

ePure CFC DNA Extraction Kit

Instructions for Use (Handbook)



E2017



Version: 1.0



48

For *in vitro* diagnostic use



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Read and follow these Instructions for Use prior to using this product. The latest revision of this document can be found at www.ecolidx.com

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Intended Use

The ePure CFC DNA Extraction Kit utilizes magnetic bead technology for automated isolation and purification of circulating cell-free DNA (cfDNA) from cell-free samples, such as plasma, or from a pool of cell-free body fluids using the ePure system.

The product is intended for professional users, such as technicians and physicians trained in molecular biology techniques.

Introduction

Product Name	ePure CFC DNA Extraction Kit
Catalogue Number	E2017
Product Overview	The ePure CFC DNA Extraction Kit is designed to extract cfDNA from cell-free samples, such as plasma, or from a pool of cell-free body fluids using the ePure instrument. The kit is applied with magnetic bead technology, which achieves superior product quality, consistent and high product yield and reproducible results. The purified DNA is suitable for a wide range of diagnostic and research applications, including sequencing, genotyping and qPCR detection.
Applicable Instrument	ePure automated nucleic acid extraction system
Display Protocol Name on The Instrument	CFC DNA_1ml CFC DNA_2ml
Sample Volume	1 000 – 2 000 µl
Processing Time	Approx. 55–105 minutes

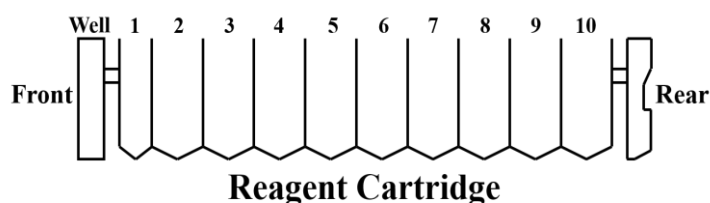
Kit Contents and Storage

Shipping and Storage	The Kit is shipped at room temperature. Upon receipt, store the Kit at room temperature. All Kit components are stable when stored properly until the expiration date shown on the kit box.	
Kit Content	The components supplied in the Kit are listed below. Sufficient reagents are supplied to perform 48 purifications.	
	Contents	Amount
	1 Reagent Cartridge	48 pcs (6x8)
	2 Reaction Chamber	48 pcs (6x8)
	3 Tip Holder	48 pcs (6x8)
	4 Piercing Pin	50 pcs
	5 Filter tip	50 pcs
	6 Sample Tube (7 mL)	50 pcs
	7 Elution Tube (1.5 mL)	50 pcs
	S Small Tip	50 pc
	RLA Buffer (100 ml)	1 pc
	Proteinase K, 10 mg/ml (10 ml)	1 pc
	Barcode sticker (on request)	50 pcs

Reagent
Cartridge
Contents

Each Reagent Cartridge has 10 positions with 10 sealed well.
Positions 1-10 contain wells filled reagents for this protocol

Reagent	Well No.
Empty	1
Washing Buffer 5	2
Washing Buffer 2A	3
Magnetic Bead Solution	4
Binding Buffer 2	5
Binding Buffer 2	6
Binding Buffer 2	7
Binding Buffer 2	8
Elution Buffer	9
Empty	10



Materials Required but not Provided

The following general laboratory equipment and consumables are required to perform the extraction. All laboratory equipment should be installed, calibrated, operated, and maintained according to the manufacturer's recommendations. The following tables display required and special equipment along with the list of consumables.

Item
ePure instrument
1.5 or 2.0 mL micro-centrifuge tubes
Pipettes and filter tips
Phosphate-buffered saline (PBS, may be required for diluting samples)
Sample Rack for 7 ml sample (OA01055-002) - it doesn't come with ePure instrument – to be ordered separately

Warnings and Precautions

For *in vitro* diagnostic use only. Read all the instructions carefully before using the kit. Use of this product should be limited to trained personnel in the techniques of DNA purification. Strict compliance with the user manual is required for optimal results. Attention should be paid to expiration dates printed on the box and labels of all components. Do not use a kit after its expiration date.

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (MSDSs, download at www.ecolidx.com).

Please report any serious incident occurred in relation to the device to your local representative/agent or the manufacturer, and to the competent authority of your country/state.

- Do not use the kit if any consumables are deformed or the cartridge is damaged, or if the conditions of transport and storage according to the instructions for use have not been kept.
- Failure to observe the operating conditions may affect the functions of the kit and the results obtained may not be valid.
- Do not eat, drink, smoke, use cosmetics or handle contact lenses in a laboratory.
- Dispose of all samples and unused reagents in accordance with local regulations.
- Samples should be considered potentially infectious and handled in a biological box in accordance with appropriate biosecurity procedures.
- Clean and disinfect any spilled samples or reagents with a disinfectant, such as 0.5% sodium

hypochlorite or other suitable disinfectant.

