carrier is visualized:

- Highlighted in red in the visual representation of the instrument deck.
- On the AltoStar® AM16 by flashing loading lights above the tracks where the selected carrier must be placed.

2. Load the material, prepared reagents and prepared samples onto the suitable carriers as follows:

Track	Carrier description	Material to be loaded
1–6	 1 tip carrier	5 x 1,000 µl tip racks

- Exchange only **completely empty** 1,000 µl tip racks for **completely full** 1,000 µl tip racks on the tip carrier.

NOTE

Exchange of tip racks, which are not completely empty as well as handling of individual tips may interfere with the automatic tip management and cause run aborts.

Track	Carrier description	Material to be loaded
7–12	 1 tip and plate carrier	3 x 300 µl tip racks 1 x eluate plate

- Exchange only **completely empty** 300 µl tip racks for **completely full** 300 µl tip racks on the tip and plate carrier.
- Place the eluate plate with well A1 to the left of the black plate position. The plate position at the front is not used during purification runs.

NOTE

Exchange of tip racks, which are not completely empty as well as handling of individual tips may interfere with the automatic tip management and cause run aborts.

Track	Carrier description	Material to be loaded
13–16	 1 or 2 container carriers	Up to 8 containers of: Lysis Buffer Wash Buffer 1 Wash Buffer 2 Wash Buffer 3

- Load 1 or 2 container carriers with up to 8 containers of Lysis Buffer, Wash Buffer 1, Wash Buffer 2 and Wash Buffer 3.
- Gently push the containers all the way to the bottom of the carrier.
- Remove and dispose of all sealing foils from the containers.

NOTE

Starting a purification run with the sealing foils still on the containers may cause the run to abort during processing.

NOTE

The position of the individual containers on the respective carriers is arbitrary.

Track	Carrier description	Material to be loaded
17	 1 tube carrier 24	Up to 24 tubes of: IC (Internal Control) Magnetic Beads Enhancer Elution Buffer

- Load a tube carrier 24 with up to 24 tubes of IC, Magnetic Beads, Enhancer and Elution Buffer.
- Gently push the tubes all the way to the bottom of the carrier and rotate the tubes until the tube barcodes are visible through the carrier windows.
- Remove all lids from the tubes and store them for reuse.
- Store the lids for reuse in a clean space.

NOTE

Reuse of lids for any other tube than the original one may lead to cross-contamination.

NOTE

The position of the individual tubes on the carrier is arbitrary.

NOTE

Starting a purification run with lids still on the tubes may cause the run to abort during processing.

Track	Carrier description		Material to be loaded
18–23	 1–6 tube carrier 32 for sample tubes of 11–14 mm diameter	 1–6 tube carrier 24 for sample tubes of 14.5–18 mm diameter	Prepared samples for the purification run to be started

- Load the prepared samples for the purification run on up to 6 sample carriers. 2 carrier types can be used in parallel in the same run:
  - For sample tubes of 11–14 mm outer diameter use the tube carrier 32.
  - For sample tubes of 14.5–18 mm outer diameter use the tube carrier 24.

- Gently push the tubes all the way to the bottom of the carrier and rotate the tubes until the tube barcodes are visible through the carrier windows.

NOTE

The position of the individual sample tubes on the carriers is arbitrary.

NOTE

Starting a purification run with lids still on the sample tubes may cause the run to abort during processing.

Track	Carrier description	Material to be loaded
24–30	 Heater shaker carrier This carrier is not removable. The items are placed by hand onto the carrier in the instrument.	1 x Processing Plate 1 x tip park plate 1 x tip park rack

- Place an unused tip park plate at the bottom of the front position and an unused tip park rack at the top of the front position and ensure both items are latched into their respective position.
- Place an unused Processing Plate at the second position from the front and ensure it is latched into position.

3. Load the carriers with the carrier barcode towards the rear facing right.

4. Insert populated carriers into the respective tracks between the front and rear slide blocks of the loading tray until they touch the stop hooks on the far side of the loading tray.

NOTE

Pushing the carriers past the stop hooks may damage the instrument and interfere with the loading process.

