

Instructions for use

AltoStar[®] Respiratory Sample Pretreatment Buffer 1.5

01/2024 EN

AltoStar[®]

AltoStar®

Respiratory Sample Pretreatment Buffer 1.5

For research use only!

(RUO)



RSPB15-04



2 x 58 ml



01 2024

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Table of contents

1.	Application	5
2.	Kit content	5
3.	Storage and handling	6
3.1	Storage	6
3.2	Handling	6
4.	Product description	6
4.1	Samples	7
4.1.1	Sample types	7
5.	Safety information	7
6.	Using the AltoStar [®] Respiratory Sample Pretreatment Buffer 1.5	8
6.1	Sample volume	8
6.2	Sample tubes	8
6.3	Sample barcodes	9
6.4	Equipment and reagents to be supplied by the user	9
6.5	General material and devices	9
6.6	Procedure	10
6.6.1	BAL sample pretreatment procedure	10
6.6.2	Tracheal secretion (TRSE) pretreatment procedure	10
6.6.3	Sputum pretreatment procedure	11
7.	Disposal	11
8.	Technical support	12
9.	Trademarks and disclaimers	12
10.	Symbols	13
11.	Revision history	14

1. Application

The AltoStar[®] Respiratory Sample Pretreatment Buffer 1.5 is a reagent suitable for the stabilization and liquefaction of bronchoalveolar lavage (BAL), tracheal secretion (TRSE) and sputum samples for the subsequent isolation and purification of nucleic acids.

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

2. Kit content

The AltoStar[®] Respiratory Sample Pretreatment Buffer 1.5 contains the following components:

Table 1: Kit components

Component	Number of bottles	Volume per bottle [ml]
RSPB*	2	58

* Respiratory Sample Pretreatment Buffer

The AltoStar[®] Respiratory Sample Pretreatment Buffer 1.5 contains enough reagents for the pretreatment of:

- 192 bronchoalveolar lavage (BAL) samples using up to 500 µl sample volume (see chapter 6.6.1 BAL sample pretreatment procedure)
- 192 tracheal secretion (TRSE) samples using up to 250 µl sample volume (see chapter 6.6.2 Tracheal secretion (TRSE) pretreatment procedure)
- 192 sputum samples using up to 250 µl sample volume (see chapter 6.6.3 Sputum pretreatment procedure)

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

· Clarity and absence of particles

If one or more bottles have been compromised during shipment or are missing, contact altona Diagnostics technical support for assistance (see chapter 8. Technical support).

3. Storage and handling

The RSPB (Respiratory Sample Pretreatment Buffer) is a ready-to-use solution.

3.1 Storage

The RSPB is shipped at room temperature and should be stored at +2 °C to +8 °C upon receipt.

3.2 Handling

The RSPB is stable after initial opening for 14 days, when closed after each use and stored as follows: bottles should be closed with the original cap after use and stored at +2 $^{\circ}$ C to +8 $^{\circ}$ C.



4. Product description

 Table
 2: Kit component description

Kit component	Description
RSPB*	Contains different salts to liquify mucin rich samples and stabilizes and protects nucleic acids against nucleases in solution.

* Respiratory Sample Pretreatment Buffer

4.1 Samples

4.1.1 Sample types

The following sample types can be used with the AltoStar[®] Respiratory Sample Pretreatment Buffer 1.5:

- Bronchoalveolar lavage (BAL)
- Tracheal secretion (TRSE)
- Sputum

Respiratory Sample Pretreatment Buffer 1.5		
	H302	Harmful if swallowed.
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.
GHS07	H373	May cause damage to organs through prolonged or repeated exposure.
	P260	Do not breathe mist, vapours, spray.
	P264	Wash hands, forearms and face thoroughly after handling.
	P270	Do not eat, drink or smoke when using this product.
GHS08	P280	Wear protective gloves, protective clothing, eye protection.
Warning!	P301+P312	IF SWALLOWED: Call a doctor, a POISON CENTER if you feel unwell.
	P302+P352	IF ON SKIN: Wash with plenty of soap and water.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P314	Get medical advice/attention if you feel unwell.
	P330	Rinse mouth.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
	P337+P313	If eye irritation persists: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
	Contains:	Guanidinium chloride (CAS 50-01-1) 25–50 %.
		Disodium edetic acid (EDTA), dihydrate (CAS 6381-92-6) 1–2.5 %.

5. Safety information

NOTE

For more information, consult the safety data sheet (SDS).

6. Using the AltoStar[®] Respiratory Sample Pretreatment Buffer 1.5

The following chapters describe the use of the AltoStar[®] Respiratory Sample Pretreatment Buffer 1.5 with the AltoStar[®] Automation System AM16 (Hamilton; in the following summarized as AltoStar[®] AM16, Order No. AM16).

6.1 Sample volume

The AltoStar[®] AM16 allows purification of 500 µl of pretreated sample. Additional pretreated sample volume has to be provided to account for the dead volume of the sample tube used. When using the sample tubes purchased from altona Diagnostics (see table 4), provide at least 700 µl pretreated sample volume in total.

NOTE

The sample volume is not checked by the system prior to processing. Samples with insufficient volume will not be processed and error flagged during the sample transfer step.

6.2 Sample tubes

Sample tubes suitable for use on the AltoStar[®] AM16 can be purchased from altona Diagnostics (see table 4). Other sample tubes can be tested for applicability by the user. For details, refer to the instructions for use of the AltoStar[®] Purification Kit 1.5.

