



# AltoStar<sup>®</sup> Connect Software Manual IVD

10/2019 EN

AltoStar<sup>®</sup>



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# 1 Safety and General Information

AltoStar® Connect Software (in the following summarized as AltoStar® Connect SW) is a software that manages the sample purification and PCR setup workflows and controls the AltoStar® Automation System AM16 instrument (in the following summarized as AltoStar® AM16).

You should carefully read the entire manual and the AltoStar® AM16 Operator's Manual IVD before beginning to operate the AltoStar® system. This first section should be read with particular attention. It contains important information about the use of the AltoStar® Connect SW and this manual.

## 1.1 About this Manual

This manual describes the capabilities of the AltoStar® Connect SW and their correct application. Since the AltoStar® Connect SW is used in connection with the AltoStar® AM16 instrument, this manual has to be used in conjunction with the AltoStar® AM16 Operator's Manual IVD (PN 627108), which is based on the Microlab STAR IVD / STARlet IVD Operator's Manual.

**Warnings** and **Notes** are part of this manual to emphasize important and critical instructions. Symbols used in this manual for these warnings and notes are:



### ATTENTION

*Any special problems, warning or important information will be accompanied by this symbol. Read these items carefully.*



### NOTE

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

— References to Manuals, Figures, Sections, etc.

## 1.2 Additional Manuals

The following additional manuals are included in the delivery of the AltoStar® AM16

- AltoStar® AM16 Operator's Manual IVD      Manual PN 627108
- Microlab® STAR UV Kit                      Manual PN 624684
- Microlab® STAR Liquid Waste              Manual PN 624208
- Hamilton Heater Shaker                      User Manual PN 624175

### 1.3 Intended Use of the AltoStar® Connect SW

The AltoStar® Connect software together with the AltoStar® Automation System AM16 is intended to be used in combination with the AltoStar® Purification Kit 1.5 and the AltoStar® Internal Control 1.5 for automated purification of nucleic acids and automated assay setup for *in vitro* diagnostic purposes.

The AltoStar® Connect SW is intended for use by professional users trained in molecular biological techniques and the operation of the AltoStar® AM16 instrument.

### 1.4 Operation

The AltoStar® Connect SW is used to operate the AltoStar® AM16. The user of the AltoStar® Connect SW must be trained in the operation of the AltoStar® Connect SW in conjunction with the AltoStar® AM16 instrument and the reagents provided by altona Diagnostics GmbH for use with the AltoStar® system. Training will be performed by altona Diagnostics GmbH after the installation of the system.

The procedures contained within this manual have been tested by the manufacturer and are deemed to be fully functional. Any deviation from the procedures given herein could lead to erroneous results or malfunction.

During instrument operation, stand clear of all moving parts and the working deck of the instrument. In general, never lean over or into the instrument while it is in operation.

If the AltoStar® AM16 is used in a manner not specified in the AltoStar® AM16 Operator's Manual IVD, the protection provided by the equipment may be impaired.

Chapters 3. and 4. describe the functionality of the AltoStar® Connect SW in detail. The software was developed to control sample purification utilizing the AltoStar® Purification Kit and the AltoStar® Internal Control and PCR setup. These reagents were explicitly developed, verified and validated for use in combination with the AltoStar® AM16 by altona Diagnostics GmbH. Therefore the following sections need to be seen in conjunction with these reagents and their respective manuals provided by altona Diagnostics GmbH.



## 2 Description of the AltoStar® AM16

The AltoStar® AM16 is a robotic pipetting workstation used for sample purification and PCR setup controlled by the AltoStar® Connect SW.

### 2.1 AltoStar® AM16 Instrument

The AltoStar® AM16 work surface is called a 'deck', for placing loadable carriers. These carriers hold reagent containers, such as tubes, microplates, and other kinds of labware.



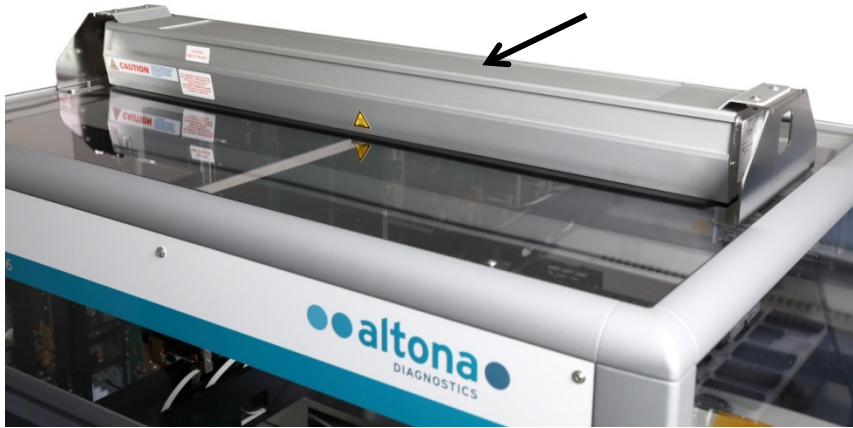
**Fig. 1.: AltoStar® AM16 Instrument**

The instrument deck is divided into equal tracks (T) for loading carriers in pre-determined positions. This eliminates the need for precise measurement of positions. The deck has partitions of 22.5mm, which is equivalent to 1-T (track). The labware carriers are adapted to those partitions.

An additional partition provides space for the tip waste container.

### 2.1.1 UV Kit

The UV Kit has been developed in order to offer the possibility of UV decontamination of the AltoStar® AM16 workspace. The required duration of the UV decontamination process is dependent on the substances used on the instrument and the user is responsible to choose the appropriate duration.



**Fig. 2.: UV Light on top of the AltoStar® AM16**

The UV Kit must be used with the AltoStar® Connect SW.

For detailed information regarding the UV decontamination process refer to [Chapter 3.6 UV Decontamination](#). The UV Kit is not suitable for decontamination of accessories such as carriers, modules, etc. as the UV (ultra-violet) light cannot reach all surfaces of such complex structures.

If the UV Kit is used in a manner not specified, the protection provided by the equipment may be impaired.



#### **NOTE**

*The UV Kit is only intended to be used in combination with the AltoStar® AM16. A stand-alone operation of the UV Kit is not foreseen.*

The UV Kit components bear the following labels:



#### **Hot Surface**

*Avoid contact with the UV light. Surfaces are hot and may cause personal injury if touched.*



#### **UV Light**

*Avoid exposure to UV light. Exposure may cause severe eye or skin injury. Wear a suitable face shield, gloves and protective clothing.*

## 2.1.2 Signal Light

A Signal Tower on top of the AltoStar® AM16 visually and audibly indicates the operating states of the system.



The green light indicates normal processing of the AltoStar® AM16.

The orange light indicates that a user interaction with the system is required (see [Chapter 4 Troubleshooting and Error Messages](#)).

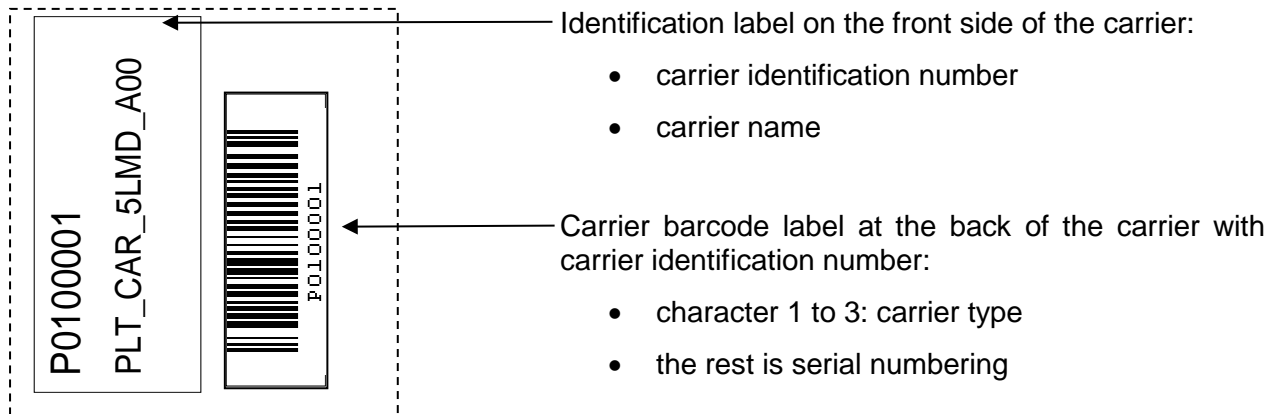
The red light indicates aborting the run due to an error (see [Chapter 4 Troubleshooting and Error Messages](#)). The red signal may or may not be accompanied by a warning sound depending on the system settings of the AltoStar® Connect SW (see [Chapter 3.3 System Settings](#)).

**Fig. 3.: Signal-Light on top of the AltoStar® AM16**

## 2.1.3 Carriers

Labware is placed on special carriers which are loaded onto the AltoStar® AM16 instrument deck. Every carrier is equipped with at least 2 labels, one identification label and one barcode label. The identification label is readable by the operator; it contains the carrier name and barcode information. The carrier name on the identification label is the one used by the AltoStar® AM16 SW.

The barcode label is for purposes of automatic identification.



**Fig. 4.: Carrier Barcode Labels**



**Fig. 5.: 1000 µl Tip Carrier**

For further information regarding the individual carriers refer to [Chapter 3.8.10 Instrument Loading for a Purification Run](#), [Chapter 3.9.9 Instrument Loading for a Sample Transfer Run](#) and [Chapter 3.11.3 Instrument Loading for a PCR Setup Run](#).

## 2.2 Sample Barcodes

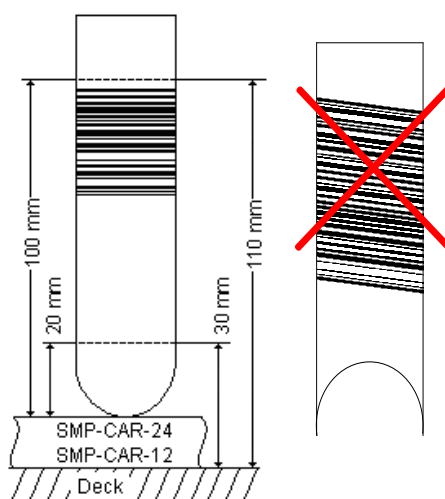
For a given sample purification run, ensure that each sample barcode is unique.

The sample barcode must contain between one and twenty characters. It is possible to use numbers (0-9) and letters (A-Z, a-z).

The label must be fixed to the tube within a range of between 20mm to 100mm 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.



**Fig. 6.: Placement of Barcodes on the Sample Tube**

### 3 AltoStar® Connect SW

The AltoStar® Connect SW comes preinstalled on a computer provided by altona Diagnostics GmbH.

It is the sole responsibility of the user to ensure sufficient protection against:

- Unauthorized access to the computer via computer network.
- Unauthorized local access to the software. Use password protected user accounts in the Microsoft Windows® installation to prevent unauthorized access.
- Software viruses and malware.
- Power outage and voltage fluctuation. For reasons of data safety and integrity, use of an Uninterruptible Power Supply (UPS) is recommended, since a loss of power or voltage fluctuations may cause data to be lost or corrupted and runs to abort.



#### NOTE

*Use password protected user accounts in the Microsoft Windows® installation to prevent unauthorized access.*

The AltoStar® Connect SW has a graphical user interface that enables the user to interact with the system. With the AltoStar® Connect SW the user can:

- Manage the system settings (depending on user account privileges)
- Manage the purification and assay protocols (depending on user account privileges)
- Perform instrument maintenance
- Perform an AltoStar® workflow run consisting of:
  - Programming a run
  - Performing a sample purification run
  - Viewing sample purification results
  - Performing a PCR setup run
  - Viewing PCR setup results
  - Transfer of the PCR plate and run information to the connected real-time PCR cyclers.
- Perform a Sample Transfer workflow run consisting of:
  - Programming a run
  - Performing a sample transfer run for purification on an external purification instrument
  - Viewing sample transfer results
  - Performing a PCR setup run with eluates from the external purification instrument
  - Viewing PCR setup results
  - Transfer of the PCR plate and run information to the connected real-time PCR cyclers.

- Perform an External Purification workflow run consisting of:
  - Programming a run
  - Performing a PCR setup run with eluates from an external purification instrument
  - Viewing PCR setup results
  - Transfer of the PCR plate and run information to the connected real-time PCR cycler.

### 3.1 User Accounts

The AltoStar® Connect SW can be used from different user accounts created in the Microsoft Windows® operating system of the computer that runs the AltoStar® Connect SW. The computer is delivered with the two user accounts 'Laboperator' and 'Labadmin' preinstalled. These accounts have different privileges:

**Table 1: User Accounts**

	Laboperator	Labadmin
<b>Windows® user group</b>	<b>Lab Operator</b>	<b>Lab Service</b>
Perform instrument maintenance	✓	✓
Perform an AltoStar® workflow run	✓	✓
Perform a Sample Transfer workflow run	✓	✓
Perform an External Purification workflow run	✓	✓
Manage the System Settings	X	✓
Manage the Purification and Assay protocols	X	✓

It is recommended to create one Windows® user account per user to ensure traceability. The Windows user account used for a workflow run is traced in the run report files.

When creating a user account in Windows®, it has to be associated with a specific Windows® user group to grant the privileges illustrated in Table 1: User Accounts.

To grant the privileges of a normal user, add the new Windows® user account to the Windows® user group 'Lab Operator' in the Windows® 'Local Users and Groups management' (lusrmgr.exe).

To grant the privileges of an administrator, add the new Windows® user account to the Windows® user group 'Lab Service' in the Windows® 'Local Users and Groups management' (lusrmgr.exe).

For further information and assistance, contact altona Diagnostics GmbH.

### 3.2 Starting the AltoStar® Connect SW

To start up the system switch on the AltoStar® AM16 instrument and the computer that runs the AltoStar® Connect SW. The order in which the instrument and the computer are started is irrelevant. Turn on the instrument with the front left green switch and start the computer by pressing the power button.

Once Windows® has booted, start the AltoStar® Connect SW using the **a\*** icon on the Windows® desktop, the Windows® task bar or in the Windows® start menu.

The software opens and displays the start screen. The start screen depicts the available workflow options as set in the system settings. The boxes depict the discrete stages of each workflow and can be clicked to access the respective user interface.

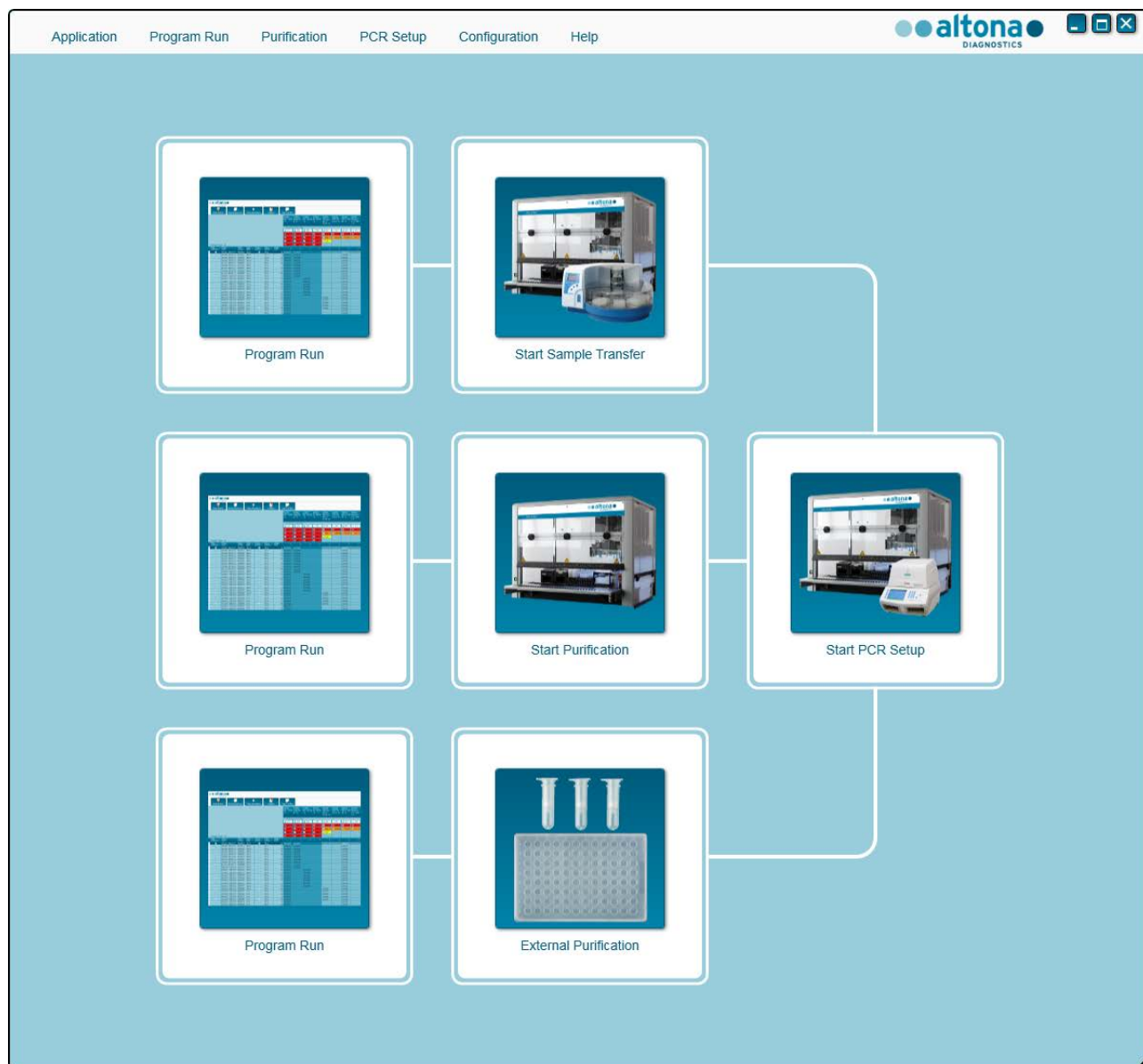


Fig. 7.: Start Screen of the AltoStar® Connect SW

### 3.3 System Settings

Users with 'labservice' privileges can access the system settings by selecting **Configuration** → **System Settings** in the menu bar. This is only possible from the start screen of the software. If not currently in the start screen, the **System Settings** menu option will be grayed out.

**altona**  
DIAGNOSTICS  
System settings

Please select a language. Restart the application for changes to take effect.

Available languages: English

Verify checksum of worklists at import

Verify checksums:

Start runs in simulation mode

Start in simulation mode:

AltoStar Purification

Purification type 'AltoStar Purification' available

Sample Transfer

Purification type 'Sample Transfer' available

External Purification

Purification type 'External Purification' available

Dead volume in external purification eluate plates

Volume in µl 10

Concentration Factor of external purification

Factor 0.000

File Settings

Default path of Purification Report (pdf) C:\altona\output files

Default path of Purification LIMS File (xml) C:\altona\output files

Default path of PCR Setup Report (pdf) C:\altona\output files

Default path of PCR Setup LIMS File (xml) C:\altona\output files

Default path of Worklist File C:\altona\input files

Default path of Cyclor File C:\altona\output files

Use Bio-Rad Cyclor

Signal Tower Settings

Signal Tower Serial Port

Signal Tower alert active

Save Cancel

**Fig. 8.: System Settings Dialog**

The following system settings can be adjusted:



### 3.3.1 Available Languages

Select the desired language of the graphical user interface from the select box. Click **Save** and restart the AltoStar® Connect SW to apply the change.

### 3.3.2 Verify Checksum of Worklists at Import

If required by local security regulation, set the checkmark in the checkbox for the AltoStar® Connect SW to check a file checksum in the LIMS import file for sample and worklist information during import. The file checksum has to be generated by the LIMS for each import file with the HMAC-SHA1 algorithm with a password as a secret key that can be requested from altona Diagnostics GmbH.

### 3.3.3 Start Runs in Simulation Mode

For testing or demonstration purposes, the AltoStar® Connect SW can be started in simulation mode. In simulation mode, no connection to the AltoStar® AM16 instrument is established. Purification or PCR setup runs can be started and are simulated in the software.

### 3.3.4 AltoStar® Purification

To activate or deactivate the availability of the AltoStar® workflow in the software, set the checkmark in the checkbox accordingly and click **Save**.

### 3.3.5 Sample Transfer

To activate or deactivate the availability of the Sample Transfer workflow in the software, set the checkmark in the checkbox accordingly and click **Save**.

### 3.3.6 External Purification

To activate or deactivate the availability of the External Purification workflow in the software, set the checkmark in the checkbox accordingly and click **Save**.

