altona DIAGNOSTICS

Instructions for use

Universal Internal Control Template 1.0

03/2022 EN

Universal

Internal Control Template 1.0

For research use only!

(RUO)

REF	00100-IC
CONT	4 x 1000 µl
	03 2022
	altona Diagnostics GmbH • Mörkenstr. 12 • D-22767 Hamburg

INS-00100-IC-EN-S01

Content

1. Application

The Universal Internal Control Template 1.0 is a mixture of artificial DNA and RNA and can be used as a nucleic acid purification, amplification and detection control for altona Diagnostics real-time PCR kits and reagents specified for research use only.

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

2. Kit content

The Universal Internal Control Template 1.0 contains the following components:

Table 1: Kit components

Lid color	Component	Number of tubes	Volume [µl/tube]
Green	UICT[1)]	4	1,000

[1)] Universal Internal Control Template

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 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 6. Technical assistance).

3. Storage and handling

The Universal Internal Control Template (UICT) is a ready-to-use solution.

3.1 Storage

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

NOTE

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

3.2 Handling

After thawing, the UICT is stable for 5 hours at up to +30 °C. Do not exceed the following thaw-freeze-sequence for each UICT tube:

Thaw 1 → Freeze 1 → Thaw 2 → Freeze 2 → Thaw 3 → Freeze 3 → Thaw 4

4. Product description

The UICT contains a defined copy number of DNA and RNA template molecules with different sequences of artificial origin. The UICT can either be used as a (RT-) PCR inhibition control or as a control of the sample preparation procedure (nucleic acid purification) and as a (RT-)PCR inhibition control.

- Purification control: The UICT is added to each sample/lysis buffer mixture and is processed simultaneously with the respective target nucleic acids in the sample. Thus, a low nucleic acid purification efficiency would lead to a low UICT (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 UICT (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 sample) 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.

5. Procedure

5.1 Preparing of the Universal Internal Control Template

Prepare the UICT as follows:

1. Thaw the required number of UICT tubes completely at room temperature (max. +30 °C).
2. Mix the reagents by gentle vortexing.
3. Centrifuge the tubes briefly to remove drops from the lid.

5.2 Nucleic acid purification

No matter which method/system is used for nucleic acid purification, the UICT must not be added directly to the sample. The UICT should always be added to the sample/lysis buffer mixture. When determining the volume of the UICT to be added to the sample/lysis buffer mixture, always take the elution volume into account. It is recommended to add UICT at 10 % of the volume of the elution buffer. For instance, if the nucleic acid is going to be eluted in 60 µl of elution buffer or water, 6 µl of UICT per sample must be added into the sample/lysis buffer mixture.

5.3 Real-time PCR setup, run and analysis

PCR setup and subsequent sealing of the reaction plate or tubes have to be performed according to the instructions for use of the respective altona Diagnostics real-time PCR kit or reagent. 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.

After completion of the real-time PCR run the signal of the UICT is used as a nucleic acid purification and/or 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 or reagent used and are described in the respective instructions for use.

6. Technical assistance

For customer support, contact altona Diagnostics technical support:

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

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

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

8. Symbols

Symbol	Explanation
RUO	For research use only
LOT	Batch code
CONT	Content
REF	Catalogue number
	Consult instructions for use
	Temperature limit
	Use-by date
	Manufacturer
	Version
CONTROL	Control
	Note: Information is given to the user that is useful but not essential to the task at hand.

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