altona DIAGNOSTICS

Instructions for use

ExtraStar®
Purification Kit 2.0

12/2022 EN

ExtraStar®

ExtraStar®

Purification Kit 2.0

For use with

KingFisher™ Flex Purification System (Thermo Fisher Scientific)

CE

IVD

REF 5012045

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1. About these instructions for use

These instructions for use guide the user in utilizing the ExtraStar® Purification Kit 2.0 in combination with the AltoStar® Internal Control 1.5 on the KingFisher™ Flex Purification System (Thermo Fisher Scientific).

The main operation steps of the KingFisher™ Flex Purification System and the AltoStar® Internal Control 1.5 during the purification procedure are described for comprehensibility.

For more detailed information about these products, refer to the respective instructions for use listed below:

- KingFisher™ Flex Purification System Manual (Thermo Fisher Scientific)
- Instructions for use AltoStar® Internal Control 1.5

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 ExtraStar® Purification Kit 2.0 uses magnetic particle technology and is intended to be used for the automated isolation and purification of nucleic acids from human respiratory swab specimens for *in vitro* diagnostic purposes.

The product is designed for use with the KingFisher™ Flex Purification System (Thermo Fisher Scientific) and altona Diagnostics kits and reagents specified for use with the ExtraStar® Purification Kit 2.0.

The ExtraStar® Purification Kit 2.0 is intended for use by professional users trained in molecular biological techniques and *in vitro* diagnostic procedures.

3. Kit content

The ExtraStar® Purification Kit 2.0 is shipped in 2 separate boxes **Box 1** and **Box 2** (see tables 1 and 2).

Table 1: Kit components **Box 1**

Component	Number of bottles	Volume per bottle [ml]
Lysis Buffer	2	120
Wash Buffer 1	2	100
Wash Buffer 2	2	100
Wash Buffer 3	2	100

Table 2: Kit components **Box 2**

Component	Number of bottles	Volume per bottle [ml]
Magnetic Beads	2	5
Elution Buffer	2	22
Enhancer	2	4

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, as product performance could be compromised.

The ExtraStar® Purification Kit 2.0 contains reagents sufficient for 384 sample purifications.

Upon receipt 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 any kit component has been compromised during shipment or is missing, contact altona Diagnostics technical support for assistance (see chapter 14. Technical support).

4. Storage and handling

All reagents included in the ExtraStar® Purification Kit 2.0 are ready-to-use solutions.

4.1 Storage

The ExtraStar® Purification Kit 2.0 is shipped at room temperature. **Box 1** has to be stored at +15 °C to +30 °C and **Box 2** has to be stored at +2 °C to +8 °C upon receipt (see table 3). The bottles must be stored in an upright position.

Table 3: Storage conditions for **Box 1** and **Box 2**

Storage conditions	
Box 1	**Box 2**
+15 °C to +30 °C	**+2 °C to +8 °C**

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 reagents of the ExtraStar® Purification Kit 2.0 are stable after initial opening for 14 days, when closed after each use and stored as follows: Magnetic Beads, Enhancer and Elution Buffer shall be closed with the original cap after use and stored at +2 °C to +8 °C. The Lysis Buffer and Wash Buffer 1, 2 and 3 shall be closed with the original cap after use and stored at +15 °C to +30 °C.

CAUTION

Do not leave reagents open in between 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 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 exceed handling durations as specified in these instructions for use, as this could compromise product performance.

CAUTION

Do not mix components from different kit lots, as this could compromise product performance.

NOTE

The Lysis Buffer may crystalize at low temperature. If crystals occur, the Lysis Buffer bottle should be heated with careful pivoting (≤ +50 °C, e.g., in a water bath) until the crystals are completely dissolved (up to 30 min).

NOTE

The Magnetic Beads should be shaken well before use (e.g., vortex for 60 seconds).

NOTE

Slight colour changes may occur to the Lysis Buffer. These slight changes in colour do not indicate a change in the quality of the buffer.