- Avoid contact of samples and reagents with skin, eyes and mucous membranes. In case of contact with these solutions, immediately rinse the affected area with water and, if necessary, disinfect or seek medical attention.
- Danger of explosion and ignition if transport, operation and storage conditions are observed.
- The isolation kit is for single use only on ePure automated extractor for a total sample count of 48. Use the kit only for its intended purpose.
- Any serious adverse event that has occurred in connection with the use of the kit must be reported to the EcoliDx manufacturer and reported in writing to the competent authority of the Member State in which the Instrument is used.
- In the event of a malfunction of the kit or deterioration of its function, which may endanger its functionality, the kit must be discontinued and the manufacturer must be contacted immediately.



CAUTION: DO NOT add bleach or acidic solutions directly to the sample preparation waste.

Quality control

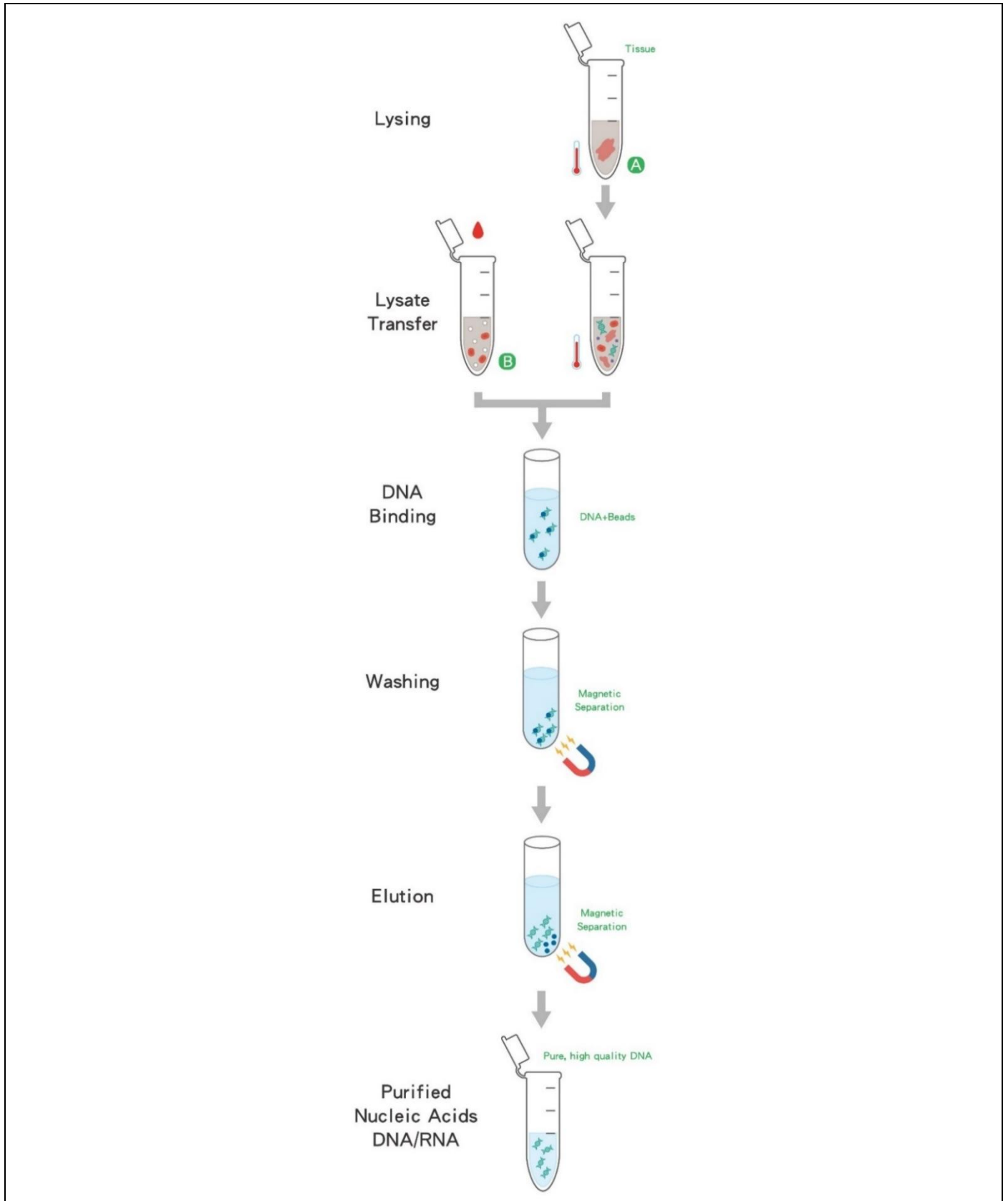
In accordance with the ISO certified EcoliDx quality management system, each kit is tested according to predetermined specifications to ensure consistent product quality.