5. Check that the tip eject sheet and the tip waste container are in the correct position and a new waste bag is placed in the container.
6. Click **OK** in the Loading dialog to proceed with the loading process.

NOTE

By clicking **Cancel** the purification run will be cancelled, but it can be started again (see chapter 8.6.6 Starting a purification run).

The Tip Park Plate dialog is displayed (see figure 14).

Figure 14: Tip Park Plate dialog

7. Scan the tip park plate barcode in duplicate with the handheld barcode scanner to ensure that the plate has not been used in prior runs.
8. Click **OK** to confirm the input.

The AltoStar® AM16 draws the carriers into the instrument and performs barcode and reagent volume verifications.

NOTE

The AltoStar® AM16 automatically verifies:

- Correct type and localization of the loaded carriers
- Correct identity and position of the items loaded on the carriers
- Lot congruence of the AltoStar® Purification Kit 1.5 components (Lysis Buffer, Wash Buffers, Magnetic Beads, Enhancer and Elution Buffer)
- Non-expiry of all loaded reagents
- Presence of sufficient reagent volumes
- Singularity of sample barcodes
- Correct positioning of the items loaded manually on the heater shaker carrier
- Correct positioning of the tip eject sheet

If any of these checks fail, the user is prompted with a message dialog specifying the problem at hand and instructions to correct the issue accordingly. For further information regarding error handling refer to the instructions for use of the AltoStar® Connect software.

NOTE

Altering of positions of any loaded item after the carrier has been drawn into the instrument results in abort of the purification run and damage to the instrument.

When all checks have passed the Loading complete dialog is displayed (see figure 15).

Figure 15: Loading complete dialog

9. Confirm the Loading complete dialog by clicking **OK** or wait 10 seconds for the automatic start of the process.

NOTE

By clicking **Cancel** the purification run will be cancelled, but it can be started again (see chapter 8.6.6 Starting a purification run).

The purification run is started and will be conducted without user intervention.

8.6.7 During the purification run

No further user interaction is required until the purification run has finished. The Processing Status screen is displayed (see figure 16) showing the status of the purification run and the estimated time remaining.

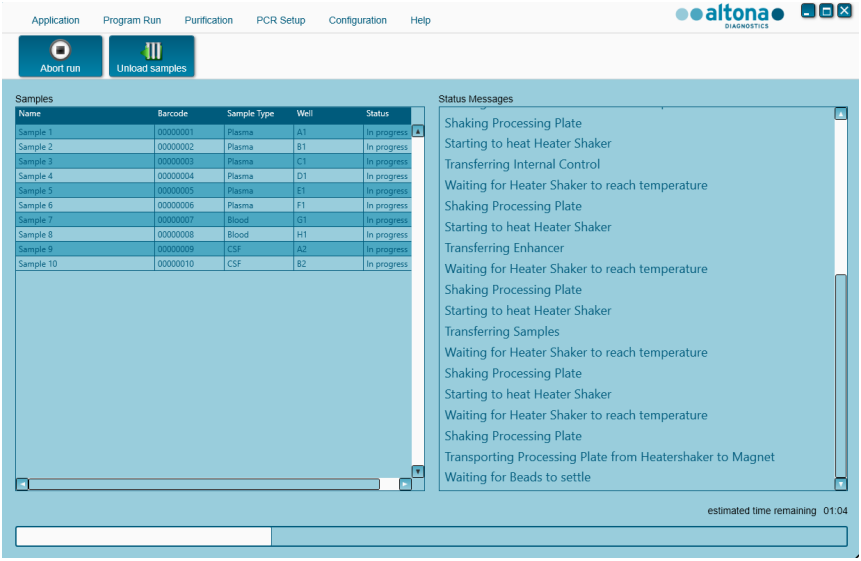


Figure 16: Processing Status screen

NOTE

Pushing or pulling carriers or the door of the AltoStar® AM16 during a purification run may abort the run.

NOTE

Aborting the purification run after the Loading complete dialog is confirmed will void the AltoStar® run, preventing a restart. To repeat aborted runs see the instructions for use of the AltoStar® Connect software.

