

Instructions for Use

AltoStar[®] Internal Control 1.5

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AltoStar[®]

Internal Control 1.5



IC15-16



1152



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1. About these Instructions for Use

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

The information needed for the operation of the AltoStar® AM16 and the AltoStar® Connect software is provided in the AltoStar® Automation System AM16 Operator's Manual IVD and the AltoStar® Connect Software Manual IVD.

If further information is needed about the AltoStar® AM16, the AltoStar® Connect software or the AltoStar® Purification Kit 1.5 please refer to the respective product manual or instructions for use.

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

CAUTION



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

NOTE



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

Read the Instructions for Use carefully before using the product.

2. Intended Use

The AltoStar® Internal Control 1.5 is intended to be used as a nucleic acid purification, amplification and detection control for *in vitro* diagnostic purposes. It is designed for use with the AltoStar® Purification Kit 1.5 and altona Diagnostics real-time PCR kits specified for use with the AltoStar® Internal Control 1.5.

The AltoStar® Internal Control 1.5 is intended for use by professional users trained in molecular biological techniques.

3. Product Components

Table 1: Product Components

Component	Number of Tubes	Volume per Tube [ml]
IC	24	2.4

CAUTION



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

Each IC (Internal Control) tube contains sufficient volume to perform 48 nucleic acid purifications with the AltoStar® Purification Kit 1.5.

Upon receipt please check the product and its components for:

- Integrity
- Completeness with respect to number, type and filling
- Correct labeling
- Frozen state upon arrival

The components of the product should arrive frozen. If one or more components are not frozen upon receipt or if tubes have been compromised during shipment or are missing, contact altona Diagnostics GmbH for assistance:

e-mail: support@altona-diagnostics.com

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

4. Storage and Handling

4.1 Storage

The AltoStar® Internal Control 1.5 is shipped on dry ice. After receipt the AltoStar® Internal Control 1.5 must be stored at -25°C to -15°C.

CAUTION



Improper storage conditions may lead to a compromised product performance.

CAUTION



Do not use product components beyond the expiration date printed on the component label.

4.2 Handling

The IC is a ready-to-use solution.

Each tube must only be thawed once. After thawing, the IC is stable for 24 hours at up to 30°C. The tubes shall be closed with the original cap after each use and stored at the specified conditions.

CAUTION



Do not exceed thaw-freeze-sequence and handling durations as specified in these Instructions for Use.

CAUTION

Improper handling of product components and samples may lead to contamination causing incorrect IVD examination results.



- Do not interchange vial or bottle caps, as cross-contamination may occur.
- To minimize the risk of carryover contamination store positive and/or potentially positive material separated from the kit components.
- Use separated working areas for sample preparation/reaction setup and amplification/detection activities.
- Always wear disposable gloves.
- Do not open the PCR plates post amplification to avoid contamination with amplicons.

5. Product Description

The AltoStar® Internal Control 1.5 contains a defined copy number of DNA and RNA template molecules with different sequences of artificial origin. The IC is automatically added at the beginning of the nucleic acid purification procedure using the AltoStar® Purification Kit 1.5 on the AltoStar® Automation System AM16.

The AltoStar® Internal Control 1.5 serves as a process control for the automated workflow:

- Purification control: The IC is added to each specimen/lysis buffer mixture and is processed simultaneously with the respective target nucleic acids in the specimen. Thus, a low nucleic acid purification efficiency would lead to a low IC signal in the real-time (RT*-)PCR, which can be considered for result interpretation.
- Real-time (RT-) PCR control: The target nucleic acids of the respective assay and the IC nucleic acids are transcribed (applicable for RNA targets only), amplified and detected in parallel and differentiated using probes linked to distinguishable dyes. Thereby, sample specific reaction inhibition (e.g. by inhibitory substances derived from the specimen) as well as systemic malfunctions due to reagent failure can be identified and considered for result interpretation.

* Reverse transcriptase

6. Sample Types

The AltoStar® Internal Control 1.5 is compatible with all sample types that are specified for use with the AltoStar® Purification Kit 1.5. For more information regarding sample types including their collection, handling and storage refer to the Instructions for Use of the AltoStar® Purification Kit 1.5 and the Instructions for Use of altona Diagnostics real-time PCR kits specified for use with the AltoStar Internal Control 1.5.