The following technical standards were also used and complied with for conformity assessment:

ČSN EN ISO 13485 Medical devices - Quality management system - Requirements for regulatory purposes

ČSN EN ISO 14971 Medical devices - Application of risk management to medical devices

Purification Principle



- A Transfer sample to extraction directly.
- B Perform certain pretreatment process before extraction.

Things to Do Before Starting

Sample Preparation

The purification procedure is optimized for the use of 1000 of plasma*, cerebrospinal fluid (CSF), or other cell-free body fluid samples.

Plasma

- a. Dispense 1000-2000 µl of specimen into each 7 ml Sample Tube.
- b. Add 100-200 µl Proteinase K and 0,8-1,6 ml RLA Buffer into each tube.
- c. Close the cap and pulse-vortex for 30 seconds.
- d. Incubate at 56°C for 30 minutes.

Cerebrospinal fluid (CSF)

- a. Dispense 1000-2000 µl of sample into each 7 ml Sample Tube.
- b. Add 100-200 µl Proteinase K and 0,8-1,6 ml RLA Buffer to each tube.
- c. Close the cap and pulse-vortex for 30 seconds.
- d. Incubate at 56°C for 30 minutes.

Urine

- a. Centrifuge the specimen at 10,000–16,000 × g for 5–10 minutes to concentrate a pellet.
 - b. Discard supernatant and resuspend the pellet in 1000-2000 µl PBS.
 - c. Transfer the 1000-2000 µl concentrated sample into 7 ml Sample Tube.
 - d. Add 100-200 µl Proteinase K and 0,8-1,6 ml RLA Buffer into each tube.
 - e. Close the cap and pulse-vortex for 30 seconds.
 - f. Incubate at 56°C for 30 minutes.
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Note:

This kit is used to work with fresh or frozen blood samples collected in tubes that contain common anti-coagulants like EDTA, heparin* and citrate. (*EDTA is recommended to be used as an anticoagulation agent, while heparin has inhibitory effects on nucleic acid amplification reaction).

Using fresh whole blood sample (within 1 week, stored at 4-8°C) for extraction is recommended. Total nucleic acid yield and quality will decrease with time or after multiple thawing. For longer storage time, whole blood should be frozen at -20°C or lower and avoid freeze-thaw cycles.

The final eluate contains total nucleic acid (DNA and RNA). RNA is not the major product in this kit (about 10 %) and would degrade soon. If the RNA-free product is needed, please add RNase to treat the eluate. (For RNase treatment, follow the manufacturer instructions of the kit used in your lab.)

Isolation procedure using the ePure

Note: Perform all steps at room temperature (20-25°C) unless otherwise notified.

Workflow of ePure operation

Place the cartridge and plastic consumables on the ePure instrument



Select the protocol and setup the condition



Follow onscreen message for worktable setup



Start the protocol



Collect elution product *



UV decontamination

* Download the run record

Purification Protocol

1	Turn on the Instrument	a. Turn on the power switch and wait for the screen to turn on.
		b. Login the instrument and enter the Home Page.
2	Load new Consumable(s) and Cartridge(s)	a. Open the door and remove the Sample Rack from the instrument.
		b. Open the Tip-Holder Lid.
		c. Load 1 Reagent Cartridge, and all plastic disposables (2 Reaction Chamber, 3 Tip Holder, 4 Piercing Pins, 5 Filtered Tips and other components if present in the kit intended to use).
		d. Close the Tip-Holder Lid.
		e. Paste the Barcode sticker on the Elution Tubes.
		f. Place 6 Sample Tubes and 7 Elution Tubes into the Sample Rack.
3	Load the Samples	a. Transfer appropriate volume of sample into each Sample Tube on the Sample Rack.
		b. Put the Sample Rack back into the instrument and close the door.

