

EUROArray SwiftX-traction

(REF: SXEA-50-IVD)

Instructions for Use

Content

Intended use	2
Principles of the method	2
Content of the kit	2
Equipment to be provided by the user	2
Storage and shelf life	3
Warnings and precautions	3
Sample types and their collection, handling, and storage	3
Overview of sample-specific extraction procedures	4
DNA extraction from solid specimens	5
DNA extraction from urine	6
DNA extraction from liquid-based cytology media	7
Performance data	8
Limitations	8
Literature references	8
Key to symbols	9
General remark	9

Intended use

EUROArray SwiftX-traction is intended to be used for manual extraction of DNA of fungi, bacteria, parasites, viruses and human epithelial cells from skin, hair, nails, culture material, dry swabs, urine, liquid-based cytology media, and FFPE tissue. For professional use only.

Principles of the method

EUROArray SwiftX-traction is designed for rapid extraction of DNA from various pathogens. The different components of EUROArray SwiftX-traction have specific functionalities within the workflow of DNA extraction.

Buffer EN stabilizes biological cells during the cell capturing step and enables efficient binding of a wide range of cells to the paramagnetic particles.

Buffer EAL enables an efficient lysis of viruses, bacteria, protozoa, and human cells. Buffer EAL is fully compatible with the EUROArray diagnostic platform.

The use of **Proteinase K** enhances the lysis efficiency of Buffer EAL especially for fungal cells as well as for sample types such as skin, hair, nails, and FFPE tissue.

The paramagnetic particles **Beads A** show a broad binding property to cells and proteins. This effect is leveraged in two ways during the extraction process. Firstly, Beads A enable a species-independent concentration of cells from liquid specimens. Secondly, during and after heat lysis, Beads A are utilized to remove cell debris and other particulate matter from the lysis mixture.

Content of the kit

Buffer EN
Buffer EAL
Proteinase K
Beads A

Equipment to be provided by the user

For performance of the nucleic acid extraction procedure, the following laboratory equipment is required and needs to be provided by the user:

- Appropriate personal protective equipment
- Pipets and disposable pipet tips (aerosol barrier tips are recommended)
- 1.5ml microcentrifuge tubes with safe lock-caps (EUROIMMUN, REF: ZG 0614-0101)
- Magnetic stand (EUROIMMUN, REF: ZM 0224-0101 or ZM 0225-0101)
- Vortexer, Mini spinner
- Heating block

Storage and shelf life

EUROArray SwiftX-traction kits must be stored at 2 °C to 8 °C. Reagents are good to be used until the expiry date indicated on the label. Do not use reagents after their indicated expiry date.

After first use, EUROArray SwiftX-traction kits are good to be used within 3 months.

Warnings and precautions

EUROArray SwiftX-traction comprises a Proteinase K solution, which is considered a hazardous substance. The Safety Data Sheet (SDS) is available upon request. The following hazard and precaution statements apply:

Proteinase K:

Danger.



H315	Causes skin irritation.
H319	Causes serious eye irritation.
P264	Wash respective body parts after accidental contact.
P280	Wear protective gloves, eye, and face protection.

Take care when working with biological samples and always treat them as potentially infectious. Users are advised to always wear appropriate personal protective equipment.

Be aware that the sample mixture remains potentially infectious until the heat lysis is conducted. Consequently, supernatants of cell capturing and washing steps must be treated as such.

Nucleic acid extracts can be disposed of with regular laboratory waste. Please take your national regulations for waste sorting and treatment into consideration.

Make sure to work with clean equipment and use pipette tips with aerosol barriers to avoid carryover of specimens or nucleic acid extracts between samples.