### 3.3.7 Dead Volume in External Purification Eluate Plates

The External Purification workflow uses eluate plates from external purification instruments as starting material for a PCR setup.

The specific format of eluate plate models that fit on the respective carriers need to be configured by altona Diagnostics GmbH outside of the system settings.

The dead volume of a correctly configured eluate plate can be set in the volume input field. This dead volume is automatically subtracted from the eluate volume specified when programming an External Purification workflow. Increase the dead volume setting if eluate transfer in the External Purification workflow frequently fails due to too little eluate available.

### 3.3.8 Concentration Factor of External Purification

If the sample input volume and the elution volume of the External Purification workflow are not identical, the sample's target concentration changes due to the purification. To account for this change quantitative PCR results generated in the External Purification workflow have to be multiplied by a specific factor. Specify the Concentration Factor of your External Purification Workflow. For further information and assistance, contact altona Diagnostics GmbH.

### **3.3.9 File Settings**

Specify the location of files that are used or generated by the AltoStar® Connect SW.

Default path of Purification Report (pdf)

At the end of a purification run and a sample transfer run a pdf report is generated. Specify where these reports shall be saved.

#### **3.3.9.1 Default path of Purification LIMS File (xml)**

At the end of a purification run and a sample transfer run an xml file is generated to pass information about the purification run back to the LIMS. Specify where these files shall be saved.

#### **3.3.9.2 Default path of PCR Setup Report (pdf)**

At the end of a PCR setup run a pdf report is generated. Specify where these reports shall be saved.

#### **3.3.9.3 Default path of PCR Setup LIMS File (xml)**

At the end of a PCR setup run an xml file is generated to pass information about the PCR setup run back to the LIMS. Specify where these files shall be saved.

#### **3.3.9.4 Default path of Worklist File**

When importing sample and worklist information in order to program a workflow run the software will default to this folder. Set this path to where the LIMS puts the LIMS worklist files.

#### **3.3.9.5 Default path of Cyclor File**

At the end of a PCR setup run a cyclor file (.plrn) is created that passes the necessary information to the connected real-time PCR instruments. Specify where these files shall be saved.

#### **3.3.9.6 Use Bio-Rad Cyclor**

Set the checkmark to activate cyclor file generation in the CFX96™ Deep Well Dx System format.

### **3.3.10 Signal Tower Settings**

#### **3.3.10.1 Signal Tower Serial Port**

Select the serial port that the signal tower is connected to. For further information, contact Altona Diagnostics GmbH.

#### **3.3.10.2 Signal Tower Alert Active**

Set the checkmark to activate the acoustic alarm for run aborts. When the acoustic alarm is sounding due to an aborted run, it can be silenced by clicking into the error dialog that is displayed.

### 3.4 Management of Purification and Assay Protocols

Users with Lab Service privileges can access the protocol management by selecting **Configuration** → **Protocol Management** in the menu bar. This is only possible from the start screen of the software. If not currently in the start screen, the **Protocol Management** menu option will be grayed out.

**Configuration**

**Purification Protocol**

Active	Name	Protocol Version
<input checked="" type="checkbox"/>	Plasma1000	1
<input checked="" type="checkbox"/>	Plasma500	1
<input checked="" type="checkbox"/>	Stool1000	1
<input checked="" type="checkbox"/>	Stool500	1
<input checked="" type="checkbox"/>	BAL1000	1
<input checked="" type="checkbox"/>	BAL500	1
<input type="checkbox"/>	Blood1000	1
<input checked="" type="checkbox"/>	Blood500	1
<input checked="" type="checkbox"/>	Swab1000	1

**PCR Assay**

Active	Name	Protocol Version
<input checked="" type="checkbox"/>	AltoStar Adenovirus PCR Kit 1.5	1
<input checked="" type="checkbox"/>	AltoStar alpha Herpesvirus PCR Kit 1.5	1
<input checked="" type="checkbox"/>	AltoStar BKV PCR Kit 1.5	1
<input checked="" type="checkbox"/>	AltoStar CMV PCR Kit 1.5	1
<input checked="" type="checkbox"/>	AltoStar EBV PCR Kit 1.5	1
<input checked="" type="checkbox"/>	AltoStar HHV-6 PCR Kit 1.5	1
<input checked="" type="checkbox"/>	AltoStar HSV PCR Kit 1.5	1
<input checked="" type="checkbox"/>	AltoStar Parvovirus B19 PCR Kit 1.5	1

Purification protocols and PCR assays cannot be disabled or changed to another version if they are selected for samples in a programming view.

Save Cancel

**Fig. 9.: Configuration Dialog**

The protocol management dialog is divided into the **Purification Protocol** part at the top and the **PCR Assay** part at the bottom.

By checking or unchecking the respective checkbox in the **Active** column, a Purification Protocol or PCR Assay can be activated or deactivated, respectively. Only activated items are available when programming runs.

Protocol Versions can be chosen by means of the select boxes in the **Protocol Version** column. Always select the Protocol Version suited to the reagents currently in use.

The Protocol Version can only be changed when it is not currently selected for samples in the Programming View or programmed runs.

New protocols and protocol versions can be added to the software by:

1. Placing the cursor in the empty textbox next to the respective **Import** button
2. Scanning a 2D barcode containing the protocol information with the hand held barcode scanner connected to the computer
3. Clicking **Import**
4. Clicking **Save**

The new protocols or protocol versions show up as active in the respective list.

The 2D barcodes for new purification protocols or PCR assays are provided by altona Diagnostics GmbH.

The order in which PCR assays are displayed when programming runs can be modified by selecting an assay in the **PCR Assay** list and repeatedly clicking the *arrow up* or *arrow down* buttons at the top of the **PCR Assay** list to modify the selected assay's position.

## 3.5 Maintenance

Periodic maintenance routines need to be run in order to ensure safe and reliable operation of the AltoStar® AM16 instrument and the accessories.

For IVD use, the maintenance routines are mandatory and are enforced by the software. It is not possible to start runs when maintenance or verification is overdue.

### 3.5.1 Maintenance Intervals

- **Daily Maintenance:** Has to be executed every 24h. Recommended after AltoStar® AM16 start-up.
- **Weekly Maintenance:** Has to be executed every 7 days. Recommended at the end of the week before AltoStar® AM16 shut-down. If any parts of the instrument, carriers, or racks have become contaminated, the weekly maintenance procedure must be performed.
- **Verification:** Has to be executed every 200 days. Preventive maintenance and verification is carried out by a Hamilton trained field service engineer.



#### NOTE

*If any parts of the instrument, carriers, or racks have become contaminated, the weekly maintenance procedure must be performed.*

### 3.5.2 Materials Required

- Disposable latex gloves
- Protective glasses
- Lab coat
- Paper towels
- Lint-free cloths or Q-tips
- Ethanol (70%)
- De-ionized water
- MICROLAB Disinfectant Spray
- MICROLAB Detergent and Disinfectant



#### ATTENTION

*Use cleaning, disinfecting and decontaminating fluid in accordance with the manufacturer's instructions. Do not use disinfecting materials which contain hypochlorite (Javel water, Chlorox) or bleaching fluids.*

*Prepare disinfectant fluids according to their labeling.*

### 3.5.3 Maintenance Procedures

Access the Maintenance screen by clicking **Application** → **Instrument Maintenance** in the menu bar.

A valid status of the Daily Maintenance, Weekly Maintenance and the semi-annual Verification is depicted by a green check mark (✓) in the column **Status**. If a red cross mark (✗) is displayed in this column, the respective maintenance procedure has to be performed by clicking the corresponding button in the tool bar. Follow the on screen instructions to complete the maintenance procedure.

By clicking **Update data**, the maintenance data which are saved on the instrument will be newly read out and will be shown in the Maintenance Dialog.

	Status	Last Run	Maintenance Result	Expiry Date
Daily Maintenance	✓	2017-08-28 13:32	✓	2017-08-29 13:32
Weekly Maintenance	✓	2017-08-23 15:57	✓	2017-08-31 03:57
Verification	✓	2017-06-20 23:59	✓	2018-01-06 23:59

Fig. 10.:Maintenance Screen

**ATTENTION**

*Always wear disposable gloves during maintenance.*

*Do not clean the instrument in the vicinity of open flames or devices which could create sparks. Do not use hot air blowers to dry the instrument. The liquids used for cleaning are flammable.*

*This manual provides indications regarding general disposal of waste. In addition, any regulations specific to the country of operation must be taken into account and observed.*

**Routine Completion**

A maintenance routine is completed once the procedure has been fully executed and the results are within the specifications.

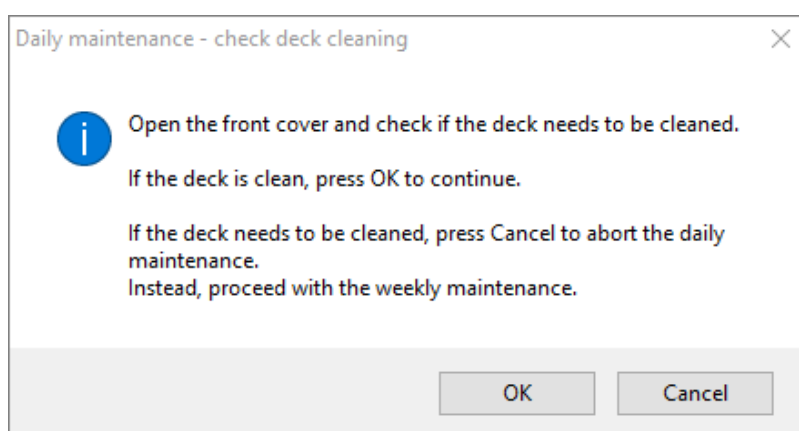
**Aborting Maintenance Procedures**

Aborting a maintenance procedure will lead to a 'failed' status, and maintenance will need to be started again.

### 3.5.4 Daily Maintenance

The following tasks are part of the daily maintenance:

- Checking if the deck is clean
  - Emptying the tip waste and liquid waste
  - Checking the tightness of the pipetting channel
  - Verifying the cLLD function
1. Start the daily maintenance by clicking the **Start Daily Maintenance** button in the tool bar. The software will issue on-screen instructions detailing all procedures required to perform the daily maintenance routine.
  2. Once the maintenance procedure has been started, the Pipetting Arm moves to the left side. The operator now has access to the deck to check if cleaning is needed or not.



**Fig. 11.: Daily Maintenance – Check Deck Cleaning Dialog**

Exact wording of content of the dialog displayed in Fig 11:

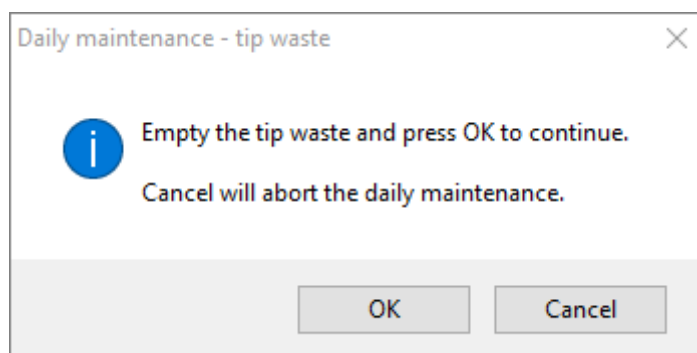
Open the front cover and check if the deck needs to be cleaned.  
If the deck is clean, press OK to continue.  
If the deck needs to be cleaned, press Cancel to abort the daily maintenance.  
Instead, proceed with the weekly maintenance.

3. Clean the Tip Eject Sheet of the tip waste station.
4. Remove the Tip Eject Sheet of the tip waste station and spray MICROLAB Disinfectant Spray directly onto the surface and wipe. Remove the plastic bag from the tip waste container and discard the plastic in the laboratory's contaminated waste. Place a new plastic bag in the tip waste container. Put the clean Tip Eject Sheet back in place.



**Fig. 12.:Tip Eject Sheet**

5. If the deck is clean, continue with the daily maintenance.
6. If the deck needs to be cleaned, the daily maintenance can be interrupted. Instead of the daily maintenance carry out the weekly maintenance.
7. Continuing the daily maintenance procedure will lead the user to the next maintenance task. The tip waste needs to be emptied. Dispose of it with the rest of the laboratory's contaminated waste.



**Fig. 13.:Daily Maintenance – Tip Waste**

Exact wording of content of the dialog displayed in Fig 13.:

Empty the tip waste and press OK to continue.  
Cancel will abort the daily maintenance.



**ATTENTION**

*The tip waste is always to be regarded as contaminated.*

8. Empty the liquid waste container and check the liquid waste
  - Inspect tubing for clogs, kinks and leakage. Tubing must be replaced if damaged.
  - Check and clean any liquid spills.
  - Check overflow for clogs and clean if required.



**ATTENTION**

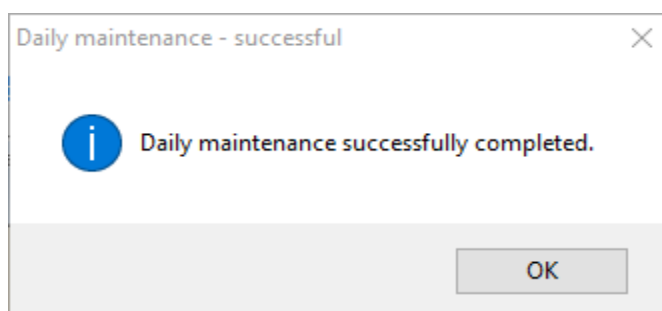
*The tip waste, the Tip Eject Sheet, the Liquid Waste Container and Tubings, and the plastic bag are always to be regarded as contaminated.*

9. For the next steps, the maintenance needles are required.



**Fig. 14.: Maintenance Needles for 1000µl Pipetting Channels**

10. The procedure continues with the tightness check of the pipetting channels. The Pipetting Arm will travel to the right side to pick up the maintenance needles. Two checks are done with the pipetting channels, the over-pressure and under-pressure check.
11. For the capacitive liquid level (cLLD) check, the needles are picked up again. One pipetting channel after the other is checked for proper cLLD function.



**Fig. 15.: Daily Maintenance – Successful**

Exact wording of content of the dialog displayed in Fig. 15.:

Daily maintenance successfully completed.

12. The daily maintenance process status is saved on the instrument and a report file is created.

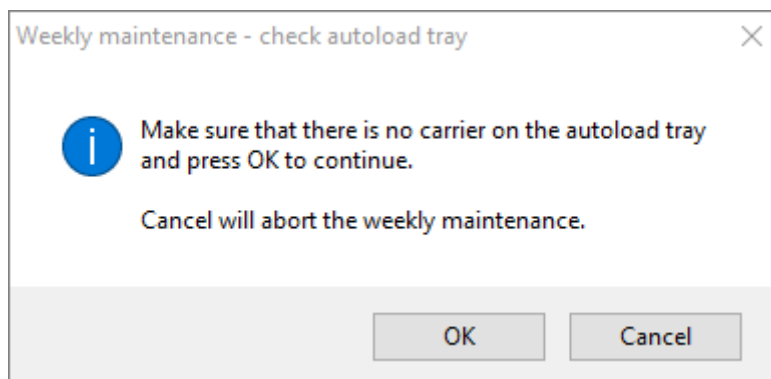
**NOTE**

*If any parts of the instrument, carriers or racks have become contaminated, the weekly maintenance procedure must be performed.*

### 3.5.5 Weekly Maintenance

The following tasks are carried out by the weekly maintenance:

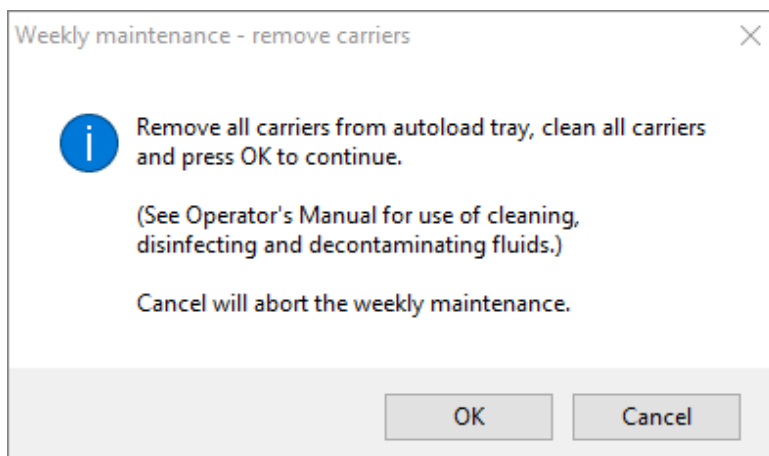
- Cleaning the deck and carriers
  - Checking the condition of the carriers
  - Emptying and cleaning of the tip waste and liquid waste
  - Checking the tightness of the pipetting channels
  - Verifying the cLLD function
  - Cleaning of the pipetting head: stop disk, O-ring, tip eject sleeve
  - Cleaning of the covers, Autoload protecting ribbon
1. Start the weekly maintenance by clicking the **Start Weekly Maintenance** button in the tool bar. The software will issue on-screen instructions detailing all procedures required to perform the weekly maintenance routine.



**Fig. 16.:Weekly Maintenance – Check Autoload Tray**

Exact wording of content of the dialog displayed in Fig. 16.:

Make sure that there is no carrier on the autoload tray  
and press OK to continue.  
Cancel will abort the weekly maintenance.



**Fig. 17.: Weekly Maintenance – Remove Carriers**

Exact wording of content of the dialog displayed in Fig. 17.:

Remove all carriers from autoload tray, clean all carriers and press OK to continue.  
(See Operator's Manual for use of cleaning, disinfecting and decontaminating fluids.)  
Cancel will abort the weekly maintenance.

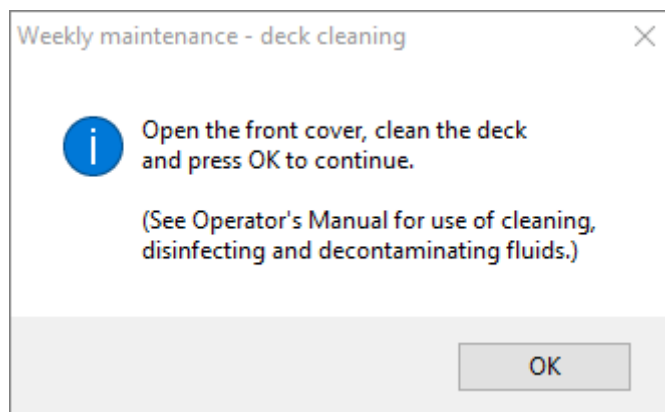
2. Clean all carriers with the MICROLAB Disinfectant Spray and leave them to dry. If they are heavily soiled, soak these carriers afterwards in a solution of MICROLAB Detergent and Disinfectant (see the product data sheet for further information).
3. Examine each carrier for scratches on the barcode and any signs of damage. If damage is apparent, replace with new carriers.



**ATTENTION**

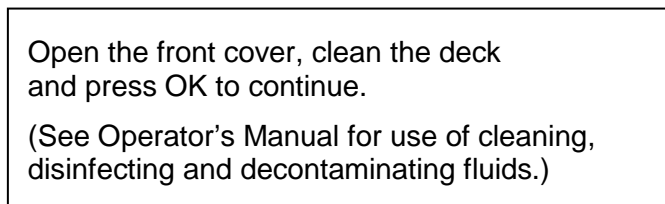
*Do not spray directly at the Autoload unit or at electrical boards or connectors.*

4. Continuing the weekly maintenance program will advise the Autoload to move to the right hand side of the instrument.

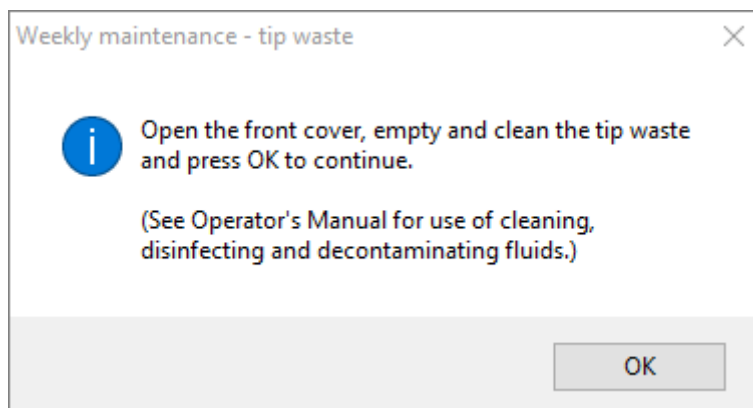


**Fig. 18.: Weekly Maintenance – Deck Cleaning**

Exact wording of content of the dialog displayed in Fig. 18:

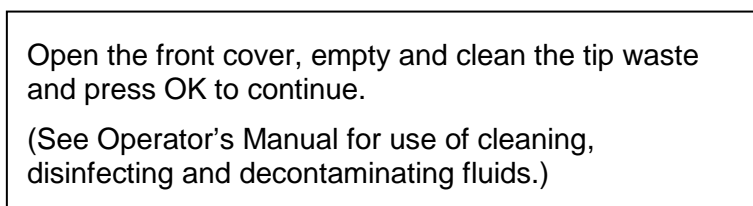


5. Open the front cover and wipe the deck with a cloth saturated with MICROLAB Disinfectant Spray. The slide blocks in particular must be checked for cleanliness. Close the front cover.
6. The next step of the maintenance procedure will advise the Autoload to move to the left hand side of the instrument. The tip waste needs to be emptied and cleaned. Dispose of tip waste with the rest of the laboratory's contaminated waste.