NOTE

After the sample transfer into the Processing Plate has finished, the sample carrier(s) can be unloaded at any time. The **Unload samples** button in the tool bar will be active and can be clicked. The sample carrier(s) will be unloaded from the deck and the sample tubes can be removed. The purification run will not be interrupted.

NOTE

Required components for the subsequent PCR setup run can be previewed to allow for preparation of these components during the preceding purification run:

- Click **PCR Setup → Start PCR Setup** in the menu bar to access the Start PCR Setup Run screen.
- Refer to the tables **Controls in selected PCR Setup Run** and **Required master tubes for the selected PCR Setup Run** for information on the required components.
- Return to the ongoing purification run by clicking **Purification → Current Purification** in the menu bar.

8.6.8 End of the purification run

At the end of the purification run the Run finished dialog is displayed (see figure 17).

Figure 17: Run finished dialog

1. Make sure that the loading tray is empty.
2. Confirm the Run finished dialog by clicking **OK**.

The AltoStar® AM16 will unload the carriers. Make sure not to stand in the way of the unloading carriers.

After unloading the Maintenance dialog is displayed (see figure 18).

3. Follow the instructions of the Maintenance dialog.

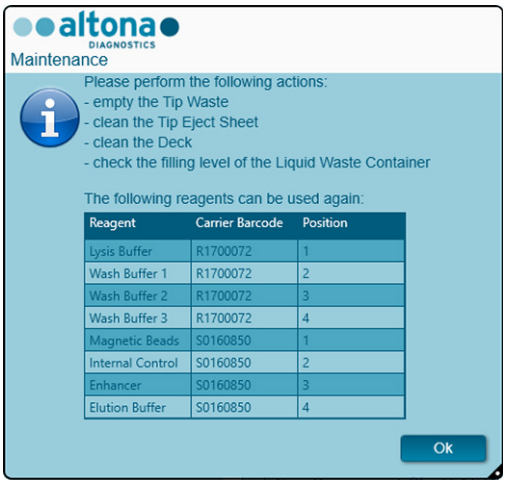


Figure 18: Maintenance dialog

The table of the dialog displays components of the AltoStar® Purification Kit 1.5 and the IC (AltoStar® Internal Control 1.5) with sufficient volume to be used again in subsequent purification runs.

1. If a PCR setup run using the currently loaded eluate plate is to be started directly after the purification run, the eluate plate can remain on the carrier position at room temperature (max. +30 °C) up to 4 hours. If the PCR setup run is **not** started directly after the purification run, seal and store the eluate plate as described in chapter 8.6.12.1 Sealing of the eluate plate.
2. Close tubes with the appropriate tube caps.

CAUTION

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

CAUTION

Do not interchange tube caps when closing product components after use to avoid contamination of reagents, which could compromise product performance.

3. Close containers with unused Container Re-Sealing Foils.

CAUTION

Do not reuse Container Re-Sealing Foils to avoid contamination of the reagents, which could compromise product performance.

4. Store reagents for reuse as described in chapter 4. Storage and handling and in the instructions for use of the AltoStar® Internal Control 1.5.
5. Dispose of the components of the AltoStar® Purification Kit 1.5 and the AltoStar® Internal Control 1.5 not listed in the table of the Maintanance dialog (see chapter 10. Disposal).

Dispose of the samples and used materials (see chapter 10. Disposal).

6. Confirm the Maintenance dialog by clicking **OK**.

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

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.

NOTE

The instructions for the daily maintenance procedure for the disposal of liquid waste and used materials can be found in the instructions for use of the AltoStar® Automation System AM16.

8.6.9 Purification run results

The Purification Run results are saved in the AltoStar® Connect software.

