

Instructions for Use

AltoStar[®] **Internal Control 1.5**

04/2020 EN

AltoStar[®]

Internal Control 1.5

For research use only!

(RUO)



IC15-06



1152



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1. About these 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.

NOTE



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

2. Application

The AltoStar® Internal Control 1.5 is intended to be used as a nucleic acid purification, amplification and detection control in conjunction with the AltoStar® Purification Kit 1.5, the AltoStar® Automation System AM16 and Altona Diagnostics real-time PCR kits specified for use with the AltoStar® Internal Control 1.5.

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

3. Product Components

Table 1: Product Components

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

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 labelling
- 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



Transfer the product components to their intended storage condition upon receipt.

4.2 Reagents in Use

The IC (Internal Control) is a ready-to-use solution.

Each tube should only be thawed once. After thawing the IC (Internal Control) is stable for 24 hours at 4°C to 30°C. The tubes should be closed with the original cap after each use and stored at the specified conditions.

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 (Internal Control) 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 (Internal Control) 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 (Internal Control) 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 (Internal Control) 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 (e.g. reduced enzyme activity due to wrong storage of (RT-)PCR reagents) can be identified and considered for result interpretation.

6. Additional Material Needed

- AltoStar® Automation System AM16 (Order No. AM16) - AltoStar® Connect software
- AltoStar® Purification Kit 1.5 (Order No. PK15-06)
- Altona Diagnostics real-time PCR kit(s) specified for use with the AltoStar® Internal Control 1.5

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.

- Vortex mixer
- Powder-free gloves (disposable)
- Appropriate real-time PCR instrument specified for use with the respective altona Diagnostics real-time PCR kit(s)

7. Warnings and Precautions

- Always wear a suitable lab coat, disposable gloves, and eye protection, when working with samples and product components.
- Dispose of hazardous or biologically contaminated materials and waste in compliance with country, federal, state, and local requirements.

8. Procedure

For 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.

8.1 Preparing of the IC (Internal Control)

Prepare the IC (Internal Control) 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.

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

CAUTION



Remove the lids of all IC (Internal Control) tubes before loading the carriers onto the Loading Tray of the AltoStar® Automation System AM16. Leaving them on may lead to aborted runs and damage to the instrument.

8.2 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. Data Analysis

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















10. 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.

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11. Explanation of Symbols

	Batch code
	Catalogue number
	Content
	Consult instructions for use
	Consult instructions for use
	Temperature limit
	Use-by date
	Manufacturer
	Temperature limit
	Use-by date
	Manufacturer
	Material number
	Control
	Global Trade Item Number

always a drop ahead.

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