**Fig. 19.: Weekly Maintenance – Tip Waste**

Exact wording of content of the dialog displayed in Fig. 19.:



7. Remove the Tip Eject Sheet of the tip waste station and spray MICROLAB Disinfectant Spray directly onto the surface and wipe. Remove the plastic bag from the tip waste container and discard the plastic in the laboratory's contaminated waste. Place a new plastic bag in the tip waste container. Put the clean Tip Eject Sheet back in place.
8. Emptying and cleaning of the liquid waste
  - a. Empty the liquid waste container.
  - b. Inspect tubing for clogs, kinks and leakage. Tubing must be replaced if damaged.
  - c. Check and clean any liquid spills.
  - d. Check overflow for clogs and clean if required.
  - e. Clean collection tray, tubing and liquid waste container using Ethanol (70%) to flush.



**ATTENTION**

*Do not spray the maintenance needles.*



**ATTENTION**

*The tip waste, the Tip Eject Sheet, the Liquid Waste Container and Tubings, and the plastic bag are always to be regarded as contaminated.*

9. To prevent unreliable barcode reading, check the laser scanner window of the barcode reader and clean it with a lint-free cloth or Q-tips lightly soaked in Ethanol (70%).



**ATTENTION**

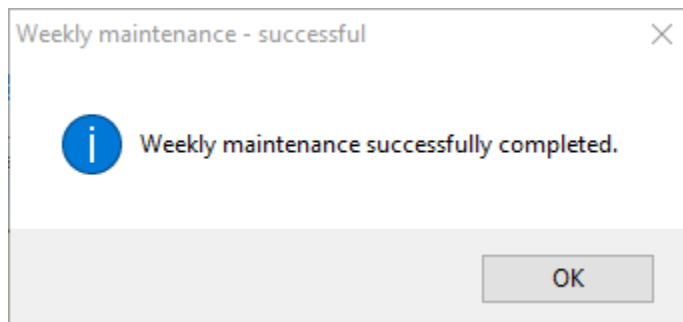
*The laser scanner window must be completely dry and free from dust and fibers before the instrument can be reused.*

10. For the next steps, the maintenance needles are required.



**Fig. 20.: Maintenance Needles 1000µl Pipetting Channels**

11. The procedure continues with the tightness check of the pipetting channels. The Pipetting Arm will travel to the right hand side to pick up the maintenance needles. Two checks are done with the pipetting channels, the over-pressure and under-pressure check.
12. For the capacitive liquid level (cLLD) check, the needles are picked-up again. One pipetting channel after the other is checked for proper cLLD function.
13. The end of the weekly maintenance program is displayed:

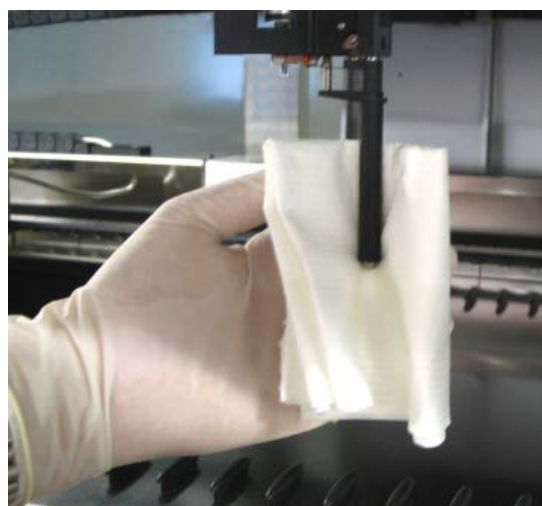


**Fig. 21.: Weekly Maintenance – Successful**

Exact wording of content of the dialog displayed in Fig. 21.:

Weekly maintenance successfully completed.

14. The weekly maintenance process status is saved on the instrument and a report file is created.
15. Clean the tip eject sleeve (outer part of the pipetting heads) with a lint-free cloth soaked in MICROLAB Disinfectant Spray.



**Fig. 22.: Cleaning the Tip Eject Sleeve**



**ATTENTION**

*Take care that no liquid gets inside the pipetting channel.*

*Whenever it is necessary to move the pipetting channels on the Pipetting Arm, move them gently by pushing close to their Y-slide. Never force them as this may lead to damage. If possible, switch on the instrument as this will result in a smoother motion when the pipetting channels have to be moved on the Pipetting Arm.*

16. Clean the stop disk and the O-rings (outer part of the pipetting heads, see [Fig. 23.: Cleaning the Stop Disk and O-Ring](#)) with a lint-free cloth soaked in MICROLAB Disinfectant Spray.



**Fig. 23.: Cleaning the Stop Disk and O-Rings**



**ATTENTION**

*Take care that no liquid gets inside the pipetting channel.*

17. Spray the front and side cover with MICROLAB Disinfectant Spray and wipe dry.
18. Clean the Autoload protecting ribbon with a cloth soaked in MICROLAB Disinfectant Spray, and wipe without exerting pressure.



**ATTENTION**

*Do not spray directly at the Autoload unit or at electrical boards or connectors.*

19. Clean the Pipetting Arm guide shaft behind the upper front cover with a dry cloth at least once a month.



**NOTE**

*Carriers must be completely clean and dry before re-using.*

### 3.5.6 If Maintenance Fails

If an error is encountered during a maintenance procedure, try to resolve the problem and restart the maintenance procedure. If you cannot resolve the error yourself, contact altona Diagnostics GmbH.

## 3.6 UV Decontamination

A UV-Lamp assembly (Microlab STAR Line UV Kit, Hamilton) has been installed in order to offer the user the option of UV decontamination of the AltoStar® AM16. The required duration and frequency is dependent on the used substances and on the frequency the system is used. The user is responsible for setting the appropriate duration and frequency.

Carriers and other accessories are not meant to be decontaminated by the UV Kit. The UV light cannot reach all surfaces of complex structures. Remove the carriers for UV decontamination.

**ATTENTION**

*Only use the UV decontamination with appropriate protection especially the UV front cover of the system.*

**NOTE**

*Read the UV Kit Manual before using the UV Kit! (Microlab STAR Line UV Kit, Hamilton)*

### 3.6.1 Operating the UV Kit

This chapter is dedicated to the user and focuses on a safe operation of the UV Kit based on the standard UV decontamination method.

**NOTE**

*Read the UV Kit Manual before using the UV Kit! (Microlab STAR Line UV Kit, Hamilton)*

**ATTENTION**

*Wear suitable face shield, gloves and protective clothing. Make sure that the UV cover is placed in the correct position to completely close the instrument before switching on the UV light.*



### 3.6.1.1 Mounting the UV Front Cover

The UV front cover shall be used to close the instrument completely whenever the UV light is switched on. Place the UV front cover as indicated in the picture below.



#### ATTENTION

*Do not use the UV front cover during a different method run, as carriers could be unloaded automatically and crash into the cover.*



Fig. 24.: Mounting the UV Front Cover

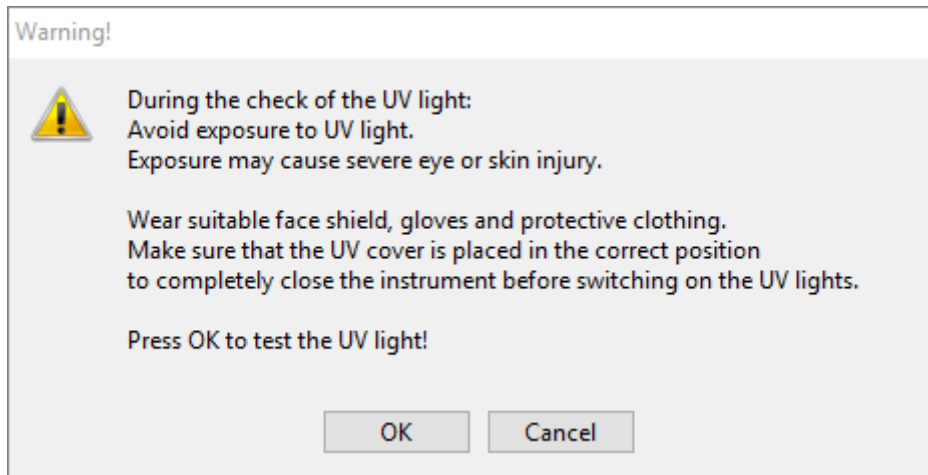
### 3.6.1.2 Running the UV Decontamination Method



#### NOTE

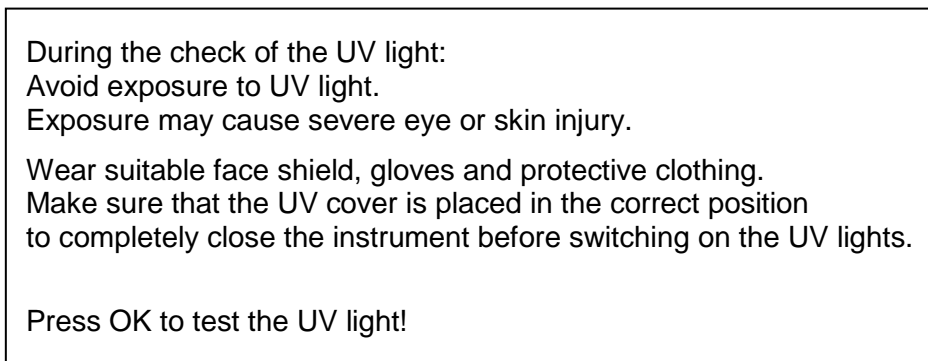
*The UV decontamination method enables automated UV irradiation. Therefore, the user can set the duration for how long the irradiation shall take place and a delay defining when the irradiation shall start.*

1. Start the UV decontamination by clicking the **Start UV Decontamination** button in the tool bar (see [Fig. 10.: Maintenance Dialog](#)). The software will issue on-screen instructions detailing all procedures required to perform the UV decontamination routine.
2. The first dialog refers to a check of the UV light. This step is performed in order for the user to check if the UV light is working properly.

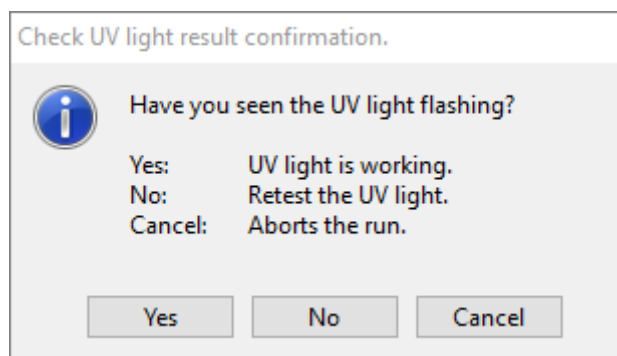


**Fig. 25.: Warning Dialog**

Exact wording of content of the dialog displayed in Fig. 25.:



3. Additionally, precautions and hazards are mentioned as well as protective measures. Make sure that all these protective measures are performed and that no collision can happen inside the instrument (the arm will move during the decontamination process!). Then, select **[OK]** to proceed to the UV light test.
4. The UV light will be switched on for a short moment. Observe if the UV light flashes.



**Fig. 26.: Check UV Light Result Confirmation**

Exact wording of content of the dialog displayed in Fig. 26.:

Have you seen the UV light flashing?  
 Yes: UV light is working.  
 No: Retest the UV light.  
 Cancel: Aborts the run.

- If the UV light was shining for a moment, confirm with **[Yes]**. Else, select **[No]** for a retest of the UV light or **[Cancel]** to abort the run.



**ATTENTION**

*In case the UV light flashing cannot be observed upon several retests, the power connections should be checked.*

*If all connections are fine but the UV light flashing can still not be observed, the UV light may be defective. Please contact Diagnostics GmbH in this case.*

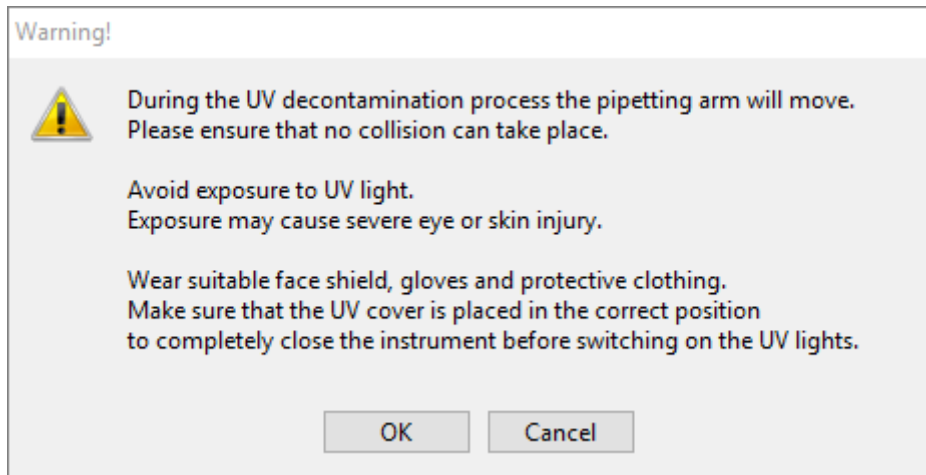
- If the UV light flashing could be observed and **[Yes]** has been selected, the UV light timer settings dialog is shown.

UV light timer: Please set the decontamination duration and delay timer for the UV light (in minutes).

Prompt	Value	Minimum	Maximum
Decontamination duration (minutes)	10	1	60
Time to wait before decontamination starts (minutes)	0	0	10

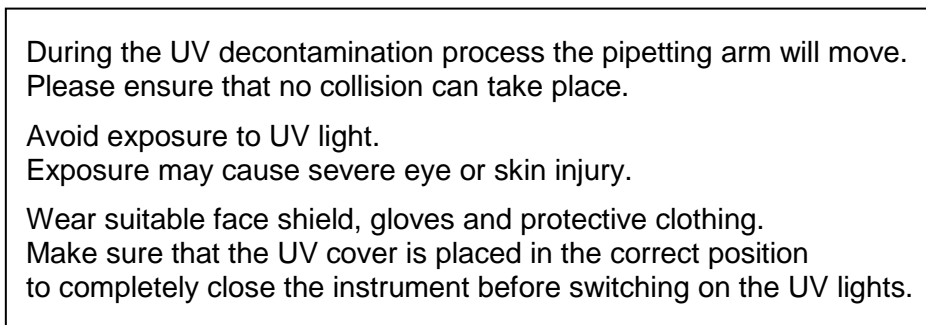
**Fig. 27.: UV Light Timer Settings Dialog**

- Enter the desired duration for UV decontamination in the upper **“Value”** field. The lower **“Value”** field can be used to enter the desired delay when the UV irradiation shall start. In this case, the user can leave the room during this duration until the UV irradiation starts. Whole numbers are required, otherwise a warning will be displayed and the value has to be changed. The **“Minimum”** and **“Maximum”** values to be used are indicated in the corresponding fields.
- Select **[OK]** to proceed.



**Fig. 28.: Warning Dialog**

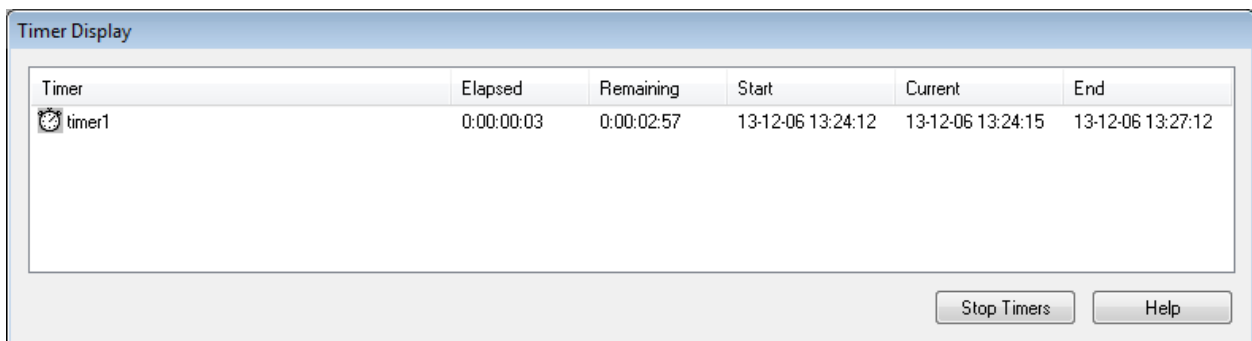
Exact wording of content of the dialog displayed in Fig. 28.:



**ATTENTION**

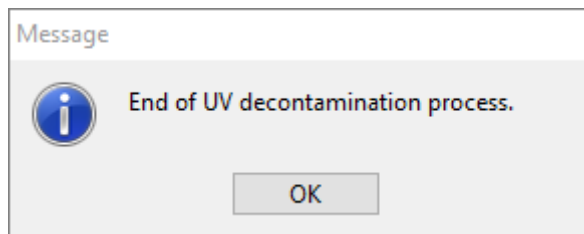
*Make sure that no collision can take place, the instrument arm will move and that the instrument is closed with the UV covers.*

9. A warning is displayed, read it carefully. If no collision can take place and all protective measures have been performed, press **[OK]** in order to start the decontamination method.
10. If a delay has been specified, a timer is started showing the time elapsed and the time remaining. If the button **[Stop Timers]** is pressed, the timer is terminated and the UV light is switched on immediately afterwards.



**Fig. 29.: Timer Display Dialog**

11. After the termination of the timer or immediately after pressing **[OK]** in the UV decontamination timer settings dialog, if no delay has been defined, the UV light will be switched on automatically and the Pipetting Arm is moving from left to right in steps every few seconds for an even irradiation of the workspace.
12. After the decontamination duration specified, the UV light will be switched off, the Pipetting Arm will stop and the following message appears.



**Fig. 30.: End of UV Decontamination Process Dialog**

Exact wording of content of the dialog displayed in Fig. 30.:

End of UV decontamination process.

13. To close the UV decontamination method, press **[OK]**. Afterwards, the UV front cover can be removed. The UV decontamination method has finished.

### 3.7 Workflows

The AltoStar® Connect SW facilitates the processing of samples through the sample purification and the PCR setup process. The purification can be performed in one of three workflow options:

- On the AltoStar® AM16 instrument in conjunction with the AltoStar® Purification Kit 1.5 (**AltoStar Workflow**)
- On an external purification instrument with the AltoStar® AM16 instrument transferring the samples from the sample tubes to the processing plate of the external purification instrument (**Sample Transfer Workflow**)
- On an external purification instrument without sample transfer on the AltoStar® AM16 instrument (**External Purification Workflow**)

Regardless of the chosen purification workflow option, the PCR setup procedure is the same and can be performed on the AltoStar® AM16 instrument for all three options. The following chapters will illustrate the processing of the three different purification options and the PCR setup process.

### 3.8 AltoStar® Workflow: Purification

The AltoStar® Connect SW facilitates the processing of the AltoStar® Workflow: Purification on the AltoStar® AM16 instrument. The workflow consists of the following sequential steps:

1. Programming of the complete workflow process for a fixed set of samples in the AltoStar® Connect SW.
2. Specimen preparation: Refer to the [AltoStar® Purification Kit 1.5 Manual](#) for instructions.

3. Sample purification on the AltoStar® AM16 as programmed in step 1.
4. PCR setup on the AltoStar® AM16 as programmed in step 1. (see [Chapter 3.11 PCR Setup](#)).
5. PCR on a CFX96™ DW as programmed in step 1. (refer to the respective [Altona Diagnostics PCR Kit Manual](#)).



