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For general laboratory use.

MagNA Pure cfNA Buffer Set

Buffer set to isolate cell-free nucleic acids (cfNA) from up to 4 mL of plasma samples

Cat. No. 07 794 398 001 Set for up to 96 isolations

Version 01
Content version: August 2016
Store the kit at +15 to +25°C
Store protected from light

1. What this Product Does

Contents

Vial/ Bottle	Cap	Label	Function	Content
1	green	cfNA Enhancement and Lysis Buffer	Creates chaotropic environment for binding of cfNA to MGPs.	2 bottles, 100 mL each
2	white	Proteinase K	Removes protein contaminants.	1 bottle, 27 mL
3	red	Isopropanol	Enhances binding to MGPs.	1 bottle, 50 mL

Storage and Stability

Storage conditions (Product)

When stored at +15 to +25°C, the set is stable through the expiration date printed on the label.

Once the set is opened, store the components at +15 to +25°C for up to four weeks.

Additional Equipment and Reagents Required

- Standard Laboratory Equipment
- Sterile, tight-fitting caps, tubes, and containers to prepare the cfNA buffer mix
- Pipettes with disposable, positive-displacement tips
- Nuclease-free, aerosol-resistant pipette tips

Application

The MagNA Pure cfNA Buffer Set is a set of reagents intended for general laboratory use to enable the isolation of cell-free nucleic acids.

Preparation Time

For 24 Samples	Time [min]
Hands-on time	20
Total Preparation Time	**45**

2. How to Use this Product

2.1 Before You Begin

Precautions

- The kit reagents contain dangerous or hazardous substances. Do not allow this reagent to touch the skin, eyes, or mucous membranes. If contact does occur, wash the affected area immediately with large amounts of water. If the reagents are spilled, dilute the spill with water before wiping it up.
- Guanidine hydrochloride in cfNA Enhancement and Lysis Buffer (CELB) is an irritant. Always wear gloves and follow standard safety precautions to minimize contact when handling.
- Good laboratory practice is essential to the proper performance of this reagent set. Avoid microbial and nuclease contamination of reagents when removing aliquots from reagent bottles. Use sterile disposable pipette tips.
- Closely follow procedures and guidelines provided to ensure proper performance. Any deviation from the procedures and guidelines may affect optimal performance.
- False-positive results may occur if carryover of samples is not adequately controlled during sample handling and processing.
- Do not allow CELB to mix with sodium hypochlorite found in commercial bleach solutions. This mixture can produce a highly toxic gas.

Laboratory Procedures

- All human sourced material and all resulting waste should be considered potentially infectious and should be handled with universal precautions. Thoroughly clean and disinfect all work surfaces with disinfectants recommended by the local authorities.
- Do not eat, drink, or smoke in the designated work area.
- Do not pipette by mouth.
- Wear laboratory gloves, laboratory coats, and eye protection when handling samples and reagents. Gloves must be changed between handling samples and the MagNA Pure cfNA Buffer Set reagents to prevent contamination. Avoid contaminating gloves when handling samples and controls.
- Wash hands thoroughly after handling samples and MagNa Pure cfNA Buffer Set reagents, and after removing the gloves.

Waste Handling

- Safety Data Sheets (SDS) are available online at www.dialog.roche.com, or upon request from the local Roche office.
- Discard unused reagents and waste in accordance with country, federal, state, and local regulations.

Sample Material

The MagNA Pure cfNA Buffer Set is specifically designed to isolate cell-free nucleic acids from up to 4 mL of plasma samples.

Control Reactions

⚠ Always run appropriate controls.

To control the entire process, starting from sample preparation to analysis, perform the following controls:

- Positive control, by using a sample material positive for your target.
- Negative control, by using a sample material negative for your target.
- Internal control (IC), by adding a defined amount of a control template to all samples to be purified. If the template is previously purified nucleic acid, it should be added to the lysate to avoid degradation in the plasma.

