

Processing Item Information Sheet (PIIS)

“Cell-Free DNA (cfDNA) Extraction from Whole Blood” Scheme [cfDNA26]

This sheet contains all the information on the **Whole Blood Processing Item** that you should be aware of to conduct the above-mentioned Scheme. **Please read carefully before performing any operation on the provided sample.**

Processing Item Description

- Source material: Human blood from a healthy donor.
- Packaging: PAXgene ccfDNA tube.
- Date of Preparation: October 2026 – on the day of shipment.
- Testing of Biological Hazard: None. Blood was taken from a healthy donor, but it is recommended to consider the Item as potentially infectious.
- Biosafety level: All operations have been conducted in a BSL 2 environment.
- Homogeneity and Stability Information: Stability of the Processing Item is up to 10 days at room temperature (15–25°C) (data from PAXgene ccfDNA tube manufacturer).

Instructions to Prepare the Processing Item for Extraction

- Any storage requirement between receipt and processing date: Store at **room temperature**. cfDNA extraction should be performed within 1 week of receipt.
- Requirements: Proceed to cfDNA extraction **immediately** after the whole blood centrifugation.

Particular Handling/Safety Requirements

- Potential risks of Processing Item: All biological material should be manipulated as potentially hazardous.
- Individual protection equipment required: Standard laboratory equipment (laboratory coat, gloves).
- In case of puncture or cuts: Wash thoroughly with water and then disinfect during 10 minutes.
- In case of contact with the eye: Wash thoroughly with water or physiologic serum during 5 minutes.
- In case of contact with the mucus membranes and skin: Wash thoroughly with water.
- Measures to take in case of accidental spillage: Use disinfectant and thoroughly clean the effected surface.
- Waste elimination procedures: Waste generated by healthcare activities, to eliminate in incinerable plastic containers.

Scheme Specifications

- Please extract **cfDNA** from the Processing Item following your **usual routine cfDNA extraction method**.
- You will be asked to report information under the following scheme: **Cell-Free DNA (cfDNA) Extraction from Whole Blood**.
- Please be ready to enter the following information:
 - Plasma isolation (centrifugation speed, duration and temperature, brake);
 - Kit used (QIAamp circulating Nucleic Acid kit (Diagnostic Sample Preparation, DSP, option) (QIAgen); QIASymphony DSP Circulating DNA Kit/QIAamp DNA blood mini kit (QIAgen); QIAamp MinElute Kit (QIAgen); MagMAX™ Cell-Free DNA Isolation Kit (Applied Biosystems-ThermoFisher Scientific); MagNA Pure Compact

(MPC) Nucleic Acid Isolation Kit I (Roche Diagnostics); Maxwell® RSC (MR) ccfDNA Plasma Kit (Promega); NextPrep-Mag™ cfdNA isolation kits (Perkin Elmer); NucleoSnap® DNA Plasma (Macherey-Nagel); FitAmp plasma/ serum DNA isolation kit (Epigentek); GenElute™ Plasma/Serum Cell-Free Circulating DNA Purification Midi Kit (Sigma); Quick-cfdNA Serum & Plasma Kit (Zymo), other);

- Extraction method (salting out, magnetic bead-based, silica membrane-based, unsure, other);
- Volume of plasma used for cfdNA extraction (ml);
- Use of RNase;
- Elution buffer composition (elution buffer from kit, water, TE, AE, other) and elution volume (µl);
- Extraction equipment.

What to Submit

- Once you have extracted DNA from the blood (according to your extraction method), you pipet all the extracted DNA in the provided labelled Matrix 0.5 ml. The tube is already labelled with your Laboratory Number and the name of the Scheme (cfDNA26). **Make sure to properly close the tube to avoid evaporation or leakage.**
- IBBL requires a **minimum of 15 µl** of extract to perform the downstream analyses planned.
- As soon as extracted, the DNA tube must be shipped to the following address, by using the courier of your choice:

IBBL, PT Programme
Biorepository – Laura GEORGES - First Floor
1B Rue Louis Rech
L-3555 Dudelange
LUXEMBOURG
Phone: +352 26970-521
Email: biorepository@ibbl.lu

- The extracted DNA can be temporarily stored at -80°C before shipment. In that case, the extracted DNA must be shipped to IBBL on dry ice.
- Shipment deliveries are accepted on weekdays between 08:30 and 16:30. Please note that IBBL cannot receive your sample on Saturdays nor Sundays.
- Your data must be submitted online to the PT website <http://biospecimenpt.ibbl.lu/> by employing the login credentials (User email and Password) used to create your account on the aforementioned PT platform.
- Please complete the questionnaire of the cfdNA26 PT scheme as accurately as possible, adding any relevant detail and comment in the appropriate section. Please note that any data that could impact group assignment and alter the final evaluation even slightly, cannot be modified after data entry has been closed as ISO/IEC 17043 considers correct identification of methods and results as part of the participant's competence assessment.

Timelines

<i>Shipment of the extracted DNA to IBBL</i>	<i>Data Submission</i>	<i>Downstream analyses & Report preparation</i>	<i>Reports available</i>
Before 10 NOV 2026	17 NOV 2026, latest	20 NOV 2026 – 31 JAN 2027	March 2027

In case of doubts in the completion phase, please contact LIH/IBBL at IBBLPT@lih.lu