**NOTE**

*The programming for the complete workflow process is concluded in step 1. No alterations to the programmed process are possible in later phases of the workflow.*



**NOTE**

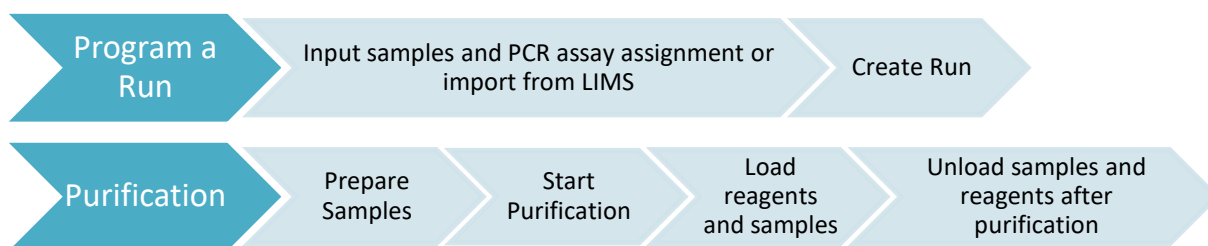
*Before starting the workflow, ensure that all required material and devices are available*



**NOTE**

*Before starting the workflow, ensure that the Daily and Weekly Maintenance have been conducted and that the semi-annual maintenance and verification procedure is not overdue. Otherwise, the instrument will not process any samples or reagents. It is recommended to conduct the Daily Maintenance when the device is turned on the first time each day and to conduct the Weekly Maintenance at the end of the week before shut-down of the system. The maintenance routine verifies the correct functionality of the instrument and will prompt necessary user actions including cleaning of the instrument.*

### 3.8.1 Overview of the AltoStar® Workflow: Purification



**Fig. 31.: Overview of the AltoStar® Workflow: Purification**

## 3.8.2 Programming a Run

### 3.8.2.1 Manual Programming

1. Click the **Program Run** button of the AltoStar® Workflow: Purification in the start screen or click **Program Run** → **Program Run (AltoStar Purification)** in the menu bar.
2. Click the **Add Samples** button to add samples manually. The **Add Samples** dialog will appear (see Fig. 32.: Add Samples Dialog).

The figure shows two screenshots of the 'Add Samples' dialog box. The left screenshot shows the dialog with 'Sample Type' set to 'Plasma', 'Predilution' unchecked, and empty fields for 'Sample Volume', 'Added Diluent', 'Sample Name', and 'Sample Barcode'. The right screenshot shows the same dialog with 'Predilution' checked, 'Sample Volume' set to 1000, and 'Added Diluent' set to 1000. Both dialogs have 'Add' and 'Close' buttons.

Fig. 32.: Add Samples Dialog

3. Select the sample type from the **Sample Type** menu, e.g. Whole blood, Plasma, Urine, etc.
4. If the sample had to be prediluted to provide the required 500 µl or 1000 µl plus dead volume of the tube, check the **Predilution** checkbox. Specify the volume of the sample used during the dilution in the **Sample Volume** field and the volume of the added diluent in the **Added Diluent** field. The predilution will be taken into account to calculate quantitative results after the PCR.
5. Optionally, a sample name can be entered in the **Sample Name** field.
6. Enter a barcode via the keyboard or use the handheld barcode scanner in the **Sample Barcode** field. A unique barcode for each sample is required.
7. Click the **Add** button to add the sample to the sample list of the software.
8. More samples can be generated by repeating steps 3. – 7. or the **Add Samples** dialog can be closed by clicking the **Close** button.



**ATTENTION**

Selecting the sample type in the **Add Samples** dialog determines the appropriate purification protocol. Make sure to select the correct Sample Type for each sample. Otherwise, the sample may not be processed or the purification performance may be compromised.

**3.8.3 Sample List**

Process Sample	Sample Name	Sample Barcode	Sample Type	Sample Priority	Sample Volume	Eluate left	Predilution	Programming	Programming
<input checked="" type="checkbox"/>	Sample 1	0000001	Plasma	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 2	0000002	Urine	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 3	0000003	CSF	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 4	0000004	Blood	<input type="checkbox"/>	500 µl	45 µl	<input checked="" type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 5	0000005	Plasma	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 6	0000006	Plasma	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 7	0000007	Plasma	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 8	0000008	Urine	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 9	0000009	Urine	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 10	0000010	Urine	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		

**Fig. 33.: Programming Screen**

The samples are listed in the left bottom area of the programming screen with their programmed properties.

- **Process Sample:** The check mark indicates that the respective sample will be included in the run definition generated next. Deselect the checkbox for a sample that should not be included in the next run definition. When more than 96 samples are selected, the run cannot be created. Deselect excess samples to create the run definition with up to 96 samples. Afterwards, reselect the deselected samples for the creation of the subsequent run definition.
- **Sample Name:** shows the name of the sample



- **Sample Barcode:** shows the Barcode of the sample
- **Sample Type:** shows the sample type
- **Sample Priority:** Samples can be prioritized by checking the respective checkbox. All prioritized samples will be sorted to one PCR plate if possible to facilitate fastest processing.
- **Sample Volume:** 500 µl is preselected as the default sample volume for the purification. As soon as an assay is selected for a sample (see [Chapter 3.8.4 Assigning PCR Assays to a Sample](#)) the appropriate sample volume is automatically selected. Make sure to provide additional dead volume suitable for the sample tube used. For further information regarding dead volume of sample tubes refer to the [AltoStar® Purification Kit 1.5 Manual](#).
- **Eluate left:** The eluate volume that is available to be allotted to assays (see [Chapter 3.8.4 Assigning PCR Assays to a Sample](#)). The volume is automatically adjusted every time assays are added or removed for this sample.
- **Predilution:** Indicating the dilution state of the sample. To specify a predilution check the checkbox and input the Sample Volume and Diluent Volume used during the predilution in the appearing **Predilution** dialog.

By clicking **Save List** the entered or modified sample data and PCR assay definitions will be saved.




#### NOTE

*All sample properties, except Eluate left, can be corrected by manual input after clicking the respective field.*

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.

One or several samples can be removed from the list by selecting them and clicking the **Delete** button in the tool bar.

By clicking the **Create run** button in the tool bar before assigning assays to the samples (see [Chapter 3.8.4 Assigning PCR Assays to a Sample](#)), all samples that are marked in the column **Process Sample** are transferred to a purification run definition without subsequent PCR setup.

Samples that have been transferred to a purification run definition disappear from the sample list.

### 3.8.4 Assigning PCR Assays to a Sample

Each sample can be run with as many PCR assays as the available eluate allows. The available assays are displayed on the right side of the programming screen.

Wells used: 10

Process Sample	Sample Name	Sample Barcode	Sample Type	Sample Priority	Sample Volume	Eluate left	Predilution	Programming	Programming
<input checked="" type="checkbox"/>	Sample 1	00000001	Plasma	<input type="checkbox"/>	500 µl	35 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 2	00000002	Urine	<input type="checkbox"/>	500 µl	35 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 3	00000003	CSF	<input type="checkbox"/>	500 µl	35 µl	<input type="checkbox"/>	qualitative	
<input checked="" type="checkbox"/>	Sample 4	00000004	Blood	<input type="checkbox"/>	500 µl	35 µl	<input checked="" type="checkbox"/>		qualitative
<input checked="" type="checkbox"/>	Sample 5	00000005	Plasma	<input type="checkbox"/>	500 µl	35 µl	<input type="checkbox"/>		qualitative
<input checked="" type="checkbox"/>	Sample 6	00000006	Plasma	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 7	00000007	Plasma	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 8	00000008	Urine	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>	qualitative	
<input checked="" type="checkbox"/>	Sample 9	00000009	Urine	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 10	00000010	Urine	<input type="checkbox"/>	500 µl	45 µl	<input type="checkbox"/>		

**Fig. 34.: Programming Screen: Assay Assignment**

To select an assay for specific samples:

1. Click the cell corresponding to the respective sample and the respective assay.
2. Select the analysis type in the appearing select box. The correct set of **Standards and Controls** and the appropriate **Sample Volume** are automatically selected depending on the analysis type.

By clicking **Save List**, the entered or modified sample data and PCR assay definitions will be saved.



**NOTE**

*If it is not possible to select a PCR assay, check whether enough eluate is left to perform this PCR assay.*

### 3.8.5 Importing from LIMS

Both the sample information 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 LIMS file (.psv) that contains the required information.

For information regarding the LIMS integration, contact altona Diagnostics GmbH.

### 3.8.6 Creating a Run

After all samples are added and the assays are programmed, you can create a run definition.

1. Click the **Create Run** button. The **Save Run Definition** dialog is displayed.
2. Enter a unique **Run Name** and optionally a **Description** for identification of the run later on.
3. Click the **Ok** button to save the run definition.

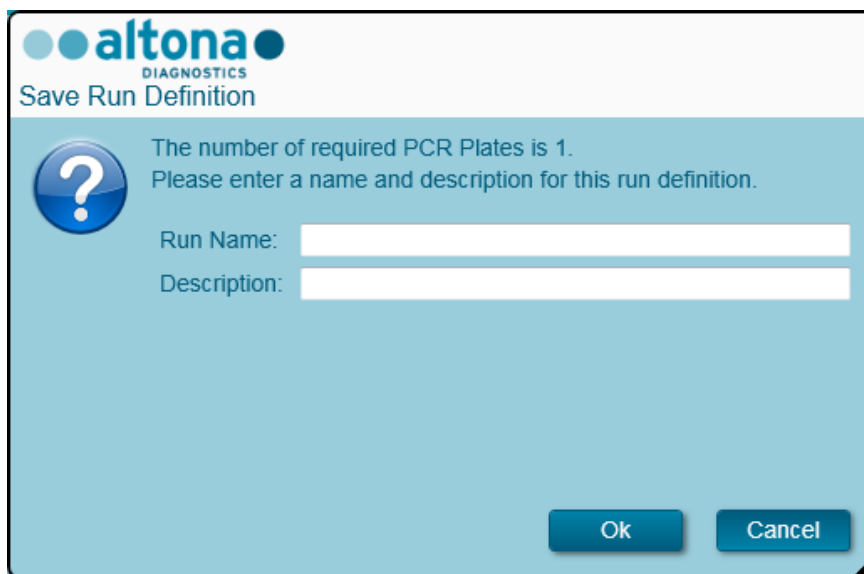


Fig. 35.: Save Run Definition Dialog

### 3.8.7 Sample Preparation

For preparation and pretreatment of samples please refer to the [AltoStar® Purification Kit 1.5 Manual](#).

### 3.8.8 Preparing Reagents for a Purification Run

All reagent containers are barcoded for automated identification, localization and verification of lot conformity and non-expiry by the AltoStar® system.



#### NOTE

*Ensure that the last four Lot Number digits of all Lysis Buffer, Wash Buffer, Magnetic Bead, Enhancer and Elution Buffer containers used in a run are identical. The software verifies lot congruence during loading and instructs the user accordingly. For your convenience, these four digits are displayed as Loading Number on the outside of each component box.*



Fig. 36.: Side View of the Box with the Loading Number



#### NOTE

Ensure that the AltoStar® Purification Kit 1.5 reagents are not expired. During loading, the software verifies use within the shelf life of the reagents and instructs the user accordingly.

### 3.8.9 Starting a Purification Run

To start a purification run, go back to the **Start Screen** of the AltoStar® Connect SW (see [Fig. 7.: Start Screen of the AltoStar® Connect SW](#)) and select **Start Purification** or select **Purification** → **Start Purification** in the menu bar. The programmed purification run definitions are displayed in the **Programmed Purification Runs** table on the left side of the screen.

Name	Description	Purification Type	No. of prioritized Samples	Date/Time created
20170824_Run1	Run programmed by Labadmin	AltoStar Purification	0	8/24/2017 3:31:06 PM
20170824_Run2	Run programmed by Laboperator	AltoStar Purification	0	8/24/2017 3:31:45 PM
20170824_Run3	Run programmed by Labadmin	AltoStar Purification	0	8/24/2017 3:35:02 PM

Name	Barcode	Sample Type	Sample Volume
Sample 1	0000001	Plasma	500 µl
Sample 2	0000002	Urine	500 µl
Sample 3	0000003	CSF	500 µl
Sample 4	0000004	Blood	500 µl
Sample 5	0000005	Plasma	500 µl
Sample 6	0000006	Plasma	500 µl
Sample 7	0000007	Plasma	500 µl
Sample 8	0000008	Urine	500 µl
Sample 9	0000009	Urine	500 µl
Sample 10	0000010	Urine	500 µl

Fig. 37.: Start Run Screen





- Select the purification run definition to be started in the **Programmed Purification Runs** table
- The samples included in the selected run definition are displayed in the table on the right side of the screen (**Samples in selected Purification Run**)
- Click the **Start Run** button in the tool bar




Click **Delete Run** to completely delete the selected programmed purification run. By clicking **Delete Run**, all associated programmed PCR Setup runs will also be deleted.

### 3.8.10 Instrument Loading for a Purification Run

At the start of a run, the **Loading** dialog is displayed (see [Fig. 38.: Loading Dialog Purification Run](#)). The material, reagents and samples have to be loaded onto suitable carriers, before these carriers can then be loaded onto the respective tracks on the Loading Tray of the instrument:

**Table 2: Carrier Description for Purification Run**

Carrier No.	Track	Material	Carrier Name	Image	Notes
1	1 - 6	5 racks of 1000 µl tips	Tip Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
2	7 - 12	3 racks of 300 µl tips 1 Elution Plate	Tip and Plate Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
					Always place plates with well A1 to the left of the respective plate position.
					The plate position at the front is not used in Purification runs.
3-4	13-16	Up to four Lysis Buffer and Wash Buffer containers per carrier	Container Carrier		One or two carriers can be loaded.
					The position of the individual containers on the carriers is arbitrary.
					Gently push the containers down all the way to the bottom of the carrier.
5	17	Up to 24 Internal Control, Magnetic Bead, Enhancer and Elution Buffer tubes	Tube Carrier 24		The position of the individual tubes on the carrier is arbitrary.
					Ensure all tube barcodes are visible through the carrier windows.
					Gently push the tubes down all the way to the bottom of the carrier.
6 - 11	18 - 23	Up to 96 samples on	Tube Carrier 24		Up to 24 sample tubes of 14.5 mm - 18 mm diameter per carrier.

Carrier No.	Track	Material	Carrier Name	Image	Notes
		any combination of these two carrier types			The position of the individual tubes on the carriers is arbitrary.
				Ensure all tube barcodes are visible through the carrier windows.	
			Tube Carrier 32		Up to 32 sample tubes of 11 mm - 14 mm diameter per carrier.
				The position of the individual tubes on the carriers is arbitrary.	
				Ensure all tube barcodes are visible through the carrier windows.	
		Gently push the tubes down all the way to the bottom of the carrier.			
12	24 - 30	1 Processing Plate 1 Tip Park Plate 1 Tip Park Rack	Heater Shaker Carrier		This carrier is not removable and is therefore not loaded by the Autoload. The items are placed by hand onto the carrier in the instrument.
					Ensure both plates and the rack are seated correctly in their positions.



**ATTENTION**

*Remove the lids of all tubes before loading the carriers onto the Loading Tray. Leaving them on may lead to false results, aborted runs and damage to the instrument. Store the lids in a clean space to avoid contamination. Reuse the lids to close the tubes after the run.*



**ATTENTION**

*Remove the sealing foils of all buffer containers before loading the carriers onto the Loading Tray. Leaving them on may lead to false results, aborted runs and damage to the instrument. Dispose of the sealing foils. To close the buffer containers after the run, use new Re-sealing foils.*





**ATTENTION**


*Always use a fresh Processing Plate to avoid false results.*



**NOTE**

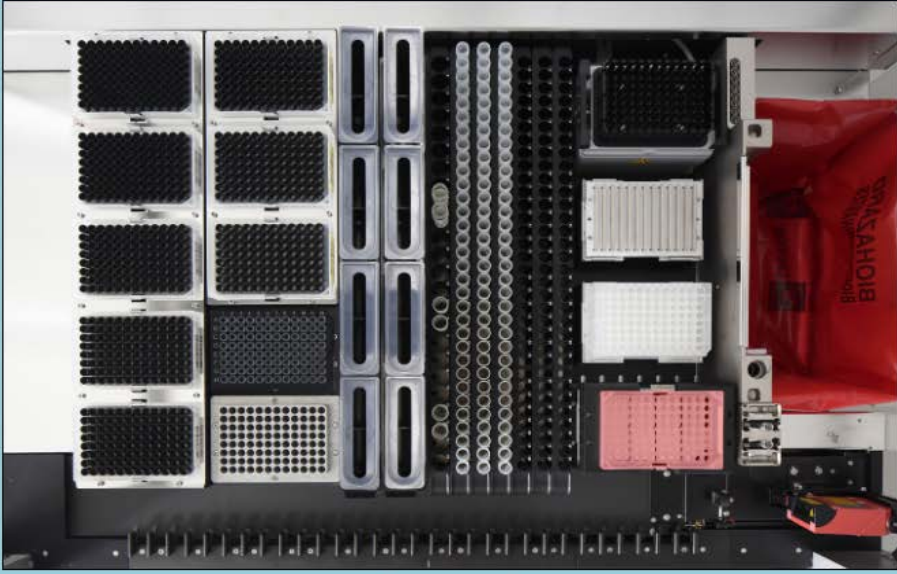
*Before loading carriers on the Loading Tray:*

- *Ensure that no carriers are loaded on the deck inside the instrument.*
- *Ensure that the barcode on each carrier is toward the rear facing right (toward the barcode reader on the Autoload).*



>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	1 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

**Fig. 38.: Loading Dialog Purification Run**

The **Loading** dialog consists of a visual representation of the instrument deck at the top half and a table specifying all items to be loaded in the bottom half.

Begin by selecting the lines of the table by clicking them one by one, starting at the top.

The position of the material currently selected in the **Loading** dialog table is further visualized:

- In red in the image at the top.
- By flashing Loading Lights of the instrument above the tracks where the carrier holding the respective items must be placed.

Follow the instructions in the **Comment** column carefully.

To load the carriers, insert them into the 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. Do not push the carriers past the stop hooks.



**ATTENTION**

*Do not move or remove individual tips on a Tip Rack as this will interfere with the tip counter of the software. In case the tip positions were modified by the user, the tip counters for the 1000 µl tips and the 300 µl tips can be reset by checking the respective check boxes at the bottom of the **Loading** Dialog. In this case, all tip positions on carriers 1 and 2 have to be filled completely. The user has to confirm that all Tip Racks are completely filled in the subsequent **Reset Tip Counters** dialog.*



**ATTENTION**

*When handling patient samples, wear personal protective apparel, including disposable gloves to avoid infection. Wash hands thoroughly after removing gloves, and dispose of gloves as biohazardous waste.*



**ATTENTION**

*To prevent damage to the carriers and decrease the risk of contamination, extend the safety guards whenever carriers are loaded on the Loading Tray.*



**ATTENTION**

*Always use a fresh Deep Well Plate in the Tip Park Module to avoid false results.*



**ATTENTION**

*Always use an empty Tip Rack in the Tip Park Module which hasn't been used in that position before.*



**NOTE**

*Do not exchange positions of any loaded material after it has been drawn into the instrument by the Autoload, as this could result in incorrect test results, aborting the run and damage to the instrument.*

**NOTE**

*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.*

After all carriers are loaded on the correct tracks of the Loading Tray, click **OK** in the loading dialog. By clicking **Cancel**, the run will be cancelled, but it can be started again.

After clicking **OK**, the **Tip Park Plate** dialog is displayed (see [Fig. 39.: Tip Park Plate Dialog](#)). The plate barcode has to be scanned in duplicate with the handheld barcode scanner or entered by keyboard to ensure that the plate has not been used in prior runs. Click **OK** to confirm the input.



**Fig. 39.:Tip Park Plate Dialog**

The instrument loads the carriers with the Autoload and automatically verifies:

- Correct identity and localization of the loaded carriers
- Correct identity of the items loaded on the carriers
- Positions of the items loaded on the carriers
- Lot congruence of the Lysis Buffer, the Wash Buffers, the Magnetic Beads, the Enhancer and the 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, see [Chapter 4 Troubleshooting and Error Messages](#).

When all checks have passed, the **Loading Complete** dialog is displayed. Confirm the **Loading Complete** message by clicking **OK** or wait 10 seconds.



Fig. 40.: Loading Complete Dialog

The system now performs the purification automatically. No further user interaction is required until the run has finished. If you click **Cancel**, the run will abort.



#### ATTENTION

*Do not push or pull carriers or the instrument door during a run as this may abort the run.*



#### NOTE

*The sample volume is not checked by the system prior to the sample transfer. Short samples will be error flagged during the sample transfer step and will not be processed further.*

### 3.8.11 During the Purification Run

The purification run will be conducted without user intervention after starting. After the sample transfer into the Processing Plate, 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 samples tubes can be removed. The run will not be interrupted.