5. Product description

Table 4: Components of the ExtraStar® Purification Kit 2.0

Kit component	Description
Lysis Buffer	The **Lysis Buffer** contains chaotropic salts and surfactants (guanidine thiocyanate, octoxynol) to disrupt cells or virions chemically. It stabilizes nucleic acids and protects them against nucleases in solution.
Wash Buffer 1	**Wash Buffer 1** contains different salts and organic solvents (guanidine thiocyanate and ethanol) to remove proteins and other impurities.
Wash Buffer 2	**Wash Buffer 2** contains organic solvents (ethanol) to remove proteins and other impurities.
Wash Buffer 3	**Wash Buffer 3** contains different salts in order to purify the nucleic acids.
Enhancer	The **Enhancer** stabilizes and protects nucleic acids against nucleases in solution.
Magnetic Beads	The **Magnetic Beads** are coated with a thin layer of silica to bind free nucleic acids in solution. The magnetic characteristic allows the separation of beads from liquids in a magnetic field.
Elution Buffer	The **Elution Buffer** is a low-salt buffer to release the nucleic acids from the Magnetic Beads for subsequent analysis.

5.1 Principle of method

The ExtraStar® Purification Kit 2.0 is intended for the automated isolation and purification of nucleic acids from specified human specimens (see chapter 6. Sample types) for *in vitro* diagnostic purposes in conjunction with the KingFisher™ Flex Purification System, the AltoStar® Internal Control 1.5 and altona Diagnostics kits and reagents specified for use with the ExtraStar® Purification Kit 2.0. The ExtraStar® Purification Kit 2.0 is based on magnetic bead technology, utilizing silica coated magnetic particles, which can bind and release nucleic acids under specific conditions [1,2,3].

The purification procedure comprises 3 automated steps on the KingFisher™ Flex Purification System (see figure 1).

1. In the first step nucleic acids are released by chemical and mechanical lysis under chaotropic high salt conditions. The conditions stabilize the nucleic acids in solution and enable their binding to the magnetic silica beads.
2. In the following washing steps different wash buffers are used to remove proteins and other impurities.
3. Finally, the nucleic acids are released from the magnetic beads with an elution buffer into the eluate plate.

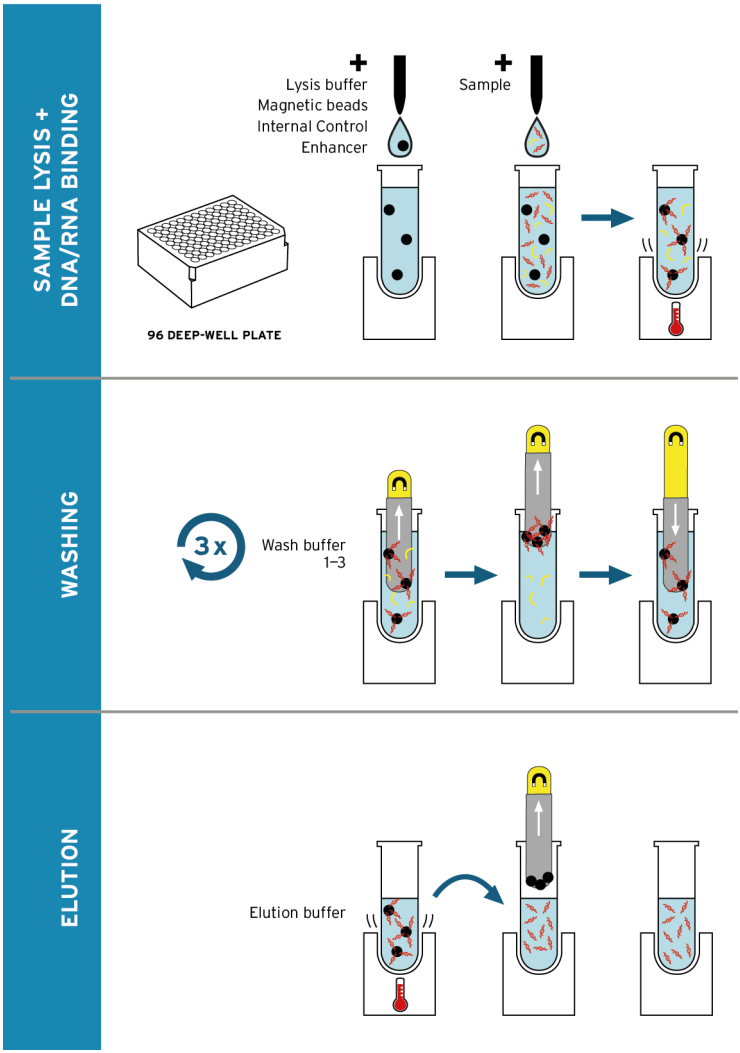

Figure 1: Illustration of the purification procedure using the KingFisher™ Flex Purification System

6. Sample types

The following sample type is validated for use with the ExtraStar® Purification Kit 2.0:

- Human respiratory swabs in transport medium

CAUTION

Do not use other sample types! The use of other sample types could compromise product performance.

