Clean Cell Free DNA Kit

Instructions for use

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CE IVD

REF CCF-D0384

CleanNA, Coenecoop 75, 2741 PH, Waddinxveen, the Netherlands

Intended for in vitro diagnostic use.

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Contents

Intended Purpose

The intended purpose of the device is to extract circulating cell-free DNA (cfDNA) from human plasma in a sufficient purity to be used in downstream detection procedures based on the principle of Polymerase Chain Reaction (PCR).

Intended User

The intended users are professional laboratory employees trained in molecular biology techniques.

Introduction and Principle

The Clean Cell Free DNA Kit is designed for isolation of cell-free DNA from human plasma. The entire procedure allows for both manual as well as automated sample processing.

By combining our proprietary buffer system with the convenience of our magnetic CleanNA CCF particles, the need for vacuum steps or funnels throughout the procedure is eliminated. As a result, the Clean Cell Free DNA Kit provides a simple 4 step process: lyse, bind, wash, and elute.

Our CleanNA Particles CCF offer a high binding capacity and, combined with the buffer system, target smaller DNA fragments (120-400 bp). This combination minimizes the risk of genomic DNA contamination. The high binding capacity of the CleanNA particles CCF decreases the amount of particles required during binding steps, thereby reducing the elution volume. This enables isolated cell-free DNA from 1 mL plasma to be eluted in as little as 30-60 µL.

The isolated cell-free DNA is ready for use in (q)PCR as a downstream application.

Schematic Overview

The uniquely formulated lysis buffer releases the circulating DNA from proteins and vesicles bound to the DNA while DNases are inactivated. DNA is isolated from the lysate in one step by binding to the magnetic particles' surface. The CleanNA magnetic particles are then separated from the lysate by using a magnetic separation device. Following a few rapid wash steps to remove trace contaminants, the purified DNA is eluted from the CleanNA particles using an Elution Buffer.

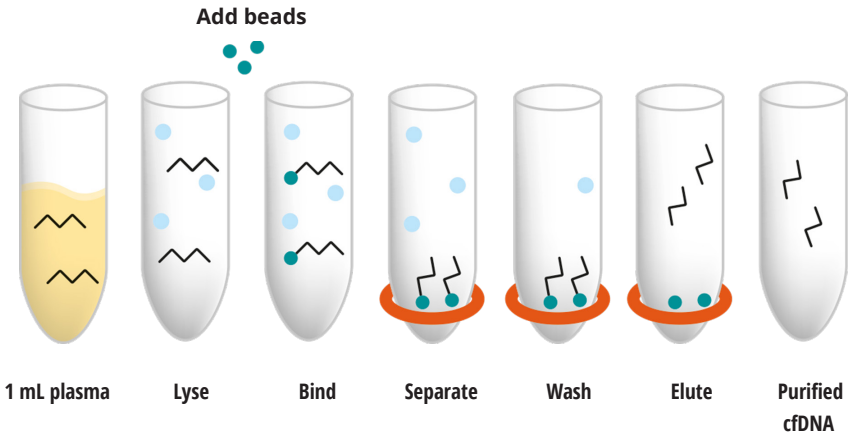

Figure 1: Schematic overview of the Clean Cell Free DNA Kit procedure.

Materials Provided

Kit Contents:

Component	Volume CCF-D0384
CCF Lysis	30 mL
CCF Binding	430 mL
CCF Wash 1	225 mL
CCF Wash 2	45 mL
Elution Buffer	100 mL
Proteinase K Solution	6.5 mL
CleanNA Particles CCF	4.3 mL

Reagent Shipping, Storage and Handling

Shipping of the Clean Cell Free DNA Kit should be done at room temperature (15-25 °C). Do not freeze the components of the Clean Cell Free DNA Kit.