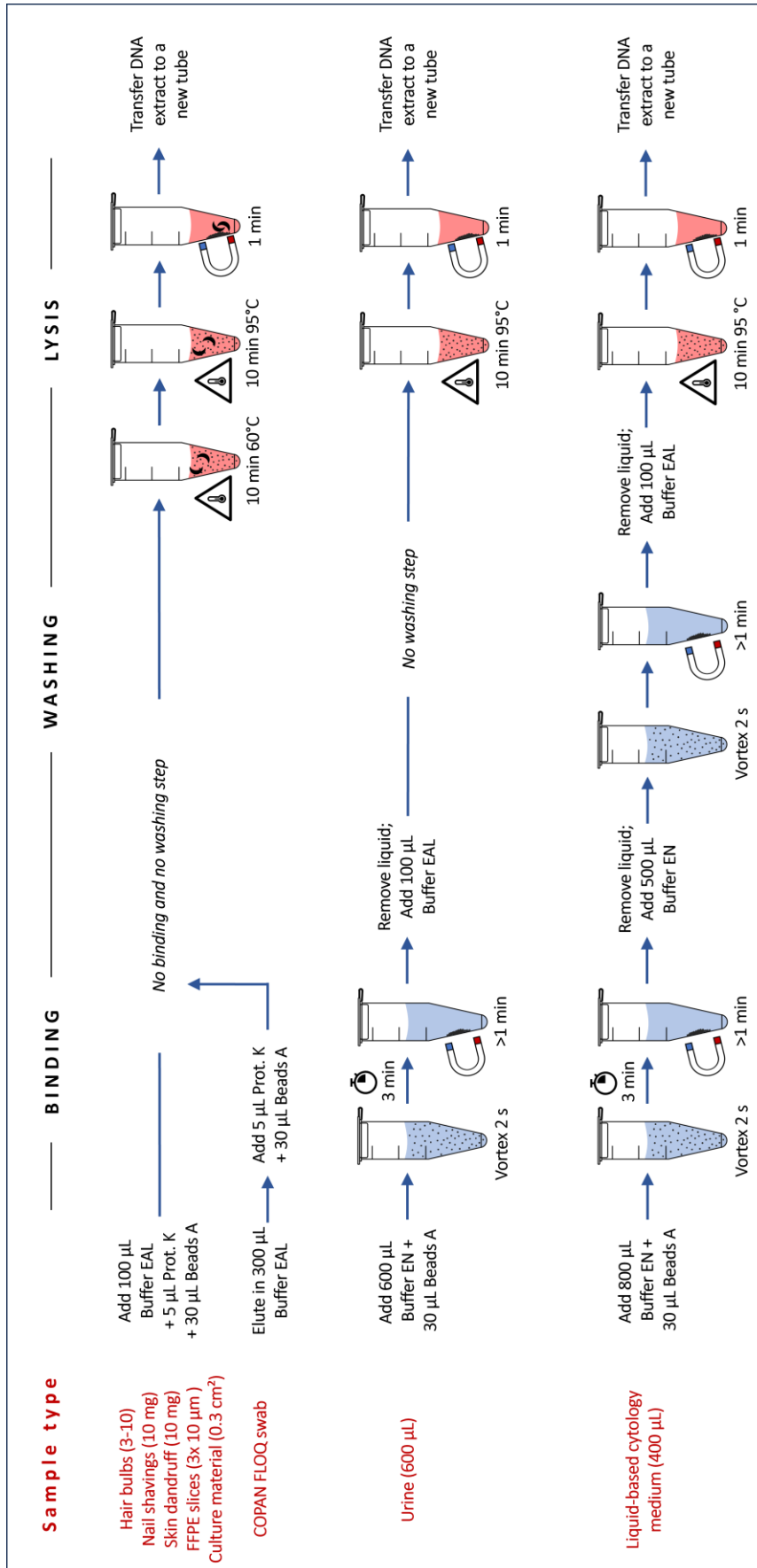
Sample types and their collection, handling, and storage

EUROArray SwiftX-traction has been validated for the following sample types:

Sample type	Recommended amount
Skin dandruff	approx. 10 mg
Hair bulbs	3 to 10
Nail shavings	approx. 10 mg
FFPE tissue	three 10 µm-slices
Culture material	approx. 0.3 cm ² (avoid transfer of any culture medium)
Dry COPAN FLOQ swab	1
Urine	600 µL
Liquid-based cytology medium	400 µL

For sample collection, handling, and storage, please refer to the Instructions for Use of EUROArray Dermatomycosis, EUROArray HPV, and EUROArray STI.