NOTE

Frozen storage of samples does not compromise kit performance. When working with frozen samples, make sure samples are completely thawed and properly mixed before use.

NOTE

For information regarding collection, handling and storage of samples refer to the instructions for use of altona Diagnostics kits and reagents specified for use with the ExtraStar® Purification Kit 2.0.

7. Warnings, precautions and limitations

Lysis Buffer		
 GHS05	H302+H312+H332	Harmful in contact with skin or if inhaled or swallowed.
	H314	Causes severe skin burns and eye damage.
	H411	Toxic to aquatic life with long lasting effects.
	EUH032	Contact with acids liberates very toxic gas.
	EUH071	Corrosive to the respiratory tract.
 GHS07	P260	Do not breathe mist, vapours, spray.
	P264	Wash hands thoroughly after handling.
	P273	Avoid release to the environment.
	P280	Wear protective clothing, eye protection, face protection, protective gloves.
 GHS09 **Danger!**	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
	P310	Immediately call a POISON CENTER, a doctor.
	Contains:	Guanidine thiocyanate (CAS 593-84-0) 50–70 %.
		Alkylphenol ethoxylat (CAS 9036-19-5) 10–20 %.

Wash Buffer 1		
 GHS02	H226	Flammable liquid and vapour.
	H314	Causes severe skin burns and eye damage.
	H412	Harmful to aquatic life with long lasting effect.
	EUH032	Contact with acids liberates very toxic gas.
	EUH071	Corrosive to the respiratory tract.
 GHS05	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P260	Do not breathe mist, vapours, spray.
	P273	Avoid release to the environment.
Danger!	P280	Wear protective clothing, eye protection, face protection, protective gloves.
	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
	P310	Immediately call a POISON CENTER, a doctor.
	Contains:	Guanidine thiocyanate (CAS 593-84-0) 25–50 %.
		Ethanol (CAS 64-17-5) 25–50 %.

Wash Buffer 2		
 GHS02	H226	Flammable liquid and vapour.
	H319	Causes serious eye irritation.
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
 GHS07	P280	Wear protective clothing, eye protection, face protection, protective gloves.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+P313	If eye irritation persists: Get medical advice/attention.
Danger!	**Contains:**	Ethanol (CAS 64-17-5) 50–70 %.

Enhancer		
 GHS05	H314	Causes severe skin burns and eye damage.
	P260	Do not breathe mist, vapours, spray.
	P280	Wear protective clothing, eye protection, face protection, protective gloves.
Danger!	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P310	Immediately call a POISON CENTER, a doctor.
	Contains:	Tris(2-carboxyethyl)phosphine (CAS 51805-45-9) 10–20 %.

NOTE

For more information, consult the safety data sheets (SDSs).

- 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, as 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 leave reagents open in between 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 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 exceed handling durations as specified in these instructions for use, as this could compromise product performance.
- Do not mix components from different kit lots, as this could compromise product performance.
- Do not use other sample types! The use of other sample types could compromise product performance.
- Do not fill more volume into plate wells as specified, as this could lead to cross-contamination and could compromise product performance.
- Always use the correct sample volume when preparing the lysis sample plate, otherwise the product performance could be compromised.

- Always fill the correct buffer into the corresponding buffer plate. Mix up of buffers could compromise product performance.
- Always check for enough buffers for each sample before starting the experiment. The use of less buffer volume than specified could compromise product performance.
- Always use the correct KingFisher™ programming for extraction process, as other settings could lead to cross-contamination and could compromise product performance.
- Make sure to fill the corresponding well positions on each plate. Do not mix up sample and buffer positions on the plate wells as this could compromise product performance.
- Do not mix up well plates and plate orientation while loading the KingFisher™. Incorrect loading of plates could compromise product performance.
- Calcium alginate swabs, swabs with wooden shafts and/or cotton tips as well as swabs containing jelly agar may reduce extraction performance.
- Improper preparation of reagents (e.g., Lysis Buffer and Magnetic Beads) may cause invalid or false negative results.
- Do not interchange bottle caps when closing product components after use to avoid contamination of reagents, which could compromise product performance.
- Do not use samples which contain solids and high-viscosity constituents, as this could compromise product performance.
- Storage of eluates under wrong conditions may lead to loss of eluate volume and/or degradation of the pathogen specific target sequence and could compromise product performance.
- 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.

8. Using the ExtraStar® Purification Kit 2.0

The following chapters describe the use of the ExtraStar® Purification Kit 2.0.