Component	Storage
CCF Lysis*	Room temperature (15-25°C)
CCF Binding	Room temperature (15-25°C)
CCF Wash 1	Room temperature (15-25°C)
CCF Wash 2	Room temperature (15-25°C)
Elution Buffer	Room temperature (15-25°C)
Proteinase K Solution	Room temperature (15-25°C) (for storage > 12 months, store at 2-8°C)
CleanNA Particles CCF	2-8°C

***** In case the lysis buffer shows a white precipitate in the bottle, pre-heat the buffer to 37°C to dissolve the precipitate.

In use stability: After opening the Clean Cell Free DNA Kit, the product can be used safely for a period of 19 days.

Do not use the Clean Cell Free DNA Kit after the expiration date on the outer box label.

Warnings

Read the instructions carefully before using the kit.

Do not mix several kit LOT numbers.

Make sure that the kit bottles are not damaged and that no liquid leaked from the bottles. Do not use a kit that has been damaged.

The LOT number on the CleanNA Particles CCF box packaging is different from the LOT number on the CleanNA Particles CCF bottle. The LOT number on the box matches the LOT number of the whole kit and the one on the bottles is specifically for the particles. Since the CleanNA Particles CCF are stored at a different temperature, please make sure that the LOT number on the box packaging of the particles matches the LOT number of the kit before use.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Precautions

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

CCF Binding

Flammable liquid and vapour. Causes serious eye damage. Harmful if swallowed. Causes skin irritation. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Wear protective gloves, protective clothing, eye protection and face protection. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment. Use non-sparking tools. Take action to prevent static discharges. Wash all exposed external body areas thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor/physician/first aider.
In case of fire: Use alcohol resistant foam or normal protein foam to extinguish.
IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
IF ON SKIN: Wash with plenty of water and soap.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
Rinse mouth.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.

CCF Lysis

Harmful to aquatic life. Causes serious eye damage. Causes skin irritation.

Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash before reuse.
IF ON SKIN: Wash with plenty of water and soap.
If skin irritation occurs: Get medical advice/attention.

CCF Wash 1	
 	Harmful if swallowed. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Do not breathe mist/vapours/spray. Wash all exposed external body areas thoroughly after handling. Wear protective gloves, protective clothing, eye protection and face protection. Do not eat, drink or smoke when using this product. Avoid release to the environment. **IF SWALLOWED:** Rinse mouth. Do NOT induce vomiting. **IF ON SKIN (or hair):** Take off immediately all contaminated clothing. Rinse skin with water [or shower]. **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/physician/first aider. Wash contaminated clothing before reuse. **IF SWALLOWED:** Call a POISON CENTER/doctor/physician/first aider if you feel unwell. **IF INHALED:** Remove person to fresh air and keep comfortable for breathing.
Proteinase K Solution	
	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Avoid breathing mist/vapours/spray. In case of inadequate ventilation wear respiratory protection. **IF INHALED:** Remove victim to fresh air and keep at rest in a position comfortable for breathing. **If experiencing respiratory symptoms:** Call a POISON CENTER or doctor/physician.

Note: For safe disposal, please consult your local waste regulations.

Quality Control

CleanNA produces each lot of the Clean Cell Free DNA Kit according to predetermined and validated protocols in the Quality Management System (QMS). Additionally, a quality check after production of each lot is performed to secure consistent product quality. CleanNA's QMS is EN-ISO 13485 certified.

Limitations

The performance of the Clean Cell Free DNA Kit has been established with human plasma preserved in the following anti-coagulants:

- EDTA
- Citrate-phosphate-dextrose (CPD)
- Sodium citrate

A range of individual plasma donors has been included in the performance evaluation. The performance of the Clean Cell Free DNA Kit has not been tested with heamolysed plasma.

It is the user's responsibility to validate the performance of sample material not used in the performance evaluation.

We recommend the use of an internal extraction control per sample to identify a false negative result in downstream detection methods, caused by potentially unknown inhibitory agents in individual patient plasma samples.