Fig. 41.: Unload Samples Button

### 3.8.12 Forced Abort

The run can be aborted by clicking the **Abort run** button in the tool bar and confirming to abort the run in the subsequent **Abort Run** dialog.

### 3.8.13 End of the Purification Run

At the end of the run, the **Run Finished** dialog is displayed. Make sure the Loading Tray is empty and confirm the **Run Finished** dialog by clicking **OK**. The instrument will unload the carriers. Make sure not to stand in the way of the unloading carriers.

After unloading, the **Maintenance** dialog is displayed (see [Fig. 42.: Maintenance Dialog after Finished Run](#)). Follow the instructions of the **Maintenance** dialog.



**Fig. 42.: Maintenance Dialog after Finished Run**

Use the table of the dialog to identify reagents that can be used again in subsequent runs. Dispose of all reagents **not** listed in the table. Refer to the AltoStar® Purification Kit 1.5 Manual for information regarding sealing, storage and disposal.

Confirm the **Maintenance** dialog by clicking **Ok**.

### 3.8.14 Purification Results

The purification run results are saved in the AltoStar® Connect SW. To access the results screen (see [Fig. 43.: Results Screen](#)) click **Purification** → **Purification Results** in the menu bar.

Name	Barcode	Sample Volume	Well	Eluate Plate Barcode	Protocol Name	Eluate Volume [µl]	Remaining Eluate [µl]	Status
Sample1	00000001	500 µl	A1	Barcode04	Plasma500v1	45	35	Processed
Sample2	00000002	500 µl	B1	Barcode04	Plasma500v1	45	35	Processed
Sample3	00000003	500 µl	C1	Barcode04	Plasma500v1	45	35	Processed
Sample4	00000004	500 µl	D1	Barcode04	Plasma500v1	45	35	Processed
Sample5	00000005	500 µl	E1	Barcode04	Plasma500v1	45	35	Processed
Sample6	00000006	500 µl	F1	Barcode04	Plasma500v1	45	35	Processed
Sample7	00000007	500 µl	G1	Barcode04	Plasma500v1	45	35	Processed
Sample8	00000008	500 µl	H1	Barcode04	Plasma500v1	45	35	Processed
Sample9	00000009	500 µl	A2	Barcode04	Plasma500v1	45	35	Processed
Sample10	00000010	500 µl	B2	Barcode04	Plasma500v1	45	35	Processed

**Fig. 43.: Results Screen**

The results screen displays the results of the latest purification or sample transfer run. To view the results of prior runs, click the **Load** button in the menu bar, select the desired run from the list in the opening **Load Results** dialog and click **OK**.

In the **Load Results** dialog, the list of prior runs can be filtered by entering the barcode of the respective Eluate Plate into the **Filter Eluate Plate barcode** field.

At the end of a purification run, two files are automatically generated by the AltoStar® Connect SW:

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

These files are stored at the location specified in the System Settings (see [Chapter 3.3.8.1 Default Path of Purification Report \(pdf\)](#) and [Chapter 3.3.8.2 Default Path of Purification LIMS File \(xml\)](#)).

If necessary, these files can be generated again by loading the respective run and clicking the **Create LIMS File** button to generate the xml file or the **Create Report** button to generate the PDF report.

A purification run that was aborted during processing can be restored in order to restart it. To restore the run presently loaded in the Results Screen, click the **Repeat Run** button in the toolbar. The restored run can then be started as described in [Chapter 3.8.9 Starting a Purification Run](#).



#### **ATTENTION**

*If repeating a run the sample volumes might be insufficient.*

### 3.9 Sample Transfer Workflow: Purification

The AltoStar® Connect SW facilitates the processing of the Sample Transfer on the AltoStar® AM16 instrument. The workflow consists of the following sequential phases:

1. Programming of the complete workflow process for a fixed set of samples in the AltoStar® Connect SW.
2. Specimen preparation: Refer to the [AltoStar® Purification Kit 1.5 Manual](#) for instructions.
3. Sample transfer to the processing plate of an external purification instrument on the AltoStar® AM16 as programmed in 1.
4. Sample purification on an external instrument.
5. PCR setup on the AltoStar® AM16 as programmed in 1. (see [Chapter 3.11 PCR Setup](#)).
6. PCR on a CFX96™ DW as programmed in 1. (refer to the respective [altona Diagnostics PCR Kit Manual](#)).

**NOTE**

*The programming for the complete workflow process is concluded in phase 1. No alterations to the programmed process are possible in later phases of the workflow.*

**NOTE**

*Before starting the workflow, ensure that all required material and devices are available.*

**NOTE**

*Before starting the workflow, ensure that the Daily and Weekly Maintenance have been conducted and that the semi-annual maintenance and verification procedure is not overdue. Otherwise, the instrument will not process any samples or reagents. It is recommended to conduct the Daily Maintenance when the device is turned on the first time each day and to conduct the Weekly Maintenance at the end of the week before shut-down of the system. The maintenance routine verifies the correct functionality of the instrument and will prompt all necessary user actions including cleaning of the instrument.*

### 3.9.1 Overview of the Sample Transfer Purification

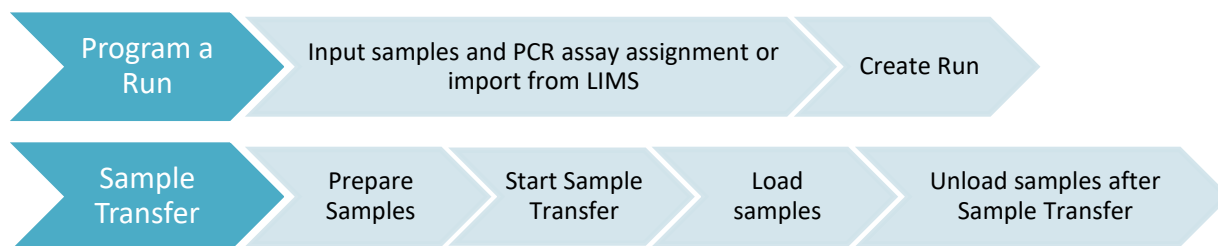


Fig. 44.: Overview of the Sample Transfer Workflow

### 3.9.2 Programming a Run

#### 3.9.2.1 Manual Programming

1. Click the **Program Run** button of the Sample Transfer Workflow in the start screen or click **Program Run → Program Run (Sample Transfer)** in the menu bar.
2. Click the **Add Samples** button to add samples manually. The **Add Samples** dialog will appear (see Fig. 45.: Add Samples Dialog).

Fig. 45.: Add Samples Dialog

3. Select the sample type from the **Sample Type** menu, e.g. Whole blood, Plasma, Urine, etc.
4. If the sample had to be prediluted to provide the required volume (transfer volume plus dead volume of the tube), check the **Predilution** checkbox. Specify the volume of the sample used during the dilution in the **Sample Volume** field and the volume of the added diluent in the **Added Diluent** field. The predilution will be taken into account to calculate quantitative results after the PCR.
5. Optionally, a sample name can be entered in the **Sample Name** field.

6. Enter a barcode via the keyboard or use the handheld barcode scanner in the **Sample Barcode** field. A unique barcode for each sample is required.
7. Click the **Add** button to add the sample to the list.
8. More samples can be generated by repeating steps 3. – 7. or the **Add Samples** dialog can be closed by clicking the **Close** button. The samples will now show up in the Sample List of the software.



**ATTENTION**

Selecting the sample type in the **Add Samples** dialog determines the appropriate sample transfer protocol. Make sure to select the correct Sample Type for each sample. Otherwise, the sample may not be processed or the transfer performance may be compromised.

**3.9.3 Sample List**

Process Sample	Sample Name	Sample Barcode	Sample Type	Sample Priority	Sample Volume	Eluate left	Predilution	Programming	Programming
<input checked="" type="checkbox"/>	Sample 1	0000001	Plasma	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 2	0000002	Urine	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 3	0000003	CSF	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 4	0000004	Blood	<input type="checkbox"/>	200 µl	40 µl	<input checked="" type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 5	0000005	Plasma	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 6	0000006	Plasma	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 7	0000007	Plasma	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 8	0000008	Urine	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 9	0000009	Urine	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 10	0000010	Urine	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		

**Fig. 46.:Programming Screen**

The samples are listed in the left bottom area of the programming screen with their programmed properties.

- **Process Sample:** The check mark indicates that the respective sample will be included in the run definition generated next. Deselect the checkbox for a sample that should not be included in the next run definition. When more than 96 samples are selected, the run cannot be created. Deselect excess samples to create the run definition with up to 96 samples. Afterwards, reselect the deselected samples for the creation of the subsequent run definition.
- **Sample Name:** shows the name of the sample
- **Sample Barcode:** shows the barcode of the sample
- **Sample Type:** shows the type of the sample
- **Sample Priority:** Samples can be prioritized by checking the respective checkbox. All prioritized samples will be sorted to one PCR plate if possible to facilitate fastest processing.
- **Sample Volume:** The default sample transfer volume is preselected. Make sure to provide additional dead volume suitable for the sample tube used. For further information regarding dead volume of sample tubes, refer to the AltoStar® Purification Kit 1.5 Manual.
- **Eluate left:** The eluate volume that is available to be allotted to assays (see [Chapter 3.9.4 Assigning PCR Assays to a Sample](#)). The volume is automatically adjusted every time assays are added or removed for this sample.
- **Predilution:** Indicating the dilution state of the sample. To specify a predilution, check the checkbox and input the **Sample Volume** and **Diluent Volume** used during the predilution in the appearing **Predilution** dialog.

By clicking **Save List**, the entered or modified sample data and PCR assay definitions will be saved.




#### NOTE

*All sample properties except Eluate left can be corrected by manual input after clicking the respective field.*

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.

One or several samples can be removed from the list by selecting them and clicking the **Delete** button in the tool bar.

By clicking the **Create run** button in the tool bar before assigning assays to the samples (see [Chapter 3.9.4 Assigning PCR Assays to a Sample](#)), all samples that are marked in the column **Process Sample** are transferred to a sample transfer run definition without subsequent PCR setup.

Samples that have been transferred to a sample transfer run definition disappear from the sample list.

### 3.9.4 Assigning PCR Assays to a Sample

Each sample can be run with as many PCR assays as the available eluate allows. The available assays are displayed on the right side of the programming screen.



Wells used: 10

Process Sample	Sample Name	Sample Barcode	Sample Type	Sample Priority	Sample Volume	Eluate left	Predilution	Programming	Programming
<input checked="" type="checkbox"/>	Sample 1	0000001	Plasma	<input type="checkbox"/>	200 µl	30 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 2	0000002	Urine	<input type="checkbox"/>	200 µl	30 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 3	0000003	CSF	<input type="checkbox"/>	200 µl	30 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 4	0000004	Blood	<input type="checkbox"/>	200 µl	30 µl	<input checked="" type="checkbox"/>		qualitative
<input checked="" type="checkbox"/>	Sample 5	0000005	Plasma	<input type="checkbox"/>	200 µl	30 µl	<input type="checkbox"/>		qualitative
<input checked="" type="checkbox"/>	Sample 6	0000006	Plasma	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 7	0000007	Plasma	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>	quantitative	
<input checked="" type="checkbox"/>	Sample 8	0000008	Urine	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>	qualitative	
<input checked="" type="checkbox"/>	Sample 9	0000009	Urine	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		
<input checked="" type="checkbox"/>	Sample 10	0000010	Urine	<input type="checkbox"/>	200 µl	40 µl	<input type="checkbox"/>		

Fig. 47.: Assigning PCR Assays

To select an assay for specific samples:

1. Click the cell corresponding to the respective sample and the respective assay.
2. Select the analysis type in the appearing select box. The correct set of **Standards and Controls** and the appropriate **Sample Volume** are automatically selected depending on the analysis type.



**NOTE**

*If it is not possible to select a PCR assay, check whether enough eluate is left to perform this PCR assay.*

### 3.9.5 Importing from LIMS

Both the sample information 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 LIMS file (.psv) that contains the required information.

For information regarding the LIMS integration contact altona Diagnostics GmbH.

### 3.9.6 Creating a Run

After all samples are added and the assays are programmed, you can create a run definition.

1. Click the **Create Run** button. The **Save Run Definition** dialog is displayed.
2. Enter a unique **Run Name** and optionally a **Description** for identification of the run later on.
3. Click the **Ok** button to save the run definition.

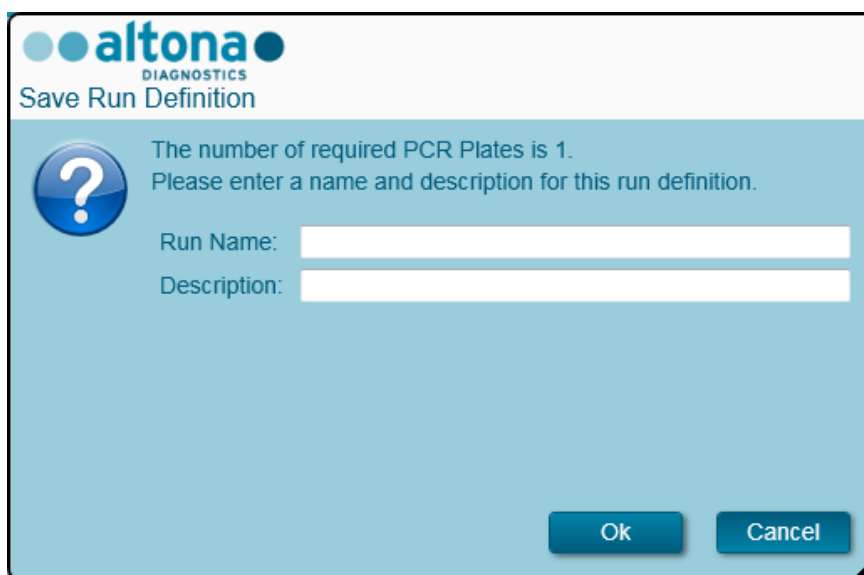


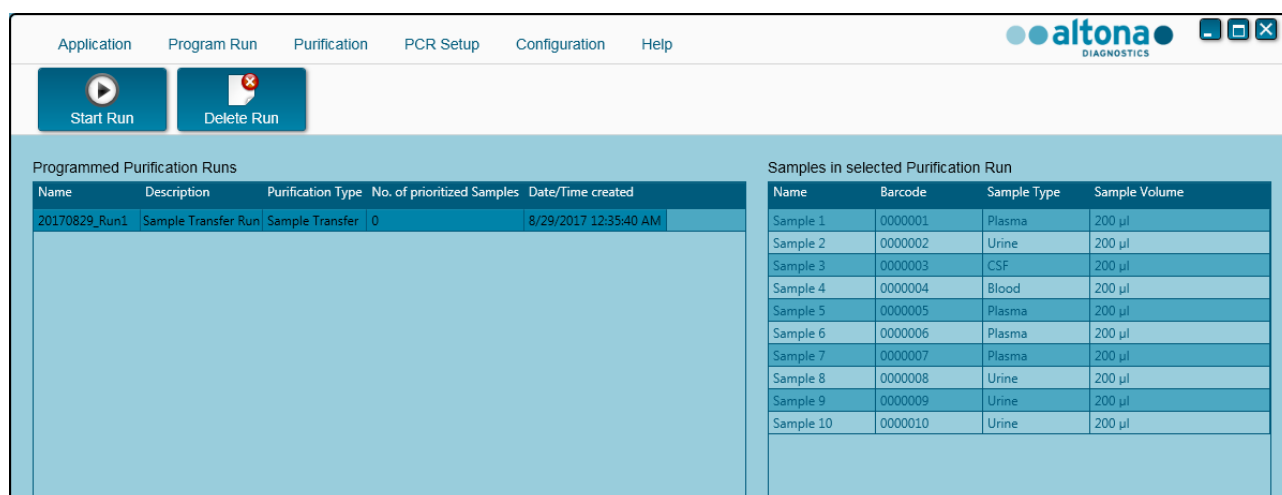
Fig. 48.: Save Run Definition Dialog

### 3.9.7 Sample Preparation

For preparation and pretreatment of samples, please refer to the [AltoStar® Purification Kit 1.5 Manual](#).

### 3.9.8 Starting a Sample Transfer Run

To start the sample transfer run, go back to the **Start Screen** of the AltoStar® Connect SW and select **Start Sample Transfer** or select **Purification** → **Start Sample Transfer** in the menu bar. The programmed purification runs are displayed in the **Programmed Purification Runs** table on the left side of the screen.



**Fig. 49.: Start Sample Transfer Run Screen**






- Select the purification run definition to be started in the **Programmed Purification Runs** table.
- The samples included in the selected run definition are displayed in the **Samples in selected Purification Run** table on the right side of the screen.
- Click the **Start Run** button in the tool bar.

Click **Delete Run** to completely delete the selected programmed purification run. By clicking **Delete Run**, all associated programmed PCR Setup runs will also be deleted.

### 3.9.9 Instrument Loading for a Sample Transfer Run

At the start of a run the **Loading** dialog is displayed (see [Fig. 50.: Loading Dialog for Sample Transfer Run](#)). The material, reagents and samples have to be loaded onto suitable carriers, before these carriers can then be loaded onto the respective tracks on the Loading Tray of the instrument:

**Table 3: List and Description of Carriers for Sample Transfer Run**

Carrier No.	Track	Material	Carrier Name	Image	Notes
1	1 - 6	5 racks of 1000 µl tips	Tip Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
2	7 - 12	3 racks of 300 µl tips 1 Elution Plate	Tip and Plate Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
					Always place plates with well A1 to the left of the respective plate position.
					The plate position at the front is not used in Sample Transfer runs.
6 - 11	18 - 23	Up to 96 samples on any combination of these two carrier types	Tube Carrier 24		Up to 24 sample tubes of 14.5 mm - 18 mm diameter per carrier.
					The position of the individual tubes on the carriers is arbitrary.
					Ensure all tube barcodes are visible through the carrier windows.
			Tube Carrier 32		Up to 32 sample tubes of 11 mm - 14 mm diameter per carrier.
					The position of the individual tubes on the carriers is arbitrary.
					Ensure all tube barcodes are visible through the carrier windows.
12	24 - 30	1 Processing Plate	Heater Shaker Carrier		This carrier is not removable and is therefore not loaded by the Autoload. The items are placed by hand onto the carrier in the instrument.
					Ensure the plate is seated correctly in its position.



**ATTENTION**

Remove the lids of all tubes before loading the carriers onto the Loading Tray. Leaving them on may lead to false results, aborted runs and damage to the instrument. Store the lids in a clean space to avoid contamination. Reuse the lids to close the tubes after the run.



**NOTE**

Before loading carriers on the Loading Tray:

- Ensure that no carriers are loaded on the deck inside the instrument.
- Ensure that the barcode on each carrier is toward the rear facing right (toward the barcode reader on the Autoload).



**Fig. 50.: Loading Dialog for Sample Transfer Run**

The **Loading** dialog consists of a visual representation of the instrument deck at the top half and a table specifying all items to be loaded in the bottom half.

Begin by selecting the lines of the table by clicking them one by one, starting at the top.

The position of the material currently selected in the **Loading** dialog table is further visualized:

- In red in the image at the top.
- By flashing Loading Lights of the instrument above the tracks where the carrier holding the respective items must be placed.

Follow the instructions in the **Comment** column carefully.

To load the carriers, insert them into the 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. Do not push the carriers past the stop hooks.



#### ATTENTION

*To prevent damage to the carriers and decrease the risk of contamination, extend the safety guards whenever carriers are loaded on the Loading Tray.*



#### ATTENTION

*Do not move or remove individual tips on a Tip Rack as this will interfere with the tip counter of the software. In case the tip positions were modified by the user, the tip counters for the 1000 µl tips and the 300 µl tips can be reset by checking the respective check boxes at the bottom of the Loading Dialog. In this case, all tip positions on carriers 1 and 2 have to be filled completely. The user has to confirm that all Tip Racks are completely filled in the subsequent Reset Tip Counters dialog.*



#### ATTENTION

*When handling patient samples, wear personal protective apparel, including disposable gloves, to avoid infection. Wash hands thoroughly after removing gloves, and dispose of gloves as biohazardous waste.*



#### NOTE

*Do not exchange positions of any loaded material after it has been drawn into the instrument by the Autoload, as this could result in incorrect test results, aborting the run and damage to the instrument.*



#### NOTE

*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.*

The instrument loads the carriers with the Autoload and automatically verifies:

- Correct identity and localization of the loaded carriers
- Correct identity of the items loaded on the carriers
- Positions of the items loaded on the carriers
- Singularity of sample barcodes
- Correct positioning of the plate 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, see [Chapter 4 Troubleshooting and Error Messages](#).