8.1 Sample volume

The ExtraStar® Purification Kit 2.0 allows purification of 300 µl sample.

CAUTION

Do not fill more volume into plate wells as specified, as this could lead to cross-contamination and could compromise product performance.

CAUTION

Always use the correct sample volume when preparing the lysis sample plate, otherwise the product performance could be compromised.

8.2 Material and devices required but not provided

- Nucleic acid extraction and PCR amplification and detection control AltoStar® Internal Control 1.5 (altona Diagnostics Ordner No. IC15-46)
- Thermo Fisher Scientific KingFisher™ 96 Flex with 96 deep-well magnet and heating block with Thermo Fisher Scientific BindIt™ 4.0 Software or higher (Thermo Fisher Scientific Order No. 5400630)
- 4x KingFisher™ 96 deep-well plate (Thermo Fisher Scientific Order No. 95040450)
- 1x KingFisher™ 96 tip comb for deep-well magnets (Thermo Fisher Scientific Order No. 97002534)
- 2x KingFisher™ 96 plate 200 µl (Thermo Fisher Scientific Order No. 97002540)

NOTE

Ensure that all instruments used have been installed, calibrated, checked and maintained according to the manufacturer's instructions and recommendations.

8.3 General material and devices

- Vortex mixer
- Powder-free gloves (disposable)
- Pipettes (adjustable, for reagent and sample preparation)
- Pipette tips with filters (disposable, for sample preparation)
- *Optional:* stepper pipette (adjustable, for reagent preparation) and suitable tips (disposable)

9. Purification using the ExtraStar® Purification Kit 2.0 in combination with the KingFisher™ Flex

For first use, a method specified for the sample type must be created using Thermo Scientific™ BindIt™ 4.0 Software or higher for KingFisher™ instruments. This method can be used on the instrument as a stand-alone unit or with a connected PC. For use of BindIt™ Software and programming, refer to the relevant user manual of the device.

Table 5: KingFisher™ program for ExtraStar® Purification Kit 2.0 extraction

KingFisher™ program for ExtraStar® Purification Kit 2.0 extraction			
Lysis sample plate		**96 deep-well plate**	
Name	**Well volume [µl]**	**Total reagent volume [µl]**	**Type**
Lysis Buffer	500	-	Reagent
Magnetic Beads	25	-	Reagent
Enhancer	20	-	Reagent
AltoStar® Internal Control 1.5	50	-	Reagent
Sample	300	-	Sample

KingFisher™ program for ExtraStar® Purification Kit 2.0 extraction			
Wash 1 plate		**96 deep-well plate**	
Name	**Well volume [µl]**	**Total reagent volume [µl]**	**Type**
Wash Buffer 1	500	-	Reagent
Wash 2 plate		**96 deep-well plate**	
Name	**Well volume [µl]**	**Total reagent volume [µl]**	**Type**
Wash Buffer 2	500	-	Reagent
Wash 3 plate		**96 deep-well plate**	
Name	**Well volume [µl]**	**Total reagent volume [µl]**	**Type**
Wash Buffer 3	500	-	Reagent
Eluate plate		**96 standard plate**	
Name	**Well volume [µl]**	**Total reagent volume [µl]**	**Type**
Elution Buffer	100	-	Reagent
Comb plate		**96 standard plate**	
Name	**Well volume [µl]**	**Total reagent volume [µl]**	**Type**
-	-	-	-

CAUTION

Always fill the correct buffer into the corresponding buffer plate. Mix up of buffers could compromise product performance.

CAUTION

Always check for enough buffers for each sample before starting the experiment. The use of less buffer volume than specified could compromise product performance.

CAUTION

Do not fill more volume into plate wells as specified, as this could lead to cross-contamination and could compromise product performance.

Table 6: Protocol

KingFisher™ protocol for ExtraStar® Purification Kit 2.0 extraction		
Tip 1	**96 deep-well tip comb**	
Pick-up	**Comb plate**	
Lysis	**Lysis sample plate**	
Beginning of step	Precollect	No
	Release time, speed	No
Mixing/heating	Shake 1 time, speed	00:00:30, slow
	Shake 2 time, speed	00:00:10, bottom mix
	Loop count	10
	Heating temperature [°C]	56
	Preheat	Yes
	Heating during mixing	Yes
End of step	Postmix	No
	Collect count	4
	Collect time [s]	1
Wash 1	**Wash 1 plate**	
Beginning of step	Precollect	No
	Release time, speed	00:00:10, slow
Mixing/heating	Shake 1 time, speed	00:00:30, slow
	Shake 2 time, speed	00:00:10, bottom mix
	Loop count	4
	Heating during mixing	No