The performance of the kit has been established with downstream detection methods based on Polymerase Chain Reaction. It is the user's responsibility to validate the performance of the device when used with other downstream detection methods.

Diagnostic results generated after using the Clean Cell Free DNA Kit must be interpreted in conjunction with other clinical or laboratory findings.

Collection and Storage of Specimen

Plasma

The nucleic acid isolation procedure should start immediately after blood donation and plasma separation*. In case this is not possible, plasma can be stored up to 24 hours at 2-8°C for short-term storage and in case of longer storage, plasma can be stored for up to 4 weeks at -20°C or -80°C. Thaw the plasma samples at room temperature prior to using the plasma for cell-free DNA extraction.

⚠ **Note:** Samples from human origin are potentially infectious. Take appropriate measures while handling them.

* For plasma preparation prior to isolate cell-free nucleic acids from blood samples, we recommend the following procedure:

1. Spin whole blood tubes by centrifuging the tube(s) for 10 minutes at 3,000 rpm (1,900 x g) at 4°C.
2. Carefully aspirate the plasma supernatant, without disturbing the blood cells.
3. Transfer the plasma supernatant into a fresh centrifuge tube.
4. To ensure the plasma is free of nucleated blood cells, repeat steps 1 till 3 for a second separation.
5. The plasma can be used for nucleic extraction this stage.

Perform steps 6-9 below to also remove intact chromatin from ruptured blood cells from the plasma. Note that this can also remove a low amount of cfDNA that is present in larger extracellurar vehicles. Otherwise, continue at step 10.

6. Centrifuge the plasma samples at 16,000 x g at 4°C using a fixed-angle rotor.
7. Carefully remove the plasma supernatant, ensuring not to disturb the pellet.
8. Transfer the plasma to a fresh tube.
9. The plasma can now be used for nucleic extraction.
10. Store the plasma according instructions above.

Materials and Equipment to be Supplied by User

For isolation in single tubes

Materials and reagents to be supplied by user for the Tube Protocol for up to 1 mL of sample input:

- Fresh ethanol absolute
- Magnetic separation device for 1.5/2.0 mL tubes
- Vortexer
- Shaker or Rocker
- Incubator capable to be set at 60°C
- 1.5 mL micro centrifuge tube(s)
- 15 mL centrifuge tube(s)

For isolation using 48-well plate format

Materials and Reagents to be supplied by user for the Plate Protocol for up to 1 mL of sample input:

- Fresh ethanol absolute
- 48-well magnetic plate, for example Alpaqua CatNo# A000530
- Vortexer
- Shaker or Rocker
- Incubator capable to be set at 60°C
- 48-deep-well plate(s), 3.5 mL; for example Wuxi NEST Biotechnology CatNo# 504102
- 96-deep-well plate(s) or 96-well PCR plate(s)

Preparation of Reagents

CCF Wash 2

Dilute CCF Wash 2 with fresh ethanol absolute as follows and store at room temperature.

Kit	Ethanol Absolute to be Added
CCF-D0384	180 mL

Clean Cell Free DNA Kit - Single Tube Protocol

Before Starting:

- Set incubator to 60°C.
- Make sure CCF Lysis is fully dissolved. If not, pre-heat to 37°C.
- Shake or vortex the CleanNA Particles CCF to fully resuspend the particles before use.
- Prepare CCF Wash 2 according to the instructions in the Preparation of Reagents section on page 13.

Protocol:

1. Add up to 1 mL plasma sample to a 15 mL centrifuge tube (not provided).

⚠ **Note:** Do not exceed the maximum sample volume, this will decrease the efficiency of the extraction procedure.

2. If the sample volume is less than 1 mL, bring the sample volume up to 1 mL with Elution Buffer (provided with this kit).
3. Add 15 µL Proteinase K Solution.
4. Add 67 µL CCF Lysis.
5. Vortex at maximum speed or pipet up and down to mix thoroughly.
6. Incubate at 60°C for 20 minutes. Mix by inverting or shaking every 10 minutes.
7. Incubate at room temperature for 10 minutes.