For applications that could produce false negative results, add an IC to all samples, whenever possible.

2.2 Protocol

If you use a MagNA Pure System, follow the instructions provided in the Instructions for Use for isolation of cell free nucleic acid. If using another method, follow the instructions below.

Step 1

Prepare the plasma samples.
If the plasma samples have been stored frozen or contain residual white blood cells, centrifuge at 1,000 - 1,900 x *g* for 5 to10 minutes.

Step 2

Combine Proteinase K with plasma samples.
For each sample, add the following volume of Proteinase K to an appropriate lysis tube:

Reagent	2 mL Plasma Sample [µl]	4 mL Plasma Sample [µl]
Proteinase K	200	400

Add the plasma sample; avoid transferring any pellets. Mix gently. Incubate for 20 minutes at 37°C.

Step 3

Prepare cfNA buffer mix.
For each sample, add the following volumes to an appropriate container.

Follow the indicated order.

Reagent	2 mL Plasma Sample [mL]	4 mL Plasma Sample [mL]
cfNA Enhancement and Lysis Buffer (CELB)	1.75	3.5
Isopropanol	0.3	0.6

Cap and mix gently by inversion.

⚠ Avoid introducing foam/bubbles.

⚠ cfNA buffer mix must be prepared freshly before each use. The solution is stable for a maximum of 2 hours.

Step 4

Combine cfNA buffer mix with Proteinase K-treated samples.
For each sample, add the following volume of cfNA buffer mix.

Reagent	2 mL Plasma Sample [mL]	4 mL Plasma Sample [mL]
cfNA buffer mix	2.0	4.0

Mix thoroughly by dispensing and aspirating the liquid approximately 8 times to produce a homogenous mixture.

⚠ During all pipetting steps, avoid introducing air which can produce foam/bubbles.

⚠ Do not store the lysate.

Step 5

Nucleic Acid Purification: Proceed immediately to the nucleic acid purification method of choice.

Changes to Previous Version

First Version

Trademarks

MAGNA PURE is a trademark of Roche

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3. Troubleshooting

Issue	Possible cause	Recommendation
Liquid level detection failure on automated platforms.	Large amount of bubbles in solution/sample containing CELB	Be sure to pipette solutions down the inside wall of the tubes.
		Bubbles may be removed by aspiration into a pipette tip held near the side of the tube just above the surface of the liquid.
		Bubbles may be removed by capping tubes and centrifuging at 2,000 x *g* for 1 minute.
Inconsistent performance of nucleic acid extraction.	Insufficient mixing of cfNA buffer mix with samples due to viscosity.	For 4 mL samples, add 2 mL of cfNA buffer mix by "pulsing" (*i.e.*, pipetting up and down 6 times, without the introduction of air). Discard tip. Add the remaining 2 mL of cfNA buffer mix and mix in a similar fashion.
		After addition of cfNA buffer mix to samples, cap tubes and mix by gentle inversion (6 times) or on a roller device for approx. 2 minutes. Centrifuge briefly at 2,000 x *g* for 1 minute to remove any liquid from the inside of caps.

4. Supplementary Information

Text Conventions

To make information consistent and understandable, the following text conventions are used in this document:

Text Conventions	Use
Numbered Instructions labeled ❶, ❷, *etc.*	Steps in a procedure that must be performed in the order listed.
Asterisk *	Denotes a product available from Roche Diagnostics.

Symbols

In this document, the following symbols are used to highlight important information:

Symbol	Description
	Information Note: Additional information about the current topic or procedure.
⚠	Important Note: Information critical to the success of the procedure or use of the product.

Regulatory Disclaimer

For general laboratory use.

License disclaimer

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Safety Data Sheet

Please follow the instructions in the Safety Data Sheets (SDS).

Contact and Support

To ask questions, solve problems, suggest enhancements or report new applications, please visit our **Online Technical Support** Site.

To call, write, fax, or email us, visit **lifescience.roche.com** and select your home country to display country-specific contact information.

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