End of step	Postmix	No
	Collect count [s]	3
	Collect time [s]	0
Wash 2	**Wash 2 plate**	
Beginning of step	Precollect	No
	Release time, speed	00:00:05, fast
Mixing/heating	Shake 1 time, speed	00:00:05, slow
	Shake 2 time, speed	00:00:30, bottom mix
	Loop count	3
	Heating during mixing	No
End of step	Postmix	No
	Collect count	3
	Collect time [s]	0
Wash 3	**Wash 3 plate**	
Beginning of step	Precollect	No
	Release time, speed	00:00:05, fast
Mixing/heating	Shake 1 time, speed	00:00:05, slow
	Shake 2 time, speed	00:00:30, bottom mix
	Loop count	2
	Heating during mixing	No
End of step	Postmix	No
	Collect count	3
	Collect time [s]	0
Elution	**Eluate plate**	
Beginning of step	Precollect	No
	Release time, speed	00:00:10, medium

Mixing/heating	Mixing time, speed	00:10:00, slow
	Heating temperature [°C]	70
	Preheat	No
	Heating during mixing	Yes
End of step	Postmix	No
	Collect count	3
	Collect time [s]	0
Leave	**Wash 2 plate**	

CAUTION

Always use the correct KingFisher™ programming for extraction process, as other settings could lead to cross-contamination and could compromise product performance.

9.1 Transport medium (swab rinse)

1. Make sure that the method (see table 5) is programmed and installed on the KingFisher™ Flex.
2. Prepare an empty standard plate (KingFisher™ 96 plate 200 µl) with a 96 deep-well tip comb.
3. Prepare the wash 1 plate (KingFisher™ 96 deep-well plate) by adding 500 µl Wash Buffer 1 into each well in use.
4. Prepare the wash 2 plate (KingFisher™ 96 deep-well plate) by adding 500 µl Wash Buffer 2 into each well in use.
5. Prepare the wash 3 plate (KingFisher™ 96 deep-well plate) by adding 500 µl Wash Buffer 3 into each well in use.
6. Prepare the eluate plate (KingFisher™ plate 200 µl) by adding 100 µl Elution Buffer into each well in use.
7. Sample preparation for transport medium (swab rinse):

   Prepare the Lysis sample plate (KingFisher™ 96 deep-well plate) by adding in following order into each well in use:

   - 500 µl Lysis Buffer

- 25 µl of well mixed (e.g., 60 seconds shaked or votexed) Magnetic Beads
- 20 µl of Enhancer solution
- 50 µl AltoStar® Internal Control 1.5: add the IC directly into the liquid and avoid hanging drops on the deep well side.
- **300 µl of sample (e.g., viral transport medium)**

8. Start the extraction method immediately and follow the instructions by placing the plates into the instrument.
9. Start the run (it takes approximately 30 min to finish).
10. After finishing the run use the eluate plate for PCR process.

CAUTION

Always fill the correct buffer into the corresponding buffer plate. Mix up of buffers could compromise product performance.

CAUTION

Always check for enough buffers for each sample before starting the experiment. The use of less buffer volume than specified could compromise product performance.

CAUTION

Do not fill more volume into plate wells as specified, as this could lead to cross-contamination and could compromise product performance.

CAUTION

Make sure to fill the corresponding well positions on each plate. Do not mix up sample and buffer positions on the plate wells as this could compromise product performance.

CAUTION

Do not mix up well plates and plate orientation while loading the KingFisher™. Incorrect loading of plates could compromise product performance.

CAUTION

Calcium alginate swabs, swabs with wooden shafts and/or cotton tips as well as swabs containing jelly agar may reduce extraction performance.

CAUTION

Improper preparation of reagents (e.g., Lysis Buffer and Magnetic Beads) may cause invalid or false negative results.

CAUTION

Do not interchange bottle caps when closing product components after use to avoid contamination of reagents, which could compromise product performance.

CAUTION

Do not use samples which contain solids and high-viscosity constituents, as this could compromise product performance.

CAUTION

Always use the correct sample volume when preparing the lysis sample plate, otherwise the product performance could be compromised.

9.1.1 Eluate stability

After completion of the purification run the eluates in the unsealed eluate plate are stable at room temperature (max. +30 °C) for a total of 4 hours.