6.3 Sample barcodes

For automated sample identification by the AltoStar[®] AM16 all sample tubes must be labeled with a suitable barcode. For details, refer to the instructions for use of the AltoStar[®] Purification Kit 1.5.

6.4 Equipment and reagents to be supplied by the user

Material	Description	Order No.
AltoStar [®] AM16 Workflow	Product bundle containing the AltoStar® Automation System AM16, the AltoStar® Connect software (Version 1.7.4 or higher) and IT hardware	AM16
AltoStar [®] Purification Kit 1.5	Nucleic acid isolation and purification chemistry for use with the AltoStar® Automation System AM16	PK15-06

Table 4: Additional laboratory material

Material	Description	Order No.
Sample tubes	e.g., 7 ml tube with cap, 82 x 13 mm	VK000010
Sample tube caps	e.g., ribbed plug for sample tubes	VK000011

6.5 General material and devices

- Vortex mixer
- Heater (e.g., water bath or block heater)
- Powder-free gloves (disposable)
- Pipettes (adjustable, for sample preparation)
- Pipette tips with filters (disposable, for sample preparation)

6.6 Procedure

6.6.1 BAL sample pretreatment procedure

- Transfer the required volume of BAL sample from the primary tube to a suitable barcode-labeled sample tube and add the same volume of RSPB to the sample to achieve a volumetric ratio of 1:1 (e.g., 400 μl of BAL sample and 400 μl of RSPB).
- 2. Immediately and thoroughly mix by vortexing for 10 seconds.
- **3.** Incubate the sample/RSPB mixture at +60 °C for 15 min (e.g., with a block heater or water bath).
- 4. After incubation, mix again thoroughly (e.g., by vortexing) for 10 seconds.
- 5. The BAL sample/RSPB mixture shall be free of solids and high viscosity constituents. If this is not the case, transfer only the liquid fraction of the mixture into a suitable AltoStar sample tube and discard the solid fraction. If the liquid fraction is not enough for the purification process, repeat the pretreatment procedure with the sample material and combine the liquid fractions until enough liquid is reached.
- 6. Start the purification run on the AltoStar® AM16 for the pretreated BAL samples.

6.6.2 Tracheal secretion (TRSE) pretreatment procedure

- **1.** Transfer the required volume of TRSE sample from the primary tube to a suitable barcode-labeled sample tube and add the same volume of RSPB to the sample to achieve a volumetric ratio of 1:2 (e.g., 250 μl of TRSE sample and 500 μl of RSPB).
- 2. Immediately and thoroughly mix by vortexing for 10 seconds.
- **3.** Incubate the sample/RSPB mixture at +60 °C for 15 min (e.g., with a block heater or water bath).
- 4. After incubation, mix again thoroughly (e.g., by vortexing) for 10 seconds.
- 5. The TRSE sample/RSPB mixture shall be free of solids and high viscosity constituents. If this is not the case, transfer only the liquid fraction of the mixture into a suitable AltoStar sample tube and discard the solid fraction. If the liquid fraction is not enough for the purification process, repeat the pretreatment procedure with the sample material and combine the liquid fractions until enough liquid is reached.
- **6.** Start the purification run on the AltoStar[®] AM16 for the pretreated TRSE samples.

6.6.3 Sputum pretreatment procedure

- 1. Transfer the required volume of sputum sample from the primary tube to a suitable barcode-labeled sample tube and add the same volume of RSPB to the sample to achieve a volumetric ratio of 1:2 (e.g., 250 μl of sputum sample and 500 μl of RSPB).
- 2. Immediately and thoroughly mix by vortexing for 10 seconds.
- **3.** Incubate the sample/RSPB mixture at +60 °C for 15 min (e.g., with a block heater or water bath).
- 4. After incubation, mix again thoroughly (e.g., by vortexing) for 10 seconds.
- 5. The sputum sample/RSPB mixture shall be free of solids and high viscosity constituents. If this is not the case, transfer only the liquid fraction of the mixture into a suitable AltoStar sample tube and discard the solid fraction. If the liquid fraction is not enough for the purification process, repeat the pretreatment procedure with the sample material and combine the liquid fractions until enough liquid is reached.
- 6. Start the purification run on the AltoStar[®] AM16 for the pretreated sputum samples.

NOTE

The sample volume is not checked by the system prior to processing. Samples with insufficient volume will not be processed and error flagged during the sample transfer step.

7. 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.

8. Technical support

For customer support, contact altona Diagnostics technical support:

e-mail:	support@altona-diagnostics.com
phone:	+49-(0)40-5480676-0

9. 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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10. Symbols

Symbol	Explanation
RUO	Research use only
LOT	Batch code
CONT	Content
REF	Catalogue number
Ĩ	Consult instructions for use
X	Temperature limit
$\mathbf{\Sigma}$	Use-by date
	Manufacturer
	Version
i	Note
UFI	Unique formula identifier

11. Revision history

 Table
 5: Revision history

Identifier	Date of issue [month/year]	Modifications
INS-RSPB1500- EN-S02	01/2024	 Chapter 1: update of the application Chapter 2: addition of TRSE and sputum Chapter 4.1.1: addition of sample volumes TRSE and sputum Chapter 5: update of safety information Addition of Chapter 6.6.2 and Chapter 6.6.3 Editorial changes

always a drop ahead.

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