When all checks have passed, the **Loading Complete** dialog is displayed. Confirm the **Loading Complete** message by clicking **OK** or wait 10 seconds.



**Fig. 51.: Loading Complete Dialog**

The system now performs the sample transfer automatically. No further user interaction is required until the run has finished. If you click **Cancel**, the run will abort. When canceling the run up to this time, it can be started again later.



#### **ATTENTION**

Do not push or pull carriers or the instrument door during a run as this may abort the run.



#### **NOTE**

*Aborting the run after the **Loading Complete** dialog is closed will void the run definition, preventing a restart.*

**NOTE**

*The sample volume is not checked by the system prior to the sample transfer. Short samples will be error flagged during the sample transfer step and will not be processed further.*

**3.9.10 During the Sample Transfer Run**

The sample transfer run will be conducted without user intervention after starting.

**3.9.11 Forced Abort**

The run can be aborted by clicking the **Abort run** button in the tool bar and confirming to abort the run in the subsequent **Abort Run** dialog.

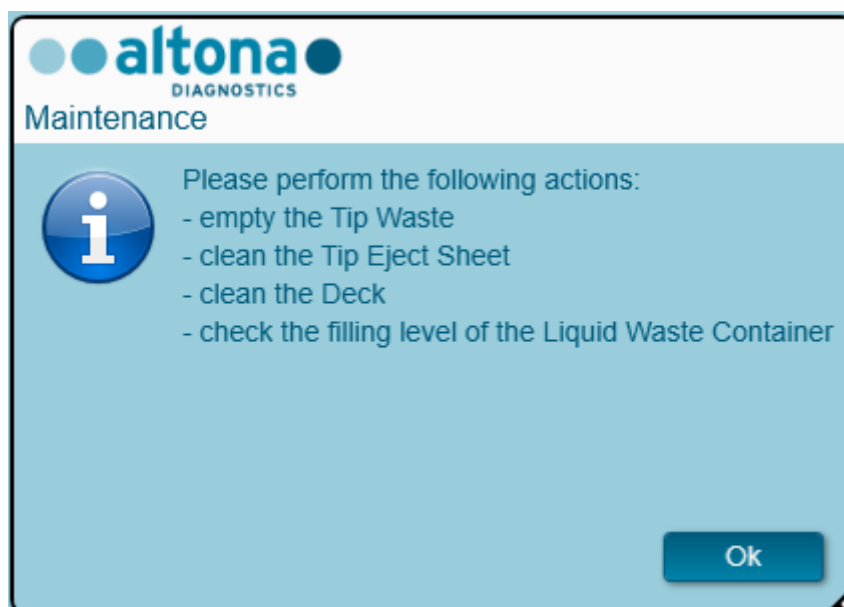
**ATTENTION**

*Once aborted, a run cannot be restarted. All data and used reagents will be lost and the run will be error flagged.*

**3.9.12 End of the Sample Transfer Run**

At the end of the run, the **Run Finished** dialog is displayed. Make sure the Loading Tray is empty and confirm the **Run Finished** dialog by clicking **OK**. The instrument will unload the carriers. Make sure not to stand in the way of the unloading carriers.

After unloading, the **Maintenance** dialog is displayed (see [Fig. 52.: Maintenance Dialog After Finished Run](#)). Follow the instructions of the **Maintenance** dialog.



**Fig. 52.: Maintenance Dialog After Finished Run**

Confirm the **Maintenance** dialog by clicking **Ok**.



### 3.9.13 Sample Transfer Results

The sample transfer run results are saved in the AltoStar® Connect SW. To access the results screen (see [Fig. 53.: Results Screen](#)) click **Purification** → **Purification Results** in the menu bar.

Name	Barcode	Sample Volume	Well	Eluate Plate Barcode	Protocol Name	Eluate Volume [µl]	Remaining Eluate [µl]	Status
Sample1	00000001	200 µl	A1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample2	00000002	200 µl	B1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample3	00000003	200 µl	C1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample4	00000004	200 µl	D1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample5	00000005	200 µl	E1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample6	00000006	200 µl	F1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample7	00000007	200 µl	G1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample8	00000008	200 µl	H1	Barcode04	TransferPlasma200v1	40	30	Processed
Sample9	00000009	200 µl	A2	Barcode04	TransferPlasma200v1	40	30	Processed
Sample10	00000010	200 µl	B2	Barcode04	TransferPlasma200v1	40	30	Processed

**Fig. 53.: Results Screen**

The results screen displays the results of the latest purification or sample transfer run. To view the results of prior runs, click the **Load** button in the menu bar, select the desired run from the list in the opening **Load Results** dialog and click **OK**.

In the **Load Results** dialog the list of prior runs can be filtered by entering the barcode of the respective Eluate Plate into the **Filter Eluate Plate barcode** field.

At the end of a sample transfer run two files are automatically generated by the AltoStar® Connect SW:

- An xml file to pass detailed information about the sample transfer run back to the LIMS.
- A pdf report containing detailed information about the sample transfer run for documentation purposes.

These files are stored at the location specified in the System Settings (see [Chapter 3.3.8.1 Default Path of Purification Report \(pdf\)](#) and [Chapter 3.3.8.2 Default Path of Purification LIMS File \(xml\)](#) ).

If necessary, these files can be generated again by loading the respective run and clicking the **Create LIMS File** button to generate the XML file or the **Create Report** button to generate the PDF report.

A Sample Transfer run that was aborted during processing can be restored in order to restart it. To restore the run presently loaded in the Results Screen, click the **Repeat Run** button in the toolbar. The restored run can then be started as described in [Chapter 3.9.8 Starting a Sample Transfer Run](#).

**ATTENTION**

*If repeating a run the sample volumes might be insufficient.*

### 3.10 External Purification Workflow: Purification

The AltoStar® Connect SW facilitates the processing of the External Purification Workflow on the AltoStar® AM16 instrument. The workflow consists of the following sequential phases:

1. Programming of the complete workflow process for a fixed set of purified samples in the AltoStar® Connect SW.
2. Sample Purification on an external instrument.
3. PCR setup on the AltoStar® AM16 as programmed in step 1. (see [Chapter 3.11 PCR Setup](#)).
4. PCR on a CFX96™ DW as programmed in step 1. (refer to respective [Altona Diagnostics PCR Kit Manual](#)).

**NOTE**

*The programming for the complete workflow process is concluded in phase 1. No alterations to the programmed process are possible in later phases of the workflow.*

**NOTE**

*Before starting the workflow, ensure that all required material and devices are available*

**NOTE**

*Before starting the workflow, ensure that the Daily and Weekly Maintenance have been conducted and that the semi-annual maintenance and verification procedure is not overdue. Otherwise, the instrument will not process any samples or reagents. It is recommended to conduct the Daily Maintenance when the device is turned on the first time each day and to conduct the Weekly Maintenance at the end of the week before shut-down of the system. The maintenance routine verifies the correct functionality of the instrument and will prompt all necessary user actions including cleaning of the instrument.*

#### 3.10.1 Overview of the External Purification

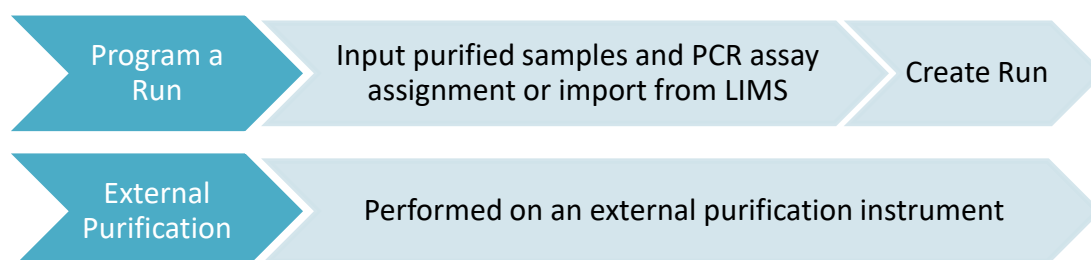


Fig. 54.: Overview of the External Purification

### 3.10.2 Programming a Run

#### 3.10.2.1 Manual Programming

1. Click the **Program Run** button of the External Purification Workflow in the start screen or click **Program Run** → **Program Run (External Purification)** in the menu bar.
2. Press the **Add Samples** button to add samples manually. The **Add Samples** dialog will appear (see [Fig. 55.: Add Samples Dialog](#)).

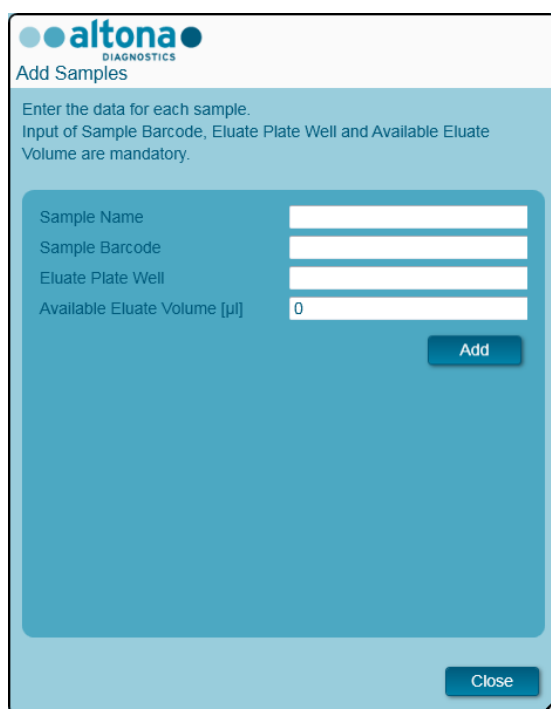


Fig. 55.: Add Samples Dialog

3. Optionally, a sample name can be entered in the **Sample Name** field.
4. Enter a barcode via the keyboard or use the handheld barcode scanner in the **Sample Barcode** field. A unique barcode for each sample is required.
5. In the **Eluate Plate Well** field, specify the well of the eluate plate of the external purification instrument that holds the respective sample in the form of A1-H12.
6. In the **Available Eluate Volume [µl]** field, specify the volume of eluate that is actually present in the respective well. The dead volume of the well will be automatically subtracted.
7. Click the **Add** button to add the sample to the list.
8. More samples can be generated by repeating steps 3. – 7. or the **Add Samples** dialog can be closed by clicking the **Close** button. The samples will now show up in the Sample List of the software.

### 3.10.3 Sample List

Wells used: 10

Process Sample	Sample Name	Sample Barcode	Sample Priority	Eluate Plate Well	Eluate available [µl]	Eluate left	Programming	Programming
<input checked="" type="checkbox"/>	Purified Sample 1	0000001	<input type="checkbox"/>	A1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 2	0000002	<input type="checkbox"/>	B1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 3	0000003	<input type="checkbox"/>	C1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 4	0000004	<input type="checkbox"/>	D1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 5	0000005	<input type="checkbox"/>	E1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 6	0000006	<input type="checkbox"/>	F1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 7	0000007	<input type="checkbox"/>	G1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 8	0000008	<input type="checkbox"/>	H1	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 9	0000009	<input type="checkbox"/>	A2	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 10	0000010	<input type="checkbox"/>	B2	50	40 µl		

**Fig. 56.: Programming Screen**

The samples are listed in the left bottom area of the programming screen with their programmed properties.

- **Process Sample:** The check mark indicates that the respective sample will be included in the run definition generated next. Deselect the checkbox for a sample that should not be included in the next run definition. When more than 96 samples are selected, the run cannot be created. Deselect excess samples to create the run definition with up to 96 samples. Afterwards, reselect the deselected samples for the creation of the subsequent run definition.
- **Sample Name:** shows the name of the sample
- **Sample Barcode:** shows the barcode of the sample

- **Sample Priority:** Samples can be prioritized by checking the respective checkbox. All prioritized samples will be sorted to one PCR plate if possible to facilitate fastest processing.
- **Eluate Plate Well:** The well of the external purification eluate plate populated by the respective sample.
- **Eluate available:** The volume of eluate in the respective well.
- **Eluate left:** The eluate volume that is available to be allotted to assays (see [Chapter 3.10.4 Assigning PCR Assays to a Sample](#)). The volume is automatically adjusted every time assays are added or removed for this sample.

**ATTENTION**


*Ensure that all sample properties are correct.*

**NOTE**

*All sample properties, except Eluate left, can be corrected by manual input after clicking the respective field.*

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.

One or several samples can be removed from the list by selecting them and clicking the **Delete** button in the tool bar.

Samples that have been transferred to an External Purification workflow run definition disappear from the sample list.

### 3.10.4 Assigning PCR Assays to a Sample

Each sample can be run with as many PCR assays as the available eluate allows. The available assays are displayed on the right side of the programming screen.

Wells used: 10

Process Sample	Sample Name	Sample Barcode	Sample Priority	Eluate Plate Well	Eluate available [µl]	Eluate left	Programming	Programming
<input checked="" type="checkbox"/>	Purified Sample 1	0000001	<input type="checkbox"/>	A1	50	30 µl	quantitative	
<input checked="" type="checkbox"/>	Purified Sample 2	0000002	<input type="checkbox"/>	B1	50	30 µl	quantitative	
<input checked="" type="checkbox"/>	Purified Sample 3	0000003	<input type="checkbox"/>	C1	50	30 µl	quantitative	
<input checked="" type="checkbox"/>	Purified Sample 4	0000004	<input type="checkbox"/>	D1	50	30 µl		qualitative
<input checked="" type="checkbox"/>	Purified Sample 5	0000005	<input type="checkbox"/>	E1	50	30 µl		qualitative
<input checked="" type="checkbox"/>	Purified Sample 6	0000006	<input type="checkbox"/>	F1	50	40 µl	quantitative	
<input checked="" type="checkbox"/>	Purified Sample 7	0000007	<input type="checkbox"/>	G1	50	40 µl	quantitative	
<input checked="" type="checkbox"/>	Purified Sample 8	0000008	<input type="checkbox"/>	H1	50	40 µl	qualitative	
<input checked="" type="checkbox"/>	Purified Sample 9	0000009	<input type="checkbox"/>	A2	50	40 µl		
<input checked="" type="checkbox"/>	Purified Sample 10	0000010	<input type="checkbox"/>	B2	50	40 µl		

Fig. 57.:Assigning PCR Assays

To select an assay for specific samples:

1. Click the cell corresponding to the respective sample and the respective assay.
2. Select the analysis type in the appearing select box. The correct set of **Standards and Controls** is automatically selected depending on the analysis type.



**NOTE**

*If it is not possible to select a PCR assay, check whether enough eluate is left to perform this PCR assay.*

### 3.10.5 Importing from LIMS

Both the sample information 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 LIMS file (.psv) that contains the required information.

For information regarding the LIMS integration, contact altona Diagnostics GmbH.

### 3.10.6 Creating a Run

After all samples are added and the assays are programmed, you can create a run definition.

1. Click the **Create Run** button. The **Save Run Definition** dialog is displayed.
2. Enter a unique **Run Name** and optionally a **Description** for identification of the run later on.
3. Enter the barcode of the external purification instrument's eluate plate in the **Barcode Eluate Plate** field.
4. Click the **Ok** button to save the run definition.

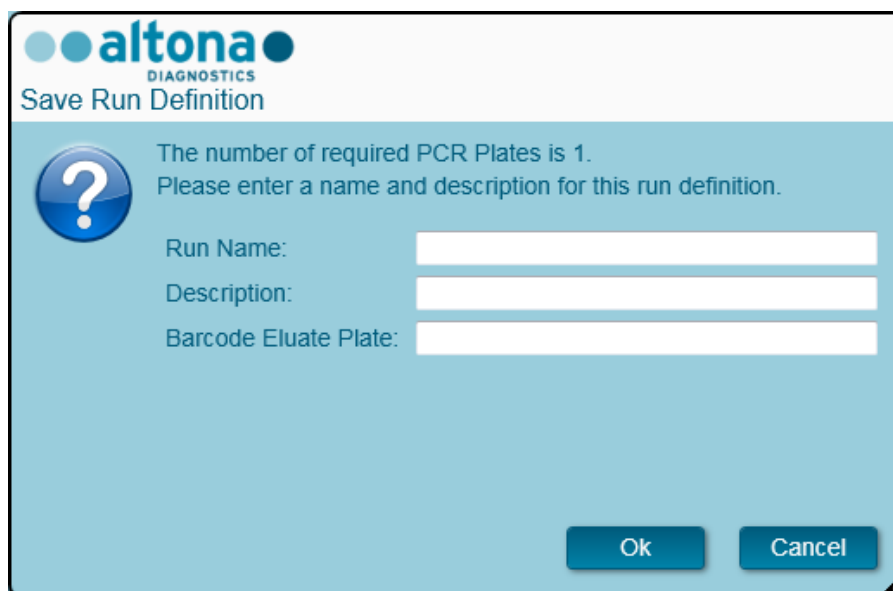


Fig. 58.: Save Run Definition Dialog

### 3.10.7 Sample Preparation

For preparation and pretreatment of samples, please refer to the manual of the external purification system.

### 3.10.8 Starting an external Purification Run

The purification of the External Purification workflow is performed outside of the AltoStar® system. Refer to the external purification system manual for information.

## 3.11 PCR Setup

The PCR setup process is the same irrespective of the purification workflow chosen for the samples (AltoStar® workflow, Sample Transfer workflow or External Purification workflow).

### 3.11.1 Preparing Reagents for a PCR Setup Run

All reagents should be thawed completely, mixed (by pipetting or gentle vortexing) and centrifuged briefly before use. For detailed information, refer to the [respective altona Diagnostics PCR Kit Manual](#).

All reagent tubes are barcoded for automated identification, localization and verification of lot congruence and non-expiry by the AltoStar® system.

**ATTENTION**

*Always wear protective disposable powder-free gloves when handling kit components.*

**ATTENTION**

*Do not manually transfer any liquids.*

**NOTE**

*Ensure that all components of the altona Diagnostics PCR Kit are from the same lot. The software verifies lot congruence during loading and instructs the user accordingly.*

**NOTE**

*Ensure that the altona Diagnostics PCR Kit reagents are not expired. The software verifies use within the shelf life of the reagents during loading and instructs the user accordingly.*

**NOTE**

*Required components of the altona Diagnostics PCR Kit for a given run can be previewed in the AltoStar® Connect SW (see [Chapter 3.11.2 Starting a PCR Setup Run](#)). This allows for preparation of the required components during the preceding purification run.*

**NOTE**

*The subsequent PCR run must be started within 30 minutes after the completion of the PCR Setup.*

Before starting the PCR Setup run, ensure that the material required for the subsequent PCR run will be available and ready to use at the end of the PCR Setup run to avoid prolonged storage of the completed PCR plate:

- PCR Plate Sealing Foil
- Heat Sealer
- CFX96™ DW Cycler



### 3.11.2 Starting a PCR Setup Run

The PCR Setup can be started as soon as the associated purification run is complete. How to program a run and start a purification run is explained in [Chapter 3.8.2 Programming a Run](#), [Chapter 3.8.9 Starting a Purification Run](#) as well as [Chapter 3.9.2 Programming a Run](#) and [Chapter 3.9.8 Starting a Sample Transfer Run](#). To start the PCR setup run, go back to the **Start Screen** of the AltoStar® Connect SW and select **Start PCR Setup** or select **PCR** → **Start PCR Setup** in the menu bar. The programmed PCR setup run definitions are displayed in the **Programmed PCR Setup Runs** table on the left side of the screen.

PCR Plate Number	Eluate Plate	Name	Description	Purification Status	Purification Type	Date/Time created
1	Barcode04	20170824_Run1	Run programmed by Labadmin	Processed	AltoStar Purification	8/24/2017 3:31:06 PM
1		20170824_Run2	Run programmed by Laboperator	Ready to start	AltoStar Purification	8/24/2017 3:31:45 PM
1		20170824_Run3	Run programmed by Labadmin	Ready to start	AltoStar Purification	8/24/2017 3:35:02 PM

Name	Barcode	Assay	Application	Status
Sample 1	0000001	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 2	0000002	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 3	0000003	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 4	0000004	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 5	0000005	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 6	0000006	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 7	0000007	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 8	0000008	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 9	0000009	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start
Sample 10	0000010	AltoStar CMV PCR Kit 1.5	quantitative	Ready to start

Name	Assay
QC1	AltoStar CMV PCR Kit 1.5
QC2	AltoStar CMV PCR Kit 1.5
QC3	AltoStar CMV PCR Kit 1.5
QC4	AltoStar CMV PCR Kit 1.5

Name	Assay	Needed tubes	Needed volume in each tube
CMV Master A	AltoStar CMV PCR Kit 1.5	2	New tube
CMV Master B	AltoStar CMV PCR Kit 1.5	2	New tube

Fig. 59.: Start Screen for PCR Setup

- Select the PCR setup run definition to be started in the **Programmed PCR Setup Runs** table
- The samples included in the selected run definition are displayed in the **Samples in selected PCR Setup Run** table on the top right side of the screen.
- The controls included in the selected run definition are displayed in the **Controls in selected PCR Setup Run** table on the middle right side of the screen.
- The number of master reagent tubes required for the selected run definition is displayed in the **Required master tubes for the selected PCR Setup Run** table on the bottom right side of the screen.
- Click the **Start Run** button in the tool bar to start the selected PCR setup run definition.
- Click **Delete Run** to completely delete the selected programmed PCR Setup run.