⚠ **Note:** This incubation step is crucial to let the sample temperature drop and obtain the most efficient DNA binding to the CleanNA Particles CCF.

8. Add 1 mL CCF Binding. Vortex at maximum speed for 30 seconds or pipet up and down to mix thoroughly.
9. Add 10 µL CleanNA Particles CCF. Invert the sample 10 times or pipet up and down to mix.

⚠ **Note:** Shake or vortex the CleanNA Particles CCF to fully resuspend particles before use.

10. Incubate for 10 minutes at room temperature with continuous mixing. The sample must be mixed throughout the 10 minute incubation period by shaking or rocking.

⚠ **Note:** Do not vortex at high speeds as this will cause foaming, resulting in a reduced yield. The speed of mixing should be set to continuously keep the CleanNA Particles CCF resuspended in solution.

11. Transfer 1 mL of the mixture to a 1.5 mL micro centrifuge tube (not provided).
12. Place the tube on a magnetic separation device to magnetize the CleanNA Particles CCF.

13. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

14. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

15. Transfer the remaining mixture from step 11 to the 1.5 mL micro centrifuge tube used in the previous steps.
16. Place the tube on a magnetic separation device to magnetize the CleanNA Particles CCF.
17. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

18. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

19. Remove the tube containing the CleanNA Particles CCF from the magnetic separation device.
20. Add 500 µL CCF Wash 1.
21. Resuspend the CleanNA Particles CCF by vortexing for 2 minutes or pipetting up and down 20 times.

⚠ **Note:** To obtain good purity, complete resuspension of the CleanNA Particles CCF is critical.

22. Place the tube on the magnetic separation device to magnetize the CleanNA Particles CCF.
23. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

24. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

25. Repeat steps 19-24 for a second “CCF Wash 1” wash step.
26. Remove the tube containing the CleanNA Particles CCF from the magnetic separation device.
27. Add 500 µL CCF Wash 2.

⚠ **Note:** CCF Wash 2 must be diluted with ethanol absolute prior to use. Please see page 13 for instructions.

28. Resuspend the CleanNA Particles CCF by vortexing for 2 minutes or pipetting up and down 20 times.
29. Place the tube on the magnetic separation device to magnetize the CleanNA Particles CCF.
30. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

31. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

32. Repeat Steps 26-31 for a second "CCF Wash 2" wash step.
33. Remove the tube from the magnetic separation device for approximately 30 seconds.
34. Place the tube on the magnetic separation device to magnetize the CleanNA Particles CCF.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

35. Aspirate and discard the residual CCF Wash 2.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

36. Leave the open tube on the magnetic separation device for 25 minutes to dry the CleanNA Particles CCF.
37. Remove the tube containing the CleanNA Particles CCF from the magnetic separation device.
38. Add 30-60 µL Elution Buffer. Resuspend the CleanNA Particles CCF by vortexing or pipetting up and down 20 times.

⚠ **Note:** Make sure the elution buffer covers the CleanNA Particles CCF. Too low elution volumes can cause lower yield. Too high volumes cause lower concentration of DNA in the eluate.

39. Incubate at room temperature for 5 minutes, while constantly vortexing.
40. Place the tube on the magnetic separation device to magnetize the CleanNA Particles CCF.
41. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead carry over can cause inhibition during downstream PCR.

42. Transfer the cleared supernatant containing purified DNA to a clean 1.5 mL micro centrifuge tube (not provided).
43. Store the extracted cell-free nucleic acids at -20°C.

Clean Cell Free DNA Kit - 48-wells Plate Protocol

Before Starting:

- Set incubator to 60°C.
- Make sure CCF Lysis is fully dissolved. If not, pre-heat to 37°C.
- Shake or vortex the CleanNA Particles CCF to fully resuspend the particles before use.
- Prepare CCF Wash 2 according to the instructions in the Preparation of Reagents section on page 13.