CAUTION

Storage of eluates under wrong conditions may lead to loss of eluate volume and/or degradation of the pathogen specific target sequence and could compromise product performance.

10. Performance data

The performance of the ExtraStar® Purification Kit 2.0 is verified in conjunction with each altona Diagnostics real-time PCR kit or reagent specified for use with the ExtraStar® Purification Kit 2.0. For information on performance data, refer to the instructions for use of the respective altona Diagnostics real-time PCR kit or reagent.

11. 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 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.

NOTE

Liquid waste and any liquids containing Lysis Buffer or Wash Buffer 1 contain guanidine thiocyanate, which can form toxic, highly reactive and volatile compounds when combined with bleach or strong acids.

12. Quality control

In accordance with the altona Diagnostics GmbH EN ISO 13485-certified Quality Management System, each lot of ExtraStar® Purification Kit 2.0 is tested against predetermined specifications to ensure consistent product quality.

13. Troubleshooting guide

Problem: precipitate in reagent

Possible cause	Suggestions
Storage of the Lysis Buffer at low temperature or prolonged storage	If the Lysis Buffer bottle is already opened, make sure to close it with the same lid. Heat the Lysis Buffer bottle (≤ +50 °C, e.g., in a water bath) with careful intermittent pivoting until the precipitates are completely dissolved.
Excessive evaporation due to improper use and/or closing may lead to increased salt concentration in reagents	Discard the reagent. Make sure to always close the reagent bottles immediately after use.

Problem: low yield or purity of nucleic acids

Possible cause	Suggestions
Storage of reagents under wrong conditions	Discard reagents. Make sure to store the product components under defined storage conditions (see chapter 4. Storage and handling).
Reagents were not closed and/or stored properly in between use	Discard reagents. Make sure to store the product components under defined storage conditions (see chapter 4. Storage and handling). Make sure to always close the reagent bottles immediately after use.
Improper preparation of samples	Make sure to prepare samples according to the instructions in chapter 9.1 Transport medium (swab rinse).
Frozen samples were not thawed or mixed properly	Make sure samples are completely thawed and properly mixed before use.
Incomplete sample lysis	Before use, check that the Lysis Buffer does not contain precipitates. If the Lysis Buffer bottle is already opened, make sure to close the bottle with the corresponding lid and heat the bottle (≤ +50 °C, e.g., in a water bath) with careful intermittent pivoting until the precipitates are completely dissolved.

Possible cause	Suggestions
Mix up of buffers while filling the plates or mix up of buffer plates while loading the KingFisher™	Make sure to fill the correct buffers into the corresponding plates and load the plates according to the instructions of the method shown in KingFisher™ display.
High sample viscosity or solids in the sample	Make sure to prepare samples according to chapter 9.1 Transport medium (swab rinse).

14. 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.

15. Literature

[1] Mark A. Lever, Andrea Torti, Philip Eickenbusch, Alexander B. Michaud, Tina Šantl-Temkiv, and Bo Barker Jørgensen: A modular method for the extraction of DNA and RNA, and the separation of DNA pools from diverse environmental sample types; Front Microbiol. 2015; 6: 476.

[2] Sonja Berensmeier: Magnetic particles for the separation and purification of nucleic acids; Appl Microbiol Biotechnol 2006 73:495–504.

[3] Peter E. Vandeventer, Jessica S. Lin, Theodore J. Zwang, Ali Nadim, Malkiat S. Johal, and Angelika Niemz: Multiphasic DNA Adsorption to Silica Surfaces under Varying Buffer, pH, and Ionic Strength Conditions; J Phys Chem B. 2012 May 17; 116(19): 5661–5670.

16. Trademarks and disclaimers

AltoStar®, ExtraStar®, RealStar® (altona Diagnostics GmbH); BindIt™, KingFisher™ (Thermo Fisher Scientific).

Registered names, trademarks, etc. used in this document, even if not specifically marked as such, are not to be considered unprotected by law.

The ExtraStar® Purification Kit 2.0 is a CE-marked product according to the European *in vitro* diagnostic Regulation (EU) 2017/746.

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

Not available in all countries.

17. Symbols

Symbol	Explanation
IVD	*In vitro* diagnostic medical device
GTIN	Global Trade Item Number
LOT	Batch code
CONT	Content
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

Symbol	Explanation
	Material number
	Version
	Note
	Unique formula identifier

18. Revision history

Table 7: Revision history

Identifier	Date of issue [month/year]	Modifications
MAN-5012040-EN-S01	12/2022	Initial release

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always a drop ahead.

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