1. Click **Purification** → **Purification Results** in the menu bar to access the Results screen (see figure 19).

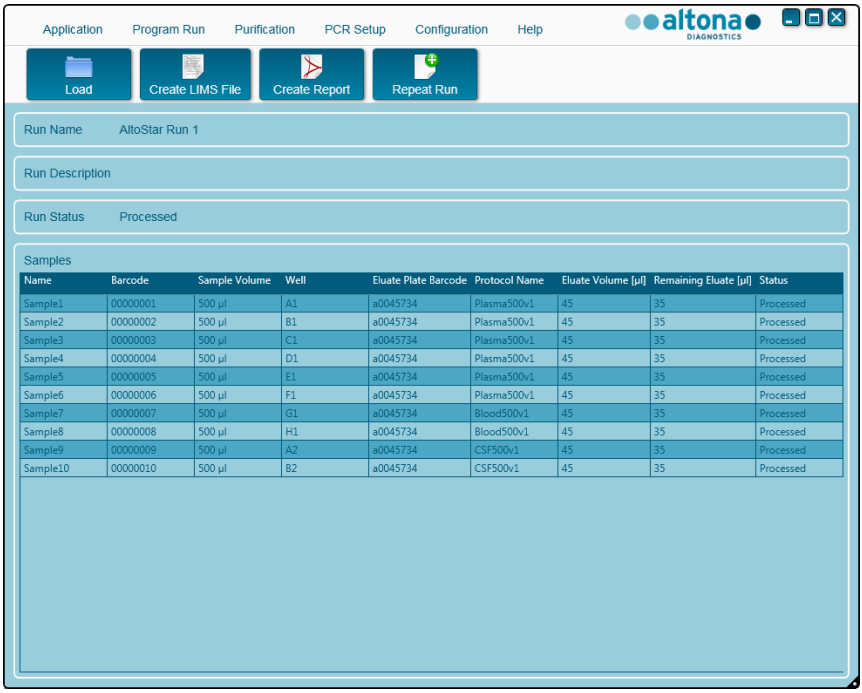


Figure 19: Results screen

The Results screen displays a table with all samples used in the latest purification run and a column **Status** at the right showing if the purification run for a given sample was conducted completely (see table 9).

Table 9: Purification run results

Status	Purification run result
Processed	• The sample was successfully processed in the purification run. • The respective eluate is ready for use in a PCR setup run.
Error	• The sample was not processed successfully. • No eluate of this sample is available. • The sample will be automatically omitted from following PCR setup runs.

2. To view the results of prior purification runs, click the **Load** button in the menu bar, select the desired purification run from the list in the opening Load Results dialog and click **OK**.

2 purification run result files are automatically generated by the AltoStar® Connect software:

- A LIMS file (.xml) to pass detailed information about the purification run including results back to the LIMS.
- A report (.pdf) containing detailed information about the purification run including results for documentation purposes.

These files are saved to the location specified in the System Settings of the AltoStar® Connect software.

NOTE

Purification run result files can be generated again by loading the respective purification run and clicking the **Create LIMS File** button to generate the LIMS file or the **Create Report** button to generate the report.

8.6.10 PCR setup and PCR run

For information about the PCR setup and PCR run refer to the instructions for use of the respective altona Diagnostics kits and reagents specified for use with the AltoStar® Purification Kit 1.5.

8.6.11 Eluate stability

After completion of the purification run the eluates in the unsealed eluate plate are stable at room temperature (max. +30 °C) for a total of 4 hours.

CAUTION

Storage of eluates under wrong conditions may lead to loss of eluate volume and/or degradation of the pathogen specific target sequence and could compromise product performancee.

8.6.12 Eluate storage

The eluates in a sealed eluate plate (see chapter 8.6.12.1 Sealing of the eluate plate) can be stored at +2 °C to +8 °C for up to 24 hours.

CAUTION

Storage of eluates under wrong conditions may lead to loss of eluate volume and/or degradation of the pathogen specific target sequence and could compromise product performance.

8.6.12.1 Sealing of the eluate plate

In case the eluates in the eluate plate are to be stored, the plate must be sealed with Eluate Plate Sealing Foil. It is recommended to use the AltoStar® Plate Sealer [4s3™ Semi-Automatic Sheet Heat Sealer (4titude)] or the PX1 PCR Plate Sealer (Bio-Rad). The suitability of plate sealers other than the recommended plate sealers has to be evaluated by the user.

NOTE

Using unsuitable plate sealers or sealing parameters may damage the eluates as well as the eluate plate, the Eluate Plate Sealing Foil and the plate sealer.