Overview of sample-specific extraction procedures



DNA extraction from solid specimens

This protocol describes the workflow of DNA extraction from skin, hair, nail, dry swabs, culture material, and FFPE tissue. See section [Sample types](#) for more information.

To do before starting

- Set the heating block to 60 °C.
- If available, set a second heating block to 95 °C.
- Shake or vortex Beads A for 30 seconds to homogenize the particle suspension.

1. **Place your sample material in a 1.5 mL microtube with safe lock-cap.**
2. **The volume of Buffer EAL is selected depending on the sample material to be extracted:**
 - a. **Dry COPAN FLOQ swab:** add 300 µL of Buffer EAL to the microtube and elute swabbed material by swirling against the tube wall for 10 seconds and dispose of the swab.
 - b. **All others:** add 100 µL of Buffer EAL to the microtube.

Important: If **culture material** is extracted then **avoid the carry-over of culture medium** into the microtube.

3. **Add 5 µL of Proteinase K and 30 µL of Beads A and vortex for 2 seconds. Ensure all liquid is collected at the bottom of the microtube. Spin the microtube briefly if necessary.**
4. **Incubate microtube in a heating block at 60 °C for 10 minutes. Samples can be shaken if a thermo-shaker is used.**
5. **Incubate microtube in a heating block at 95 °C for 10 minutes. Samples can be shaken if a thermo-shaker is used.**
6. **Remove microtube from heating block and mix well for 2 seconds. Remove condensate from the lid by spinning the tube briefly.**
7. **Place microtube in a magnetic stand for 1 minute.**
8. **Do not remove the microtube from the magnetic stand! Use the supernatant directly for the EUROArray analysis or transfer to a new microtube.**

Important: If **FFPE samples** are extracted, use a pipette tip to **remove the thin wax layer** on top of the lysate and dispose of the tip **before transferring the supernatant**.

Extracts can be stored for up to 7 days at 4 - 8 °C or up to 4 weeks at -20 °C.

Note: If DNA samples are not directly used, mix them by vortexing for 2 seconds before use for EUROArray analysis.

DNA extraction from urine

This protocol describes the workflow of DNA extraction from urine. This protocol includes a cell binding step before the actual DNA extraction.

To do before starting:

- Set the heating block to 95 °C.
 - Shake or vortex Beads A for 30 seconds to homogenize the particle suspension.
1. **Add 600 µL of Buffer EN and 30 µL of Beads A to a 1.5 mL microtube with safe lock-cap.**
 2. **Add 600 µL of urine and mix well by pipetting up and down or by vortexing for 5 seconds. Ensure that no liquid is resting at the tube lid.**
 3. **Incubate microtube at room temperature for 3 minutes.**
 4. **Place microtube in a magnetic stand for 1 minute.**
 5. **Open the microtube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**
 6. **Add 100 µL of Buffer EAL to the microtube and resuspend the Beads A by vortexing for 5 seconds. Ensure all liquid is collected at the bottom of the tube.**
 7. **Incubate microtube in a heating block at 95 °C for 10 minutes. Samples can be shaken if a thermo-shaker is used.**
 8. **Remove microtube from heating block and mix well for 2 seconds. Remove condensate from the lid by spinning the tube briefly.**
 9. **Place microtube in a magnetic stand for 1 minute.**
 10. **Do not remove the microtube from the magnetic stand! Use the supernatant directly for the EUROArray analysis or transfer to a new microtube.**

Extracts can be stored for up to 7 days at 4 - 8 °C or up to 4 weeks at -20 °C.

Note: If DNA samples are not directly used, mix them by vortexing for 2 seconds before use for EUROArray analysis.

DNA extraction from liquid-based cytology media

This protocol describes the workflow of DNA extraction from liquid-based cytology media (LCM), such as ThinPrep or PreserveCyt. This protocol includes a cell binding step before the actual DNA extraction.