Protocol:

1. Add up to 1 mL plasma/serum samples to a 48-deep-well plate (not provided).

⚠ **Note:** Do not exceed the maximum sample volume, this will decrease the efficiency of the extraction procedure.

2. If the sample volume is less than 1 mL, bring the sample volume up to 1 mL with Elution Buffer (provided with this kit).
3. Add 15 µL Proteinase K Solution.
4. Add 67 µL CCF Lysis and seal the plate.
5. Vortex at maximum speed or pipet up and down to mix thoroughly.
6. Incubate at 60°C for 20 minutes. Mix by inverting or shaking every 10 minutes.
7. Incubate at room temperature for 10 minutes.

⚠ **Note:** This incubation step is crucial to let the sample temperature drop and obtain most efficient DNA binding to the CleanNA Particles CCF.

8. Add 1 mL CCF Binding. Vortex at maximum speed for 30 seconds or pipet up and down to mix thoroughly.
9. Add 10 µL CleanNA Particles CCF. Invert the samples 10 times or pipet up and down to mix.

⚠ **Note:** Shake or vortex the CleanNA Particles CCF to fully resuspend particles before use.

10. Incubate for 10 minutes at room temperature with continuous mixing. The samples must be mixed throughout the 10 minute incubation period by shaking or rocking.

⚠ **Note:** Do not vortex at high speeds as this will cause foaming, resulting in a reduced yield. The speed of mixing should be set to continuously keep the CleanNA Particles CCF resuspended in solution.

11. Place the 48-deep-well plate on the 48-well magnetic plate to magnetize the CleanNA Particles CCF. The Particles from each well will be collected by the magnets at the bottom.

12. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

13. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

14. Remove the 48-well plate containing the CleanNA Particles CCF from the magnetic separation device.
15. Add 500 µL CCF Wash 1.
16. Resuspend the CleanNA Particles CCF by vortexing for 2 minutes or pipetting up and down 20 times.

⚠ **Note:** To obtain good purity, complete resuspension of the CleanNA Particles CCF is critical.

17. Transfer the resuspended CleanNA Particles CCF to a new 48-deep-well plate (not provided).

⚠ **Note:** Continue to work in 48-well format for the remaining procedure.

18. Place the 48-deep-well plate on the 48-well magnetic plate to magnetize the CleanNA Particles CCF.
19. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

20. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

21. Remove the 48-well plate containing the CleanNA Particles CCF from the magnetic separation device.
22. Add 500 µL CCF Wash 1.
23. Resuspend the CleanNA Particles CCF by vortexing for 2 minutes or pipetting up and down 20 times.

⚠ **Note:** To obtain good purity, complete resuspension of the CleanNA Particles CCF is critical.

24. Place the 48-deep-well plate on the 48-well magnetic plate to magnetize the CleanNA Particles CCF.
25. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

26. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

27. Remove the 48-well plate containing the CleanNA Particles CCF from the magnetic separation device.
28. Add 500 µL CCF Wash 2.

⚠ **Note:** CCF Wash 2 must be diluted with ethanol absolute prior to use. Please see page 13 for instructions.

29. Resuspend the CleanNA Particles CCF by vortexing for 2 minutes or pipetting up and down 20 times.
30. Place the 48-deep-well plate on the 48-well magnetic plate to magnetize the CleanNA Particles CCF.
31. Incubate at room temperature until the CleanNA Particles CCF are completely cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

32. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

33. Repeat Steps 28-32 for a second “CCF Wash 2” wash step.
34. Remove the 48-well plate containing the CleanNA Particles CCF from the magnetic separation device.
35. Place the 48-deep-well plate on the 48-well magnetic plate to magnetize the CleanNA Particles CCF.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead loss can cause lower yield.

36. Aspirate and discard the residual CCF Wash 2.

⚠ **Note:** Do not disturb or pipet the CleanNA Particles CCF. This can cause lower yield.