#### NOTE

The PCR setup run definitions can be accessed any time after programming, including during an ongoing purification or PCR setup run. This way the required reagents for an upcoming PCR setup run can be previewed and prepared in advance so that a PCR setup run can be started right after the end of the ongoing run.




**NOTE**


If the **Start Run** button is inactive, the purification leading up to the currently selected PCR setup run definition has not been completed. Refer to column **Purification Status** in the **Programmed PCR Setup Runs** table for information.

### 3.11.3 Instrument Loading for the PCR Setup Run

At the start of a run, the **Loading** dialog is displayed (see [Fig. 60.: Loading Dialog for PCR Setup Run](#)). The material, reagents and samples have to be loaded onto suitable carriers, before these carriers can then be loaded onto the respective tracks on the Loading Tray of the instrument:

**Table 4: Description of Carriers for a PCR Setup Run**

Carrier No.	Track	Material	Carrier Name	Image	Notes
1	1 - 6	5 racks of 1000 µl tips	Tip Carrier		Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
					Only exchange completely empty Tip Racks for completely full ones. Do not handle individual tips.
2	7 - 12	3 racks of 300 µl tips 1 Elution Plate 1 PCR Plate	Tip and Plate Carrier		Always place plates with well A1 to the left of the respective plate position.
					The PCR plate is placed at the front most position, the Eluate Plate at the second front most position of this carrier.
3	13	One Pooling Tube per assay	Tube Carrier 24		One carrier can be loaded.
					The position of the individual tubes on the carrier is arbitrary.
4 - 7	14 - 17	Master tubes and	Reagent Tube		Gently push the tubes down all the way to the bottom of the carrier.
					The position of the individual tubes on the carrier is arbitrary.

Carrier No.	Track	Material	Carrier Name	Image	Notes
		standard/control tubes of the assays	Carrier 32		<p>Ensure all tube barcodes are visible through the carrier windows.</p> <p>Gently push the tubes down all the way to the bottom of the carrier.</p>



**ATTENTION**

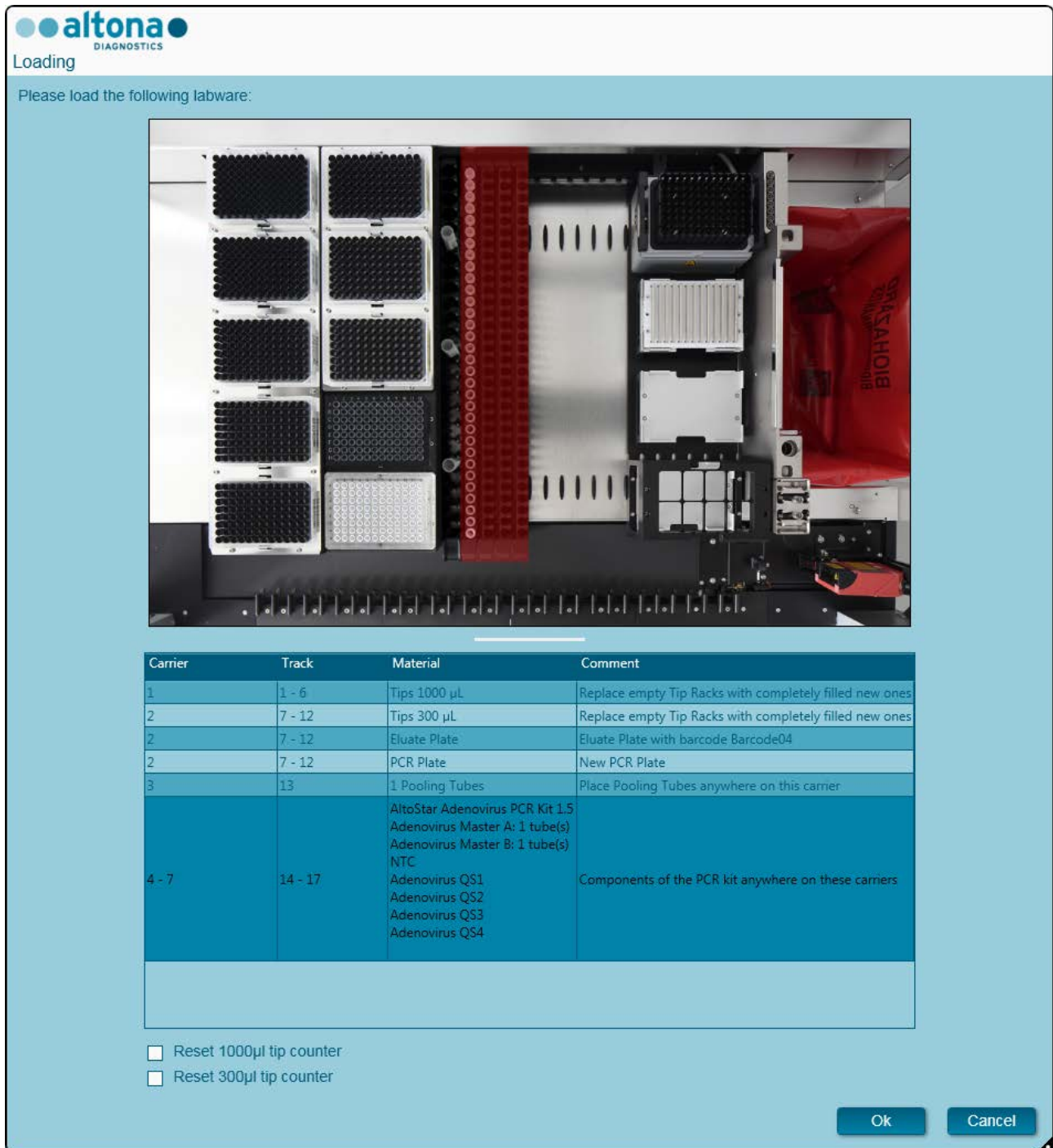
*Remove the lids of all tubes before loading the carriers onto the Loading Tray. Dispose of all lids. To close tubes after the run use new lids.*



**NOTE**

*Before loading carriers on the Loading Tray:*

- *Ensure that no carriers are loaded on the deck inside the instrument.*
- *Ensure that the barcode on each carrier is toward the rear facing right (toward the barcode reader on the Autoload).*



**Fig. 60.: Loading Dialog for a PCR Setup Run**

The **Loading** dialog consists of a visual representation of the instrument deck at the top half and a table specifying all items to be loaded in the bottom half.

Begin by selecting the lines of the table by clicking them one by one, starting at the top.

The position of the material currently selected in the **Loading** dialog table is further visualized:

- In red in the image at the top.
- By flashing Loading Lights of the instrument above the tracks where the carrier holding the respective items must be placed.

Follow the instructions in the **Comment** column carefully.

To load the carriers, insert them into the 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. Do not push the carriers past the stop hooks.

**ATTENTION**

*Always wear protective disposable powder-free gloves when handling kit components.*

**ATTENTION**

*To prevent damage to the carriers and decrease the risk of contamination, extend the safety guards whenever carriers are loaded onto the Loading Tray.*

**ATTENTION**

*Do not move or remove individual tips on a Tip Rack as this will interfere with the tip counter of the software. In case the tip positions were modified by the user, the tip counters for the 1000 µl tips and the 300 µl tips can be reset by checking the respective check boxes at the bottom of the **Loading Dialog**. In this case, all tip positions on carriers 1 and 2 have to be filled completely. The user has to confirm that all Tip Racks are completely filled in the subsequent **Reset Tip Counters** dialog.*

**NOTE**

*Do not exchange positions of any loaded material after it has been drawn into the instrument by the Autoload, as this could result in incorrect test results, aborting the run and damage to the instrument.*

**NOTE**

*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.*

After all carriers are loaded on the correct tracks of the Loading Tray, click **OK** in the **Loading Dialog**. By clicking **Cancel**, the run will be cancelled, but it can be started again.

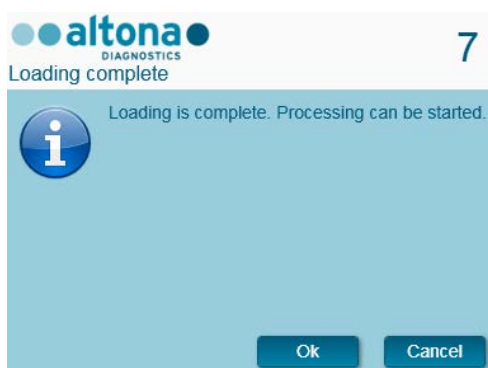
The instrument loads the carriers with the Autoload and automatically verifies:

- Correct identity and localization of the loaded carriers
- Correct identity of the items loaded on the carriers
- Positions of the items loaded on the carriers
- Lot congruence of the reagents from the individual kits

- Non-expiry of all loaded reagents
- Correct positioning of the Tip Eject Sheet

If any of these checks fail, the user is prompted with a message dialog specifying the problem and instructions to correct the issue accordingly. For further information regarding error handling, see [Chapter 4 Troubleshooting and Error Messages](#).

When all checks have passed, the **Loading Complete** dialog is displayed. Confirm the **Loading Complete** message by clicking **OK** or wait 10 seconds.



**Fig. 61.: Loading Complete Dialog**

The system now performs the PCR setup automatically. No further user interaction is required until the run has finished. If you click **Cancel**, the run will abort. When canceling the run up to this time, it can be started again later.



#### **ATTENTION**

*Do not push or pull carriers or the instrument door during a purification run as this may abort the run.*



#### **NOTE**

*Aborting the run after the **Loading Complete** dialog is confirmed will void the run definition, preventing a restart.*



#### **NOTE**

*The volumes of the loaded reagents are not checked during loading. Make sure to only load unused Master reagent tubes. The tubes containing the controls and quantification standards contain sufficient volumes for four runs. Do not use the controls and quantification standard tubes for more than four runs.*

### **3.11.4 During the PCR Setup Run**

The PCR setup run will be conducted without user intervention after starting.

### 3.11.5 Forced Abort

The run can be aborted by clicking the **Abort run** button in the tool bar and confirming to abort the run in the subsequent **Abort Run** dialog.

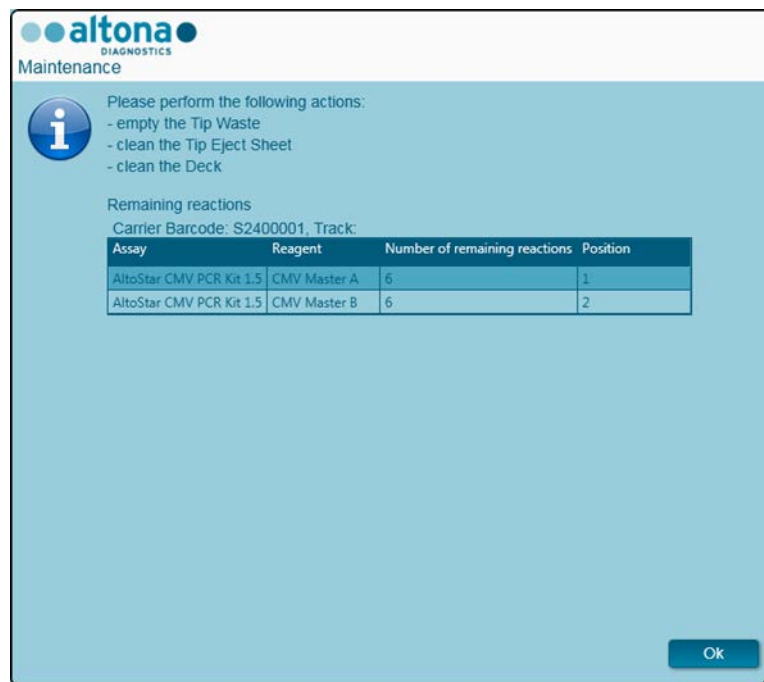


#### ATTENTION

*Once aborted, a run cannot be restarted. All data and used reagents will be lost and the run will be error flagged.*

### 3.11.6 End of the PCR Setup Run

At the end of the run, the **Run Finished** dialog is displayed. Make sure the Loading Tray is empty and confirm the **Run Finished** dialog by clicking **OK**. The instrument will unload the carriers. Make sure not to stand in the way of the unloading carriers. After unloading, the **Maintenance** dialog is displayed (see [Fig. 62.: Maintenance After Run Dialog](#)).



**Fig. 62.: Maintenance After Run Dialog**

Follow the instructions of the **Maintenance** dialog and then confirm by clicking **Ok**.

### 3.11.7 PCR Setup Results

The PCR setup run results are saved in the AltoStar® Connect SW. To access the results screen (see [Fig. 63.: PCR Setup Results Screen](#)), click **PCR Setup** → **PCR Setup Results** in the menu bar.



Name	Barcode Sample	Application	PCR Plate Well	PCR Plate Barcode	Assay Name	Cyclor Protocol	Volume Sample [µl]	Volume Master [µl]	Status
Sample1	00000001	quantitative	F1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample2	00000002	quantitative	G1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample3	00000003	quantitative	H1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample6	00000006	quantitative	A2	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample7	00000007	quantitative	B2	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample8	00000008	quantitative	C2	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample9	00000009	quantitative	D2	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample10	00000010	quantitative	E2	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Sample4	00000004	qualitative	B3	Barcode05	AltoStar alpha Herpesvirus PCR Kit 1.5	1	10	20	Processed
Sample5	00000005	qualitative	C3	Barcode05	AltoStar alpha Herpesvirus PCR Kit 1.5	1	10	20	Processed

Name	Barcode Control	PCR Plate Well	PCR Plate Barcode	Assay Name	Cyclor Protocol	Volume Sample [µl]	Volume Master [µl]	Status
NTC	1012012349912	A1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Adenovirus QS1	1010312349912	B1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Adenovirus QS2	1010412349912	C1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Adenovirus QS3	1010512349912	D1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
Adenovirus QS4	1010612349912	E1	Barcode05	AltoStar Adenovirus PCR Kit 1.5	1	10	20	Processed
NTC	1022012349912	F2	Barcode05	AltoStar alpha Herpesvirus PCR Kit 1.5	1	10	20	Processed
VZV PC	1021112349912	G2	Barcode05	AltoStar alpha Herpesvirus PCR Kit 1.5	1	10	20	Processed
HSV-2 PC	1021212349912	H2	Barcode05	AltoStar alpha Herpesvirus PCR Kit 1.5	1	10	20	Processed
HSV-1 PC	1021312349912	A3	Barcode05	AltoStar alpha Herpesvirus PCR Kit 1.5	1	10	20	Processed

Fig. 63.: PCR Setup Results Screen

The results screen displays the results of the latest PCR setup run. To view the results of prior runs, click the **Load** button in the menu bar, select the desired run from the list in the opening **Load Results** dialog and click **OK**.

In the **Load Results** dialog, the list of prior runs can be filtered by entering the barcode of the respective Eluate Plate into the **Filter Eluate Plate barcode** field.

At the end of a PCR setup run, three files are automatically generated by the AltoStar® Connect SW:

- An xml file to pass detailed information about the purification run back to the LIMS.
- A pdf report containing detailed information about the PCR setup run for documentation purposes.
- A cyclor file to program the CFX96™ Deep Well IVD Real-Time PCR Detection System.

These files are stored at the location specified in the System Settings (see [Chapter 3.3.8.3 Default Path of PCR Setup Report \(pdf\)](#), [Chapter 3.3.8.4 Default Path of PCR Setup LIMS File \(xml\)](#), and [Chapter 3.3.8.6 Default Path of Cyclor File](#)).

If necessary, these files can be generated again by loading the respective run and clicking the **Create LIMS File** button to generate the XML file, the **Create Report** button to generate the PDF report or the **Create Bio-Rad Cyclor File** button to generate the cyclor file.

A PCR Setup run that was aborted during processing can be restored in order to restart it. To restore the run presently loaded in the PCR Setup Results Screen, click the **Repeat Run** button in the toolbar. The restored run can then be started as described in [Chapter 3.11.2 Starting a PCR Setup Run](#).



#### ATTENTION

*If repeating a run the eluate and reagent volumes might be insufficient.*



## 4 Troubleshooting and Error Messages

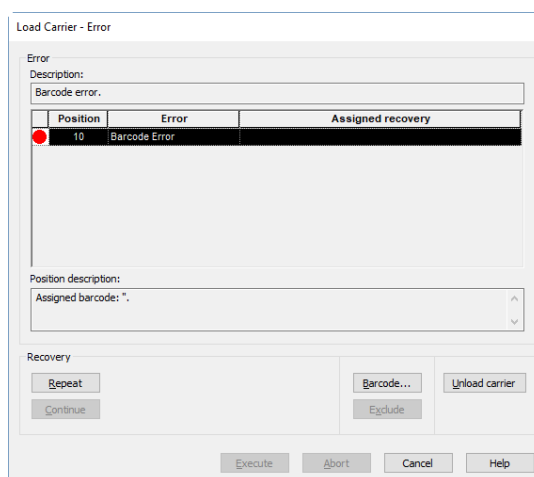
### 4.1 Error flags

During a purification or PCR Setup run, the status of each sample is displayed at the left of the screen in the **Status** column of the **Samples** table.

- If a sample cannot be processed due to physical or technical reasons, the status of the sample is set to **Error** in the **Status** columns of the **Samples** table as well as in the run reports.
- If a sample is set to **Error** during a purification run, this sample will not be processed in the subsequent PCR Setup and PCR.
- If a sample is set to **Error** during a PCR setup run, this sample will not be programmed in the subsequent PCR.

### 4.2 Barcode Reading Errors

If during loading one or more barcode labels cannot be read, the **Error** dialog box (see [Fig. 64.: Load Carrier – Error Dialog](#)) is displayed. The reason for this error may be poor-quality, damaged or missing barcode labels.



**Fig. 64.: Load Carrier - Error Dialog**

There are several options for handling barcode errors.

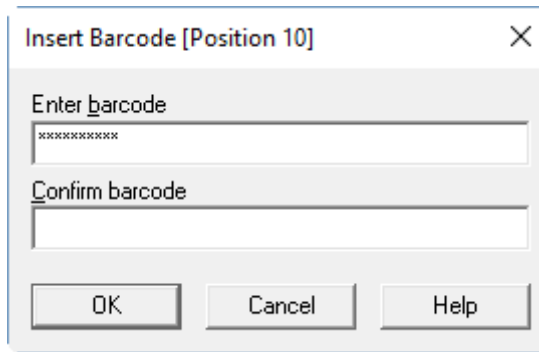
- If the item to be scanned is missing or the barcode is not facing towards the barcode reader, click **Unload carrier** and load the missing item or correctly orient the barcode. Click **Repeat** and then **Execute**.
- If the barcode is not read despite being present and correctly positioned, click **Repeat** and then **Execute**. The carrier will be unloaded and then loaded slower to facilitate barcode reading.
- If the barcode error persists, click **Unload carrier** and the carrier will be unloaded. Click **Barcode...** and type in the barcode twice (see [Fig. 65.: Enter Barcode Dialog](#)) or use the handheld barcode scanner. Make sure the item is in the correct position on the carrier.

Confirm with **OK**. Repeat until all error entries are resolved. Click **Execute** and the carrier will be loaded with the entered barcode at the corresponding positions.



