

Instructions for use

AltoStar[®] Internal Control 1.5

10/2021 EN

AltoStar[®]

Internal Control 1.5



IC15-46



1152



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Content

1.	About these instructions for use.....	6
2.	Intended use.....	7
3.	Kit content	7
4.	Storage and handling	8
4.1	Storage.....	8
4.2	Handling	9
5.	Product description	9
5.1	Sample types.....	10
6.	Warnings, precautions and limitations	10
7.	Using the AltoStar® Internal Control 1.5.....	11
7.1	Preparing the IC for a purification run	11
7.2	Material and devices required but not provided.....	12
7.3	General material and devices.....	12
7.4	Procedure.....	12
7.4.1	Nucleic acid purification.....	12
7.4.2	Real-time PCR setup and run.....	12
8.	Data analysis	13
9.	Performance data.....	13
10.	Disposal	13
11.	Quality control.....	14
12.	Technical support	14
13.	Literature.....	15

14.	Trademarks and disclaimers.....	15
15.	Symbols	16
16.	Revision history	17

1. About these instructions for use

These instructions for use guide the user in utilizing the AltoStar® Internal Control 1.5.

The AltoStar® Internal Control 1.5 is used for nucleic acid purification procedure in combination with the AltoStar® Purification Kit 1.5 and for real-time (RT*-)PCR analysis in combination with altona Diagnostics real-time PCR kits and reagents specified for use with the AltoStar® Internal Control 1.5. For details on the use of these products, refer to the respective instructions for use.

* Reverse Transcriptase

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

CAUTION



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

NOTE



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

Read the instructions for use carefully before using the product.

2. Intended use

The AltoStar® 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 kits and reagents 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 and *in vitro* diagnostic procedures.

3. Kit content

The AltoStar® Internal Control 1.5 contains the following components:

Table 1: Kit components

Lid color	Component	Number of tubes	Volume per tube [ml]
Transparent	IC ¹⁾	24	2.4

¹⁾ Internal Control

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, product performance could be compromised.

The AltoStar® Internal Control 1.5 contains enough reagents to perform 1,152 reactions.

The product is shipped on dry ice. Upon receipt and before first use, check the product and its components for:

- Integrity
- Completeness with respect to number, type and filling
- Correct labeling
- Expiration date
- Frozen state
- Clarity and absence of particles

If one or more product components are not frozen upon receipt, if tubes have been compromised during shipment or are missing, contact altona Diagnostics technical support for assistance (see chapter 12. Technical support).

4. Storage and handling

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

4.1 Storage

The IC must be stored at -25 °C to -15 °C upon arrival.

CAUTION



Improper storage conditions could compromise product performance.

CAUTION



Do not use products beyond the expiration date. The use of expired products could compromise product performance.

4.2 Handling

Each tube of IC 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 specified in these instructions for use, as this could compromise product performance.

CAUTION



Improper handling of product components and samples may cause contamination and could compromise product performance:

- Do not interchange vial or bottle caps.
- Store positive and/or potentially positive material separated from the kit components.
- Use separated working areas for sample preparation/reaction setup and amplification/detection activities.
- Always dispose gloves after handling positive and/or potentially positive material.
- Do not open the PCR plates and/or tubes post amplification.

5. Product description

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

The IC serves as a process control for the sample preparation procedure (nucleic acid extraction) and the following real-time (RT-)PCR.

- **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, 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.

5.1 Sample types

The IC 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 and reagents specified for use with the AltoStar® Internal Control 1.5.

6. 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, product performance could be compromised.
- Improper storage conditions could compromise product performance.
- Do not use products beyond the expiration date. The use of expired products could compromise product performance.
- Do not exceed thaw-freeze-sequence and handling durations specified in these instructions for use, as this could compromise product performance.
- Improper handling of product components and samples may cause contamination and could compromise product performance:
 - Do not interchange vial or bottle caps.
 - Store positive and/or potentially positive material separated from the kit components.

- Use separated working areas for sample preparation/reaction setup and amplification/detection activities.
- Always dispose gloves after handling positive and/or potentially positive material.
- Do not open the PCR plates and/or tubes post amplification.
- Always treat samples as infectious and (bio-)hazardous material in accordance with safety and laboratory procedures. For sample material spills promptly use an appropriate disinfectant. Handle contaminated materials as biohazardous.
- Disposal of hazardous and biological waste shall comply with local and national regulations to avoid environmental contamination.

7. Using the AltoStar® Internal Control 1.5

The following part of these instructions for use describes the use of the AltoStar® Internal Control 1.5.

7.1 Preparing the IC 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 lid.
- Remove the lid(s) and include the IC in the nucleic acid extraction procedure as described in the Instructions for use of the AltoStar® Purification Kit 1.5.
- 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 using the AltoStar® Purification Kit 1.5.

NOTE



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

7.2 Material and devices required but not provided

The material and devices shown in table 2 must be ordered from altona Diagnostics.

Table 2: Required material and devices

Material	Description	Order No.
AltoStar® Purification Kit 1.5	Nucleic acid isolation and purification chemistry for use with the AltoStar® Automation System AM16	PK15-16/ PK15-46
altona Diagnostics real-time PCR kit or reagent specified for use with the AltoStar® Internal Control 1.5	---	---

7.3 General material and devices

- Vortex mixer
- Powder-free gloves (disposable)

7.4 Procedure

7.4.1 Nucleic acid purification

The purification of nucleic acids from a sample is achieved using the AltoStar® Purification Kit 1.5. 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 (RT-)PCR analyses.

7.4.2 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 or reagent.

After PCR setup the PCR plate has 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 (RT-)PCR analysis depend on the Altona Diagnostics real-time PCR kit or reagent used. For details, refer to the instructions for use of the respective Altona Diagnostics real-time PCR kit or reagent.

8. 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 depends on the Altona Diagnostics real-time PCR kit or reagent used. For further information refer to the respective instructions for use.

9. Performance data

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

The performance of the IC is verified in conjunction with each Altona Diagnostics real-time PCR kit and reagent specified for use with the AltoStar® Internal Control 1.5. For details, refer to the instructions for use of the respective Altona Diagnostics real-time PCR kit or reagent.

10. Disposal

Dispose of hazardous and biological waste in compliance with local and national regulations. Leftover product components and waste should not be allowed to enter sewage, water courses or the soil.

CAUTION



Always treat samples as infectious and (bio-)hazardous material in accordance with safety and laboratory procedures. For sample material spills promptly use an appropriate disinfectant. Handle contaminated materials as biohazardous.

CAUTION



Disposal of hazardous and biological waste shall comply with local and national regulations to avoid environmental contamination.

11. Quality control

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

12. Technical support

For customer support, contact altona Diagnostics technical support:

e-mail: support@altona-diagnostics.com

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

NOTE



Any serious incident that has occurred in relation to this product shall be reported to altona Diagnostics and the competent authority of your country.

13. Literature

- 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.
- RiliBÄK 09/2014; Guidelines of the "Bundesärztekammer" (Germany) for quality assurance of laboratory medical examinations.

14. 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 diagnostic kit according to the European *in vitro* diagnostic directive 98/79/EC.

Product not FDA cleared or approved.

Not available in all countries.

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15. 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
	Version
	Control
	Note

16. Revision history

Table 3: Revision history

Identifier	Date of issue [month/year]	Modifications
MAN-IC1540- EN-S01	10/2021	Initial release

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always a drop ahead.

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