7. Material and Devices required, but not provided

- AltoStar® Automation System AM16 (Order No. 806160)
- AltoStar® Connect software (Order No. 911275)
- AltoStar® Purification Kit 1.5 (Order No. PK15-16)
- altona Diagnostics real-time PCR kit(s) specified for use with the AltoStar® Internal Control 1.5
- Vortex mixer
- Powder-free gloves (disposable)
- Appropriate real-time PCR instrument specified for use with the respective altona Diagnostics real-time PCR kit(s)

NOTE



Refer to the Instructions for Use of the AltoStar® Purification Kit 1.5 and the altona Diagnostics real-time PCR kit(s) for a list of required consumables.

8. Warnings, Precautions and Limitations

- Before first use check the product and its components for completeness with respect to number, type and filling. Do not use a defective or incomplete product, performance could be compromised.
- Improper storage conditions may lead to a compromised product performance.
- Do not exceed thaw-freeze-sequence and handling durations as specified in these Instructions for Use.
- Do not use product components beyond the expiration date printed on the component label.
- Improper handling of product components and samples may lead to contamination causing incorrect IVD examination results.
 - Do not interchange vial or bottle caps, as cross-contamination may occur.
 - To minimize the risk of carryover contamination store positive and/or potentially positive material separated from the kit components.
 - Use separated working areas for sample preparation/reaction setup and amplification/detection activities.
 - Always wear disposable gloves.
 - Do not open the PCR plates post amplification to avoid contamination with amplicons.
- Dispose of hazardous and biological waste only in compliance with local and national regulations to avoid environmental contamination.
- Always treat samples as infectious and (bio-)hazardous in accordance with safe laboratory procedures. For sample material spills promptly use an appropriate disinfectant. Handle contaminated materials as biohazardous.

9. Procedure

For detailed instructions regarding the use of the AltoStar® Internal Control 1.5 in conjunction with the AltoStar® Purification Kit 1.5 refer to the Instructions for Use of the AltoStar® Purification Kit 1.5.

9.1 Preparing of the IC (Internal Control) for a Purification Run

Prepare the IC as follows:

- Completely thaw the appropriate number of IC tubes at room temperature (max. 30°C) and vortex for 5 seconds. Avoid drops in the cap.
- Remove the lid(s) and load the IC tube(s) onto the respective carrier according to the Loading dialog of the AltoStar® Connect software.
- Store the lids in a clean space to avoid contamination as the lids shall be reused to close the tubes after the run.

The IC will be added automatically to each specimen/lysis buffer mixture at the beginning of the sample purification procedure on the AltoStar® Automation System AM16.

NOTE



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

9.2 Nucleic Acid Purification

The purification of nucleic acids from a sample is achieved using the AltoStar® Purification Kit 1.5 on the AltoStar® Automation System AM16. For details refer to the Instructions for Use of the AltoStar® Purification Kit 1.5. The eluates containing the purified nucleic acids are the starting material for subsequent real-time PCR analyses.

9.3 Real-Time PCR Setup and Run

The PCR setup has to be performed in alignment with the Instructions for Use of the respective altona Diagnostics real-time PCR kit.

After PCR setup the PCR plates have to be sealed and transferred to the real-time PCR instrument. The real-time PCR instrument, the PCR conditions as well as the controls to be used for real-time PCR analysis depend on the altona Diagnostics real-time PCR kit used. For details refer to the Instructions for Use of the respective altona Diagnostics real-time PCR kit.

10. Data Analysis

After completion of the real-time PCR run the signal of the IC is used as a nucleic acid purification and real-time (RT-)PCR control. The detailed analysis procedure including fluorescence detection channel and validity criteria depend on the altona Diagnostics real-time PCR kit used. For further information refer to the respective Instructions for Use.

11. Performance Evaluation

In silico analysis demonstrated that the DNA and the RNA target included in the AltoStar® Internal Control 1.5 do neither have significant homology to each other nor to any known naturally occurring sequences.

The performance of the AltoStar® Internal Control 1.5 is verified in conjunction with each altona Diagnostics kit specified for use with the AltoStar® Internal Control 1.5.

12. Quality Control

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

13. Technical Assistance

For customer support, please contact our Technical Support:

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

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

14. References

- [1] CTS 2009/108/EC: Commission Decision of 3 February 2009 amending Decision 2002/364/EC on common technical specifications for *in vitro* diagnostic medical devices.
- [2] RiliBÄK 09/2014; Guidelines of the "Bundesärztekammer" (Germany) for quality assurance of laboratory medical examinations

15. Trademarks and Disclaimers

AltoStar® (altona Diagnostics)
















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

The AltoStar® Internal Control 1.5 is a CE-marked product according to the European *in vitro* diagnostic directive 98/79/EC.

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

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16. Explanation of Symbols

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

always a drop ahead.

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