**ATTENTION**

*Do not alter the positions of any item on the respective carrier during this process as this may lead to false results or aborted runs.*

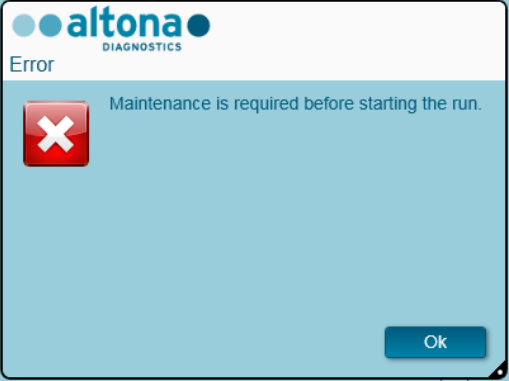
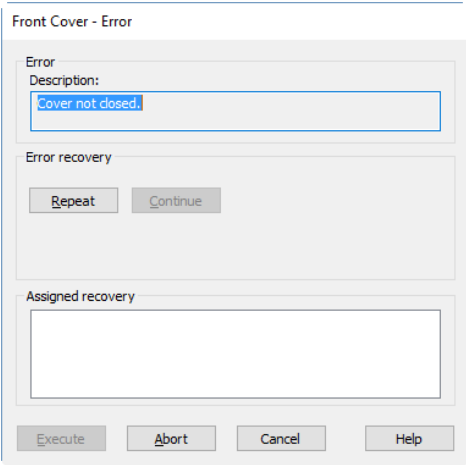
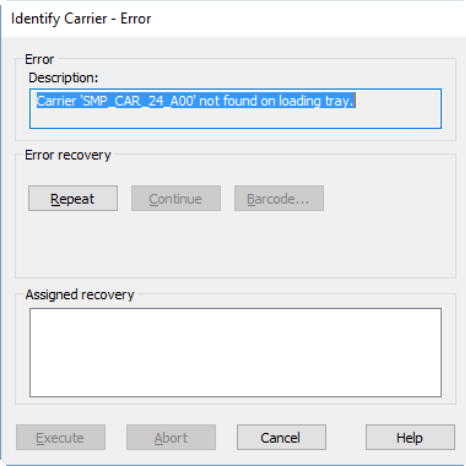
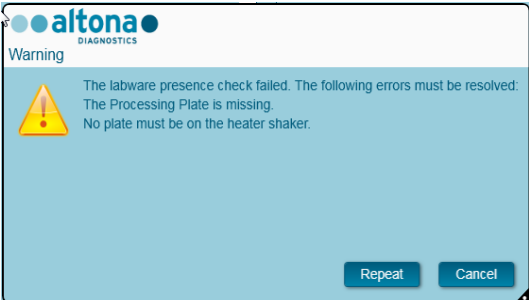


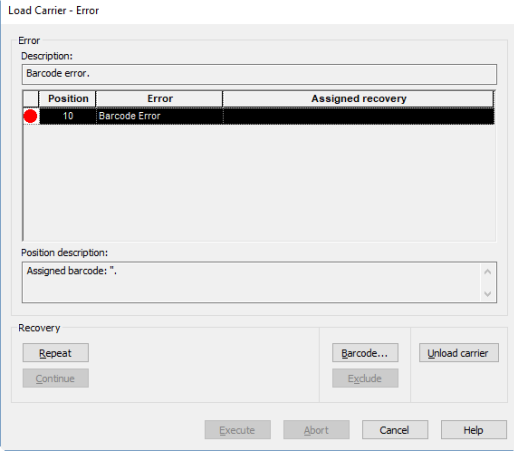
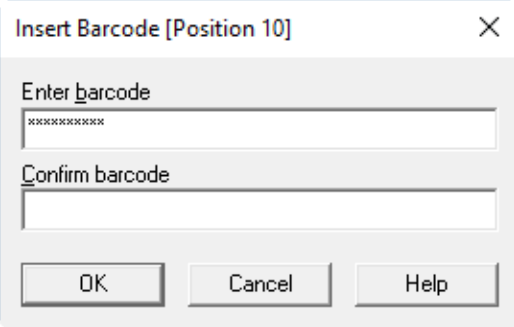
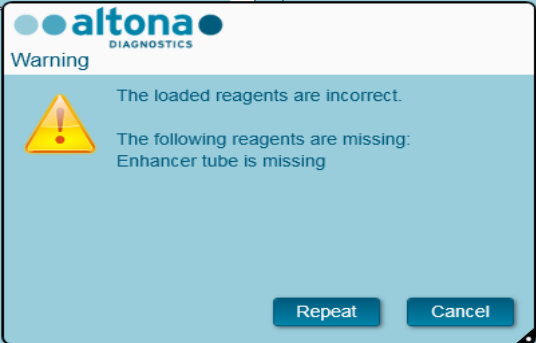
**Fig. 65.: Enter Barcode Dialog**

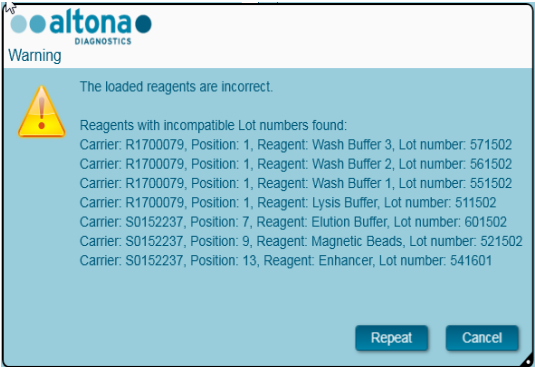
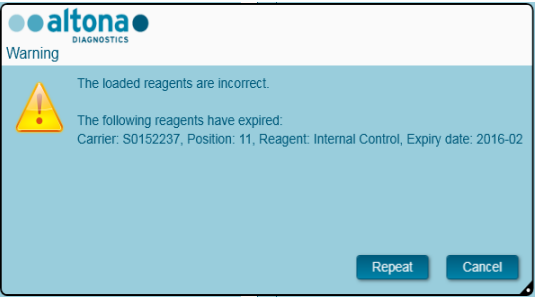
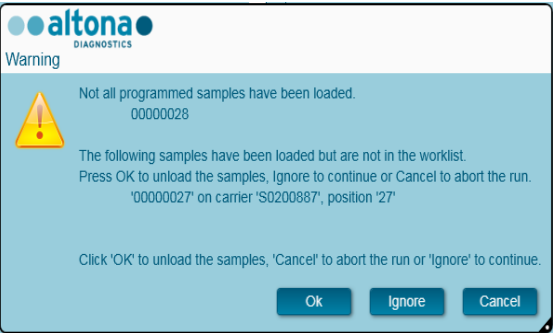
**4.3 Error Messages**


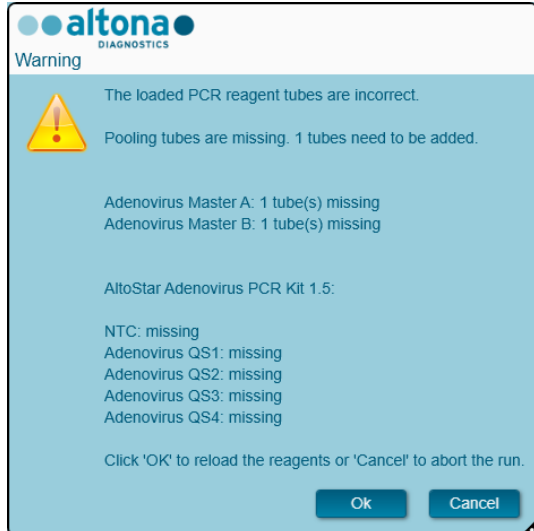
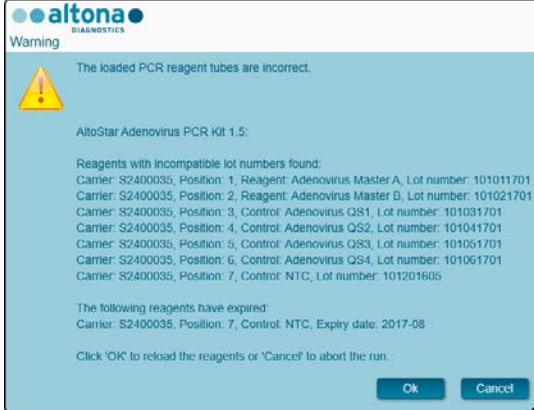
Most issues occurring during use of the system can be resolved by the user by acting upon the error prompts the software displays. For errors not listed below please contact the altona Diagnostics GmbH Technical Support.

Error Prompt	Message	Solution/To Do
	<p>There is no connection to the instrument.</p> <p>Please check the cable and plugs.</p>	<p>Please check if the instrument is turned on.</p> <p>Check the USB connection between the instrument and the computer.</p> <p>Click <b>Retry</b>.</p>
	<p>The maintenance data could not be loaded.</p> <p>An error occurred while running Vector.</p> <p>There is no connection to the instrument.</p> <p>Please check the cable and plugs.</p>	<p>The maintenance data could not be loaded because there is no connection to the instrument.</p> <p>Please check if the instrument is turned on.</p> <p>Check the USB connection between the instrument and the computer.</p> <p>Click <b>OK</b>.</p>

Error Prompt	Message	Solution/To Do
	<p>Maintenance is required before starting the run.</p>	<p>The maintenance is overdue. Perform the required maintenance procedure. Click <b>OK</b>.</p>
	<p>Front Cover – Error (e.g. Cover not closed.)</p>	<p>Please close the cover and click <b>Repeat</b>, then <b>Execute</b>.</p>
	<p>Identify Carrier – Error (e.g. Carrier 'Carriename' not found on loading tray.)</p>	<p>The wrong carrier or no carrier is on the track. Please check if the correct carrier was loaded onto the Loading Tray.  The carrier might not be at the stop position. Carefully push the carrier against the stop position on the Loading Tray.  Click <b>Repeat</b> and <b>Execute</b> after correction of the carrier position.</p>
	<p>The labware presence check failed. The following errors must be resolved:  (e.g. The Processing Plate is missing. No plate must be on the heater shaker.)</p>	<p>The manually placed items on the Heater Shaker Carrier are not placed correctly.  Please correct the positions of the items listed in the error message, then click <b>Repeat</b></p>

Error Prompt	Message	Solution/To Do
	<p>Loading Carrier – Error (e.g. Barcode error.)</p>	<p>The Barcode of one or several items cannot be read. The position of the item is listed.</p> <p>Click <b>Unload Carrier</b> and ensure that the barcode is in the correct position and visible.</p> <p>Push the carrier to the stop position on the Loading Tray and click <b>Repeat</b> and <b>Execute</b>.</p>
	<p>Barcode error.</p>	<p>If the barcode is not readable after repeating the step, click on one of the positions so that it is highlighted. Then click on "<b>Barcode...</b>" The <b>Insert Barcode</b> dialog is displayed.</p> <p>Enter the barcode twice manually or by the handheld scanner. Click <b>OK</b>.</p> <p>Repeat the procedure for other affected positions.</p> <p>Click <b>Execute</b>.</p>
	<p>The loaded reagents are incorrect.</p> <p>The following reagents are missing: (e.g. Enhancer tube is missing)</p>	<p>One or several reagent tube(s) or container(s) is (are) missing.</p> <p>Please add the listed reagent(s) and click <b>Repeat</b>.</p>

Error Prompt	Message	Solution/To Do
	<p>The loaded purification reagents are incorrect.</p> <p>Reagents with incompatible Lot numbers found: (e.g. <i>List of Reagents, Carriers, Positions</i>)</p>	<p>All reagents of the purification kit have to be from the same Lot. Look at the last four numbers of the lot number. These have to be the same for all mentioned reagents. In the displayed screenshot the enhancer on position 13 has a different number than the other reagents.</p> <p>Replace this tube with a tube of the same lot number as the other reagents.</p> <p>Click <b>Repeat</b>.</p>
	<p>The loaded reagents are incorrect.</p> <p>The following reagents have expired: (e.g. <i>List of Reagents, Carriers, Positions</i>)</p>	<p>One or several reagents are expired.</p> <p>Replace the listed reagent(s) with non-expired reagents of the compatible lot.</p> <p>Click <b>Repeat</b>.</p>
	<p>Not all programmed samples have been loaded: (<i>Sample Barcode</i>)</p> <p>The following samples have been loaded but are not in the worklist: (<i>Sample barcode, carrier and position</i>)</p>	<p>If a sample is not loaded which is in the worklist, or if there are samples which are not in the worklist, following options can be chosen:</p> <p><b>OK:</b> The carrier will be unloaded and the samples can be loaded correctly.</p> <p><b>Ignore:</b> The system will continue the run. Samples that were not programmed will be ignored. Missing samples will be passed back to the sample list in the programming screen to be included in a subsequent run.</p> <p><b>Cancel:</b> The run will be canceled and can be started again.</p>

Error Prompt	Message	Solution/To Do
 <p>Warning</p> <p>Not enough Lysis Buffer available.          Not enough Magnetic Beads available.          Not enough Internal Control available.          Not enough Enhancer available.          Not enough Wash Buffer 1 available.          Not enough Wash Buffer 2 available.          Not enough Wash Buffer 3 available.          Not enough Elution Buffer available.</p> <p>Repeat Cancel</p>	<p>Not enough (<i>reagent</i>) available.</p>	<p>The volume check detected shortage of one or several reagents.</p> <p>Please add a tube or container of the listed reagent(s) from the same lot.</p> <p>Click <b>Repeat</b>.</p>
 <p>Warning</p> <p>The loaded PCR reagent tubes are incorrect.          Pooling tubes are missing. 1 tubes need to be added.</p> <p>Adenovirus Master A: 1 tube(s) missing          Adenovirus Master B: 1 tube(s) missing</p> <p>AltoStar Adenovirus PCR Kit 1.5:</p> <p>NTC: missing          Adenovirus QS1: missing          Adenovirus QS2: missing          Adenovirus QS3: missing          Adenovirus QS4: missing</p> <p>Click 'OK' to reload the reagents or 'Cancel' to abort the run.</p> <p>OK Cancel</p>	<p>The loaded PCR reagent tubes are incorrect.</p> <p>Pooling tubes are missing: 1 tubes need to be added</p> <p>(<i>e.g. List of reagents: Number of tubes missing</i>)  <i>assay:</i>          (<i>e.g. List of missing standard/controls</i>)</p>	<p>One or several reagent tube(s) is (are) missing.</p> <p>Please add the listed tube(s) and click <b>OK</b></p>
 <p>Warning</p> <p>The loaded PCR reagent tubes are incorrect.</p> <p>AltoStar Adenovirus PCR Kit 1.5:</p> <p>Reagents with incompatible lot numbers found:          Carrier: S2400035, Position: 1, Reagent: Adenovirus Master A, Lot number: 101011701          Carrier: S2400035, Position: 2, Reagent: Adenovirus Master B, Lot number: 101021701          Carrier: S2400035, Position: 3, Control: Adenovirus QS1, Lot number: 101031701          Carrier: S2400035, Position: 4, Control: Adenovirus QS2, Lot number: 101041701          Carrier: S2400035, Position: 5, Control: Adenovirus QS3, Lot number: 101051701          Carrier: S2400035, Position: 6, Control: Adenovirus QS4, Lot number: 101061701          Carrier: S2400035, Position: 7, Control: NTC, Lot number: 101201605</p> <p>The following reagents have expired:          Carrier: S2400035, Position: 7, Control: NTC, Expiry date: 2017-08</p> <p>Click 'OK' to reload the reagents or 'Cancel' to abort the run.</p> <p>OK Cancel</p>	<p>The loaded PCR reagent tubes are incorrect.</p> <p><i>assay:</i></p> <p>Reagents with incompatible lot numbers found:          (<i>e.g. List of Carriers, Positions, Reagents, Lot Number</i>)</p> <p>The following reagents have expired:          (<i>e.g. List of Carriers, Positions, Reagents, Lot Number</i>)</p> <p>Click 'OK' to reload the reagents or 'Cancel' to abort the run</p>	<p>All reagents of the PCR kit have to be from the same Lot. Look at the last four numbers of the lot number. These have to be the same for all reagents of the kit. In the displayed screenshot the NTC on position 7 has a different number than the other reagents. Replace this tube with a tube of the same lot as the other reagents. Click <b>OK</b>.</p> <p>One or several reagents are expired. Replace the listed reagent(s) with non-expired reagents from the compatible lot.</p>

## **5 Appendices:**

### **5.1 Appendix A:**

#### **5.1.1 Regulatory Affairs**

CE conformity is maintained for the AltoStar® Connect SW. See the Declaration of Conformity provided with the software.

#### **5.1.2 In Vitro Diagnostics**

Through the compliant assessment of the AltoStar® Connect SW according to the IEC 62304 the development of the software covers the In Vitro Diagnostic Directive 98/79/EC of the European Parliament and of the Council of 1998-10-27 on in vitro diagnostic medical devices.

#### **5.1.3 Applied Company Quality Management Systems**

Applied company quality management systems EN ISO 9001 and EN ISO 13485 Certification Body is TÜV Rheinland LGA Products GmbH, Am Grauen Stein 29, D-51105 Köln-Poll, Germany.

#### **5.1.4 Declaration of Conformity**

The declaration of conformity is part of the delivery of the AltoStar® Connect SW.

## 5.2 Appendix B: Glossary

Term	Definition
<b>Autoload</b>	Hardware assembly that enables automatic loading of the AltoStar® AM16. It consists of a loading head movable in Y direction, which draws the carriers into the AltoStar® AM16 and reads the barcodes on them.
<b>Autoload Tray</b>	Hardware unit. The carriers can be placed on it and held outside the AltoStar® AM16. The Loading Tray is attached to the AltoStar® AM16, to support the automatic loading and unloading process.
<b>Barcode Reader</b>	Device for reading sample/plate Barcodes. Part of the Autoload.
<b>Carrier</b>	Unit for loading plates, tubes and tips on the AltoStar® AM16 deck. Loading process is carried out by the Autoload unit.
<b>Deck</b>	The work area of the AltoStar® AM16. The area where the pipetting channels perform liquid handling or transport steps. The deck is divided into tracks, which are occupied by labware.
<b>Dispense</b>	To distribute quantities of liquid from a pipetting device.
<b>Front Cover</b>	Protective covering for the AltoStar® AM16, featuring a hinged front window made of transparent Plexiglas. With this option and assembly, the work surface of the AltoStar® AM16 is covered in such a way that it is shielded from user intervention and other outside influences (such as dust). At the same time, it protects the user from the movements of the AltoStar® AM16.
<b>Hardware Error</b>	Type of error that is caused by a technical problem with the hardware.
<b>HHS</b>	Hamilton Heater Shaker. Unit to heat and shake microplates in SBS format.
<b>Instrument</b>	Hardware of the AltoStar® AM16 (mechanics, electronics, and firmware)
<b>Labware</b>	Refers to movable items to be placed on the AltoStar® AM16 deck, such as carriers, containers, or racks.
<b>LIMS</b>	Higher level data processing system, generally known as Laboratory Information Management System, also LIS.
<b>Liquid</b>	Includes all kinds of liquids, among which are included reagents, controls, standards, wash fluids.
<b>LLD</b>	<i>Liquid Level Detection</i> – Detection of liquid surface which may be achieved either by pressure or capacitive signal detection.
<b>Loading/Unloading</b>	The process by which plate, tube and tip carriers are brought on and off the AltoStar® AM16 deck. This is automatically performed via the Autoload unit except for labware placed on the Heater Shaker Carrier.
<b>Method</b>	The method contains all instruction that must be executed during a run.



Term	Definition
<b>AltoStar® Connect SW</b>	Software to run the AltoStar® AM16.
<b>Pipetting</b>	Transfer of liquids from one container to another.
<b>Pipetting Arm</b>	Assembly equipped with the pipetting device and/or plate handler, as well as the common X-drive.
<b>Pipetting Channel</b>	Hardware assembly including the function of picking up a tip aspirating, dispensing, tip eject, liquid level detection and the Y/Z-movements.
<b>Pooling</b>	Pipetting of different liquids into one container.
<b>Run</b>	Execution of the processing steps defined in the method with the aim of processing a discrete part of the workflow. The run is a series of timed commands, in order to carry out processing on the AltoStar® AM16 according to the processing plan.
<b>Run Abort</b>	Cancelled run by the user or by the AltoStar® AM16.
<b>Sample</b>	Refers to a liquid in a unique identified container which is to be processed.
<b>Tip</b>	Disposable tip for pipetting.
<b>Tip Rack</b>	Frame that holds the tips.
<b>Tip Waste</b>	Container for ejected tips.
<b>Trace</b>	Record of the status during processing.
<b>Tube</b>	A container for liquid, usually having a circular cross-section, and a cylindrical length section.
<b>Waste Container</b>	A device on the AltoStar® AM16 deck to collect used disposable tips.
<b>Well</b>	The individual container of a Microtiter Plate or Deep Well Plate.

### 5.3 Appendix B: Manual Update Information

Modifications of the AltoStar Connect SW Manual IVD are listed here.

Date of Change	Revision	Description of Change
October 2017	00	Initial Version
January 2018	01	Updated Version
October 2019	02	Updated Version

The AltoStar Connect SW Manual IVD is valid for the AltoStar® Connect SW in conjunction with the AltoStar® AM16 instrument.



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