altona DIAGNOSTICS

Instructions for use

FlexStar®
(RT-)PCR Amplification Mix 1.5

02/2022 EN

FlexStar®

FlexStar®

(RT-)PCR Amplification Mix 1.5

For use with

AltoStar® Purification Kit 1.5

CE

IVD

REF FS0011515

Σ 384

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Content

1. About these instructions for use

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 FlexStar® (RT-)PCR Amplification Mix 1.5 is an enzyme mix for *in vitro* diagnostic purposes. It is intended to be used with FlexStar® Detection Mixes for the real-time PCR based amplification and detection of pathogen specific nucleic acids in human specimen types.

The FlexStar® (RT-)PCR Amplification Mix 1.5 is intended for use by professional users trained in molecular biological techniques and *in vitro* diagnostic procedures.

3. Product content

The FlexStar® (RT-)PCR Amplification Mix 1.5 contains the following components:

Table 1: Kit components

Lid color	Component	Number of tubes	Nominal volume [µl/tube]
Purple	Amplification Mix[1)]	8	720

[1)] Contains biological material of animal origin

CAUTION

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

Each Amplification Mix tube contains sufficient volume to perform 48 real-time PCRs in combination with FlexStar® (RT-)PCR Detection Mixes 1.5.

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 and filling
- Correct labeling
- Expiration date
- Frozen state upon arrival
- Clarity and absence of particles

If one or more product components are not frozen upon receipt or if tubes have been compromised during shipment or are missing, contact altona Diagnostics technical support for assistance (see chapter 14. Technical assistance).

4. Storage and handling

4.1 Storage

All components of the FlexStar® (RT-)PCR Amplification Mix 1.5 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

The Amplification Mix is a ready-to-use solution.

After thawing, the Amplification Mix is stable for 5 hours at up to +30 °C.

After use, close the Amplification Mix tubes and freeze them immediately.

Do not exceed the following thaw-freeze-sequence for each Amplification Mix tube: *Thaw 1 → Freeze 1 → Thaw 2 → Freeze 2 → Thaw 3 → Freeze 3 → Thaw 4 → Freeze 4 → Thaw 5*

The Amplification Mix should be protected from light.

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.

CAUTION

Do not mix components from different FlexStar® (RT-)PCR Amplification Mix 1.5 lots, as this could compromise product performance.

5. Material required but not provided

- Desktop centrifuge with a rotor for 2 ml reaction tubes
- Vortex mixer
- Pipettes (adjustable)
- Pipette tips with filters (disposable)
- Powder-free gloves (disposable)

6. Product description

The FlexStar® (RT-)PCR Amplification Mix 1.5 is an enzyme mix for *in vitro* diagnostic purposes. It is intended to be used with FlexStar® (RT-)PCR Detection Mixes 1.5 for the real-time PCR based detection of pathogen specific nucleic acids in human specimen types with the aim to aid for diagnosis of pathogen infection.

Real-time PCR technology utilizes polymerase chain reaction (PCR) for the amplification of specific target sequences and target specific probes for the detection of the amplified DNA. The probes are labeled with fluorescent reporter and quencher dyes.

The Amplification Mix contains reverse transcriptase and DNA polymerase to allow reverse transcription, as well as PCR mediated amplification and target detection in conjunction with FlexStar® (RT-)PCR Detection Mixes 1.5 in one reaction setup.

7. Sample types

The FlexStar® (RT-)PCR Amplification Mix 1.5 is compatible with all sample types that are specified for use with FlexStar® (RT-)PCR Detection Mixes 1.5. For more information regarding sample types including their collection, handling and storage refer to the instructions for use of the FlexStar® (RT-)PCR Detection Mixes 1.5.

8. Warnings, precautions and limitations

- Before first use check the product and its components for completeness with respect to number 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.
- Do not mix components from different FlexStar® (RT-)PCR Amplification Mix 1.5 lots, as this could compromise product performance.
- A lack of centrifugation of the product components after thawing may cause contamination with reagent residues in the lids and could compromise product performance.
- The presence of PCR inhibitors (e.g. heparin) could cause false negative or invalid results.
- 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.

9. Procedure

9.1 Preparing the Amplification Mix

Prepare the Amplification Mix as follows:

- Completely thaw the appropriate number of Amplification Mix tubes at room temperature (max. +30 °C) and vortex for 5 seconds.
- Briefly centrifuge the Amplification Mix tubes before usage to avoid drops in the lid.

CAUTION

A lack of centrifugation of the product components after thawing may cause contamination with reagent residues in the lids and could compromise product performance.

CAUTION

Do not mix components from different FlexStar® (RT-)PCR Amplification Mix 1.5 lots, as this could compromise product performance.

9.2 Real-time PCR setup and run

The PCR setup and run have to be performed in alignment with the instructions for use of the respective FlexStar® (RT-)PCR Detection Mix 1.5.

CAUTION

The presence of PCR inhibitors (e.g. heparin) could cause false negative or invalid results.

10. Data analysis

The data analysis procedure including fluorescence detection channel selection as well as run and result validity criteria depend on the FlexStar® (RT-)PCR Detection Mix 1.5 used. For further information refer to the respective instructions for use.

11. Performance evaluation

The performance of the FlexStar® (RT-)PCR Amplification Mix 1.5 is evaluated in conjunction with each altona Diagnostics FlexStar® (RT-)PCR Detection Mix 1.5. For further information refer to the respective instructions for use.

12. 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.

13. Quality control

In accordance with the altona Diagnostics GmbH EN ISO 13485-certified Quality Management System, each lot of FlexStar® (RT-)PCR Amplification Mix 1.5 is tested against predetermined specifications to ensure consistent product quality.

14. Technical assistance

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.

15. Trademarks and disclaimers

FlexStar® (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 FlexStar® (RT-)PCR Amplification Mix 1.5 is a CE-marked diagnostic kit according to the European *in vitro* diagnostic directive 98/79/EC.

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

Not available in all countries.

16. Explanation of symbols

Symbol	Explanation
IVD	*In vitro* diagnostic medical device
GTIN	Global Trade Item Number
LOT	Batch code
CONT	Content
CAP	Cap color
REF	Catalogue number
NUM	Number
COMP	Component
	Consult instructions for use
	Contains sufficient for "n" tests/reactions (rxns)
	Temperature limit
	Use-by date
	Manufacturer
	Caution
MAT	Material number

Symbol	Explanation
	Version
	Note
	Contains biological material of animal origin

17. Revision history

Table 2: Revision history

Identifier	Date of issue [month/year]	Modifications
MAN-FS0011510-EN-S01	02/2022	Initial release

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