To do before starting

- Set the heating block to 95 °C.
 - Shake or vortex Beads A for 30 seconds to homogenize the particle suspension.
1. **Add 800 µL of Buffer EN and 30 µL of Beads A to a 1.5 mL microtube with safe lock-cap.**
 2. **Add 400 µL of LCM and mix well by pipetting up and down or by vortexing for 5 seconds. Ensure that no liquid is resting at the tube lid.**
 3. **Incubate microtube at room temperature for 3 minutes.**
 4. **Place microtube in a magnetic stand for 1 minute.**
 5. **Open the microtube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**
 6. **Add 500 µL of Buffer EN and mix well by pipetting up and down or by vortexing for 2 seconds. Ensure that no liquid is sitting at the tube lid. Spin the tube briefly if necessary.**
 7. **Place microtube in a magnetic stand for 1 minute.**
 8. **Open the microtube while remaining in the magnetic stand. Remove and discard the supernatant by pipetting.**
 9. **Add 100 µL of Buffer EAL to the microtube and resuspend the Beads A by vortexing for 5 seconds. Ensure all liquid is collected at the bottom of the tube.**
 10. **Incubate microtube in a heating block at 95 °C for 10 minutes. Samples can be shaken if a thermo-shaker is used.**
 11. **Remove microtube from heating block and mix well for 2 seconds. Remove condensate from the lid by spinning the tube briefly.**
 12. **Place microtube in a magnetic stand for 1 minute.**
 13. **Do not remove the microtube from the magnetic stand! Use the supernatant directly for the EUROArray analysis or transfer to a new microtube.**

Extracts can be stored for up to 7 days at 4 - 8 °C or up to 4 weeks at -20 °C.

Note: If DNA samples are not directly used, mix them by vortexing for 2 seconds before use for EUROArray analysis.

Performance data

The performance of EUROArray SwiftX-traction was determined using a total of 207 clinical samples. The number of samples is distributed across all sample types for which EUROArray SwiftX-traction is intended to be used. The diagnostic results were determined using the EUROArray Dermatomycosis Assay, STI Assay and HPV Assay. Comparative data for other DNA extraction methods were available for a total of 81 samples. In all cases, the results were in full agreement (100% clinical sensitivity and 100% clinical specificity). Individual pathogens for which no positive material was available were either assessed using commercial reference material spiked into different sample types or had already been tested in previous studies. It can therefore be concluded that EUROArray SwiftX-traction was successfully evaluated for all sample types and pathogens specified in the intended use statement.









Limitations

- Transport media with high content of salts, e.g. guanidine hydrochloride, such as eNAT® are not compatible with EUROArray SwiftX-traction.

Literature references

- Grody WW, Nakamura RM, Strom CM, Kiechle FL (2010). “Molecular Diagnostics: Techniques and Applications for the Clinical Laboratory”. ISBN 978-0-12-369428-7.
- Shalon *et al.* (1996) “A DNA microarray system for analyzing complex DNA samples using two-color fluorescent probe hybridization”. *Genome Res.* 6 (7): 639–645.
- Gräser Y, Czaika V, Ohst T (2012) “Diagnostic PCR of dermatophytes – an overview”. *J Dtsch Dermatol Ges* 10: 721-726.
- Munoz *et al.* (2003) “International Agency for Research on Cancer Multicenter Cervical Cancer Study Group. Epidemiologic classification of human papillomavirus types associated with cervical cancer”. *N Engl J Med* 348 (2003) 518-527.
- World Health Organization: Laboratory diagnosis of sexually transmitted infections, including human immunodeficiency virus. 2013.

Key to symbols

	For in-vitro diagnostic use
	Catalog number
	Number of extractions
	Storage temperature
	Batch number
	Expiry date
	Read Instructions for Use
	Legal manufacturer

General remark

Please be reminded that any serious incident that has occurred in relation to the use of EUROArray SwiftX-traction shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the affected patient is located.

Legal manufacturer

Xpedite Diagnostics GmbH

Lilienthalstr. 2a
85399 Hallbergmoos
Germany

Phone: +49-811-998538-10

E-Mail: info@xpedite-dx.com

Web: www.xpedite-dx.com