37. Leave the tube on the magnetic separation device for 25 minutes to dry the CleanNA Particles CCF.
38. Remove the 48-well plate containing the CleanNA Particles CCF from the magnetic separation device.
39. Add 30-60 µL Elution Buffer. Resuspend the CleanNA Particles CCF by vortexing or pipetting up and down 20 times.

⚠ **Note:** Make sure the elution buffer covers the CleanNA Particles CCF. Too low elution volumes can cause lower yield. Too high volumes cause lower concentration of DNA in the eluate.

40. Incubate at room temperature for 5 minutes, while constantly mixing by pipetting, shaking or vortexing.
41. Place the 48-deep-well plate on the 48-well magnetic plate to magnetize the CleanNA Particles CCF.
42. Incubate at room temperature until the CleanNA Particles CCF are completely

cleared from solution.

⚠ **Note:** Make sure to incubate until all particles are cleared from solution, bead carry over can cause inhibition during downstream PCR.

43. Transfer the cleared supernatant containing purified DNA to a clean 96-well plate or to clean individual tubes (not provided).
44. Store the extracted cell-free nucleic acids at -20°C.

Troubleshooting Guide

Please use this guide to troubleshoot any problems that may arise. For further assistance, please contact your local distributor.

Possible Problems and Suggestions

Problem	Cause	Suggestion
Low DNA Yield	Incomplete resuspension of CleanNA Particles CCF.	Resuspend the CleanNA Particles CCF by vortexing vigorously before use.
	Inefficient binding of the DNA to the CleanNA Particles CCF.	Ensure to let the sample cool at room temperature for 10 minutes prior to adding CCF Binding.
		Ensure to mix each sample continuously throughout the binding incubation.
	Loss of CleanNA Particles CCF during operation.	Avoid disturbing the CleanNA Particles CCF during aspiration.
	DNA remains bound to CleanNA Particles CCF.	Dilute CCF Wash 2 by adding appropriate volume of ethanol absolute prior to use (see Page 13 for instructions).
		Make sure the elution buffer covers all the CleanNA Particles CCF.
	Ethanol carryover.	Dry the CleanNA Particles CCF at room temperature for 25 minutes before elution.
CleanNA particles CCF do not completely clear from solution	Too short magnetizing time.	Increase collection time on the magnetic separation device.
High Molecular Weight Co- Purification	Two CCF Wash 1 Steps must be performed.	Perform two CCF Wash 1 steps as instructed in the Instructions for Use. Increase the volume of wash buffer if necessary.
Problems in downstream applications	Salt carryover.	CCF Wash 2 must be at room temperature.

Abnormal bioanalyzer data	Bioanalyzer shows multiple sharp peaks during analysis.	Ensure to remove all traces of the cleared supernatant after each wash step.
		Ensure to incubate the tube/plate for 25 minutes to dry the CleanNA Particles CCF.
	Bioanalyzer shows base line climbing towards the end.	Check the bioanalyzer chip for air bubbles. Load samples onto a new freshly prepared chip.
	Bioanalyzer shows high blob at the beginning of the trace.	Ensure the purified sample does not contain traces of CleanNA particles CCF.

Symbols

IVD	In-vitro Diagnostics
CE	CE mark. This product meets the requirements for CE-IVD device under the EU Regulation for In Vitro Diagnostic Medical Devices (2017/746)
REF	Order number
	Manufacturer
	Caution
	Temperature limit
	Expiration date
LOT	Lot number

Ordering Information

Contact your local distributor to order.

Product	Part Number
Clean Cell Free DNA Kit (384 preps)	CCF-D0384

Document Revision History

Manual Version	Date of Revision	Revised Chapter	Explanation of Revision
1	2023/AUG/28	N/A	Initial version
2	2023/OCT/02	Reagent Shipping, Storage and Handling	Correction in In use stability and overall minor text corrections.

Notes

Notes

Notes

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