If one of the recommended plate sealers is used for sealing, proceed as follows:

1. Turn on the plate sealer and make sure that the plate adapter is not in the drawer.
2. Ensure that the settings of the plate sealer are as follows:

Table 10: Settings of the plate sealer

Plate Sealer	Settings	
	Temperature [°C]	Time [s]
AltoStar® Plate Sealer [4s3™ Semi-Automatic Sheet Heat Sealer (4titude)]	170	2
PX1 PCR Plate Sealer (Bio-Rad)	175	3

3. Wait until the set temperature is reached. This may take several minutes.
4. Place the eluate plate on the plate adapter of the plate sealer.
5. Place one Eluate Plate Sealing Foil on the eluate plate so that the print ‘THIS SIDE UP’ is readable. Make sure that all wells of the eluate plate are covered with foil and no well is obscured by the writing.

NOTE

Operating the plate sealer without the plate adapter placed in the drawer may render the sealer nonfunctional. In this case contact altona Diagnostics technical support for assistance (see chapter 13. Technical support).

NOTE

If the Eluate Plate Sealing Foil or the frame is placed incorrectly, the foil may stick to the heating plate within the plate sealer during sealing. This will render the sealer nonfunctional. In this case, or if the sealing step has been initiated without Eluate Plate Sealing Foil, let the plate sealer cool down to room temperature and contact altona Diagnostics technical support for assistance (see chapter 13. Technical support).

6. Assemble the sealing frame on top to hold down the sealing foil.
7. Open the drawer by pressing the **Operate***/ ⏏** button.
8. Place the assembly consisting of the plate adapter, the eluate plate, the Eluate Plate Sealing Foil and the sealing frame into the plate sealer and press the **Operate***/ ⏏** button.
9. The drawer closes automatically, seals for the set time and reopens automatically.
10. Take the sealed eluate plate and the plate adapter out of the plate sealer and close the plate sealer by pressing the **Close***/ ⏏** button.

* AltoStar® Plate Sealer [4s3™ Semi-Automatic Sheet Heat Sealer (4titude)]

**PX1 PCR Plate Sealer (Bio-Rad)

8.6.12.2 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.

9. Performance data

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

10. 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.

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.

11. Quality control

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

12. 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 4. 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 4. 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 8.6.6.1 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 8.6.6.1 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 8.2 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 8.6.6.1 Sample preparation).

13. 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.

14. Literature

[1] Mark A. Lever, Andrea Torti, Philip Eickenbusch, Alexander B. Michaud, Tina Šantl-Temkiv, and Bo Barker Jørgensen: A modular method for the extraction of DNA and RNA, and the separation of DNA pools from diverse environmental sample types; Front Microbiol. 2015; 6: 476.

[2] Sonja Berensmeier: Magnetic particles for the separation and purification of nucleic acids; Appl Microbiol Biotechnol 2006 73:495–504.

[3] Peter E. Vandeventer, Jessica S. Lin, Theodore J. Zwang, Ali Nadim, Malkiat S. Johal, and Angelika Niemz: Multiphasic DNA Adsorption to Silica Surfaces under Varying Buffer, pH, and Ionic Strength Conditions; J Phys Chem B. 2012 May 17; 116(19): 5661–5670.

15. Trademarks and disclaimers

4s3™ (4titude); 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.

The AltoStar® Purification Kit 1.5 is a CE-marked product according to the European *in vitro* diagnostic Regulation (EU) 2017/746.

Product not FDA cleared or approved.

Not available in all countries.

16. Symbols

Symbol	Explanation
IVD	*In vitro* diagnostic medical device
GTIN	Global Trade Item Number
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
	Caution
MAT	Material number
	Version

Symbol	Explanation
i	Note
UFI	Unique formula identifier

17. Revision history

Table 11: Revision history

Identifier	Date of issue [month/year]	Modifications
MAN-PK1540-EN-S01	11/2021	Initial release
MAN-PK1540-EN-S02	04/2022	Chapter 15: exchange of “European *in vitro* diagnostic directive 98/79/EC” with “European in *vitro* diagnostic Regulation (EU) 2017/746”

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