4	Program Set up	a. Select the appropriate protocol program on the instrument. Press NEXT. b. Select an appropriate Sample Volume / Elution Volume and press NEXT. c. Press the number button to select the right Sample Numbers. d. Scan / Edit each primary Sample ID directly. After finished, Press NEXT. e. Scan / Edit each Elution Tube ID directly. After finished, Press NEXT. f. Scan Reagent Cartridge Barcode. Press NEXT. *If the cartridge expired, the next step cannot be performed. g. Follow the instructions on screen to double-check the operating steps being completed before running the program. Press NEXT.
5	Start Extraction	a. Check “PROGRAM CONFIRMATION” on screen. b. Press “START” to start the experiment. Instrument will run the protocol program automatically until whole process is completed. c. At the end of the run (approximately 55-105 minutes), instrument alarms briefly and the screen indicates “PROGRAM FINISH”. d. If you want to perform the same protocol, press “RERUN” to perform the same experiment. If you do not need to re-run the experiment, press the function button “ HOME” to exit the experiment mode.
6	Collect the Elution tubes	a. Open the instrument door. b. Collect the Elution Tubes containing the purified nucleic acids and place in temperature lower than 8°C immediately . c. The purified nucleic acids are ready for immediate use. Store the purified cfDNA at -20°C or lower temperature However, freeze-thaw cycles should be avoided, and samples should be accurately quantified once thawed prior to starting downstream analysis. d. Discard the used cartridges, all plastic consumables into biohazard waste. *Do not reuse the cartridges. e. If you are not using the instrument immediately, please put the Sample Rack back into the instrument, close the instrument door, and press the “ POWER” function button to enter sleep mode. If the instrument will not be used in an extended period of time, please turn off the power switch.

Troubleshooting

This table is helpful for solving common problems. If you need other technical support, please contact ecolidx@ecolidx.com or contact your distributor.

Problem	Possible Cause	Comments and suggestions
Poor DNA quality or yield	Deterioration or contamination of reagents.	Please ensure that the reagents of kit are still in the effective shelf-life period before use. Discard any kit reagent that shows discoloration or evidence of microbial contamination.
	Kit stored under non-optimal conditions	Store kit at 15-25°C at all times after arrival. If either Reagent or Buffer precipitates upon shipping in cold weather or during long-term storage, dissolve precipitates by gently warming and stirring the solution. Please do not freeze the Reagent Cartridges.
	Insufficient sample input	DNA yield depends on the sample type and the number of nucleated cells in the sample. Please proportionally adjust the total input amount of sample to increase the DNA yield.
	Too much of elution buffer was used	The elution volume can be reduced proportionally.
	The eluent of final product(s) is not enough.	Please collect issue information and provide it to your Support Representative / Technical Support as soon as possible.
Clogged issue	Too much sample material was used.	Decrease the input amount of sample material or dilute your sample.
No results in downstream analysis	No signal / The PCR was inhibited.	Using appropriate controls for analysis. Check the positive control, negative control, water (NTC) and internal control to clarify the possible causes.
Instrument malfunction / abnormal sound	Abnormal consumables: 1. Deformed filter tip 2. Deformed reaction chamber 3. Deformed Tip holder	Please replace the batch with normal consumables.
	Abnormal action of instrument: 1. Inaccurate correction value 2. Spare parts or components damaged	Please collect issue information (videos and pictures) and provide it to your Support Representative / Technical Support as soon as possible to calibrate or replace any other damaged or worn parts.

Related Products

Product Name	Cat. no.
ePure Blood DNA Extraction Kit	E2001
ePure Viral Nucleic Acid Extraction Kit	E2003
ePure Tissue DNA Extraction Kit	E2004
ePure Bacterial DNA Extraction Kit	E2006
ePure HPV DNA Extraction Kit	E2007
ePure TB DNA Extraction Kit	E2008
ePure FFPE DNA Extraction Kit	E2009
ePure Forensic DNA Extraction Kit	E2010
ePure Total RNA Extraction Kit	E2015
ePure CFC DNA Extraction Kit	E2017

Limited Product Warranty

Ecoli Dx is committed to provide customers with high-quality products and services. Our goal is to ensure that every customer is 100 % satisfied with our products and services. If you have any question or concerns, contact our Technical Support Representatives.

Ecoli Dx guarantees the performance of all products according to the specifications stated in our product literature. The purchaser / user must determine the suitability of the product for his particular use. We reserve the right to change, alter, or modify any product to enhance its performance and design.

No warranty is granted for products beyond their listed expiration date. No warranty is applicable unless all product components are stored and used in accordance with instructions.

Symbols

The following symbols are used on labels and in Instructions for Use (IFU), in compliance with EN ISO 15223-1 standard.

Symbol	Explanation
	CE mark
	For In Vitro Diagnostic Use
	Catalogue number
	Lot/Batch number
	Sufficient for [n] samples
	Instructions for Use
	Expiry date
	Storage temperature (15°C – 25°C)
	For single use only
	Manufacturer
	Caution

Revision History

Version	Date	Description
1.0	13 Oct. 2026	New document release

