

Processing Item Information Sheet (PIIS)

“Cell-Free DNA (cfDNA) Extraction from Whole Blood” 2019_R1 Scheme

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 2019 – on the day of shipment.
- Testing of Biological Hazard: The Processing Item has been tested negative for HIV (ELISA and PCR), HCV (ELISA and PCR); Syphilis (ELISA), HBsAg (ELISA), HBV (PCR), HAV (PCR), Parvovirus B19 (PCR).
- Biosafety level: All operations have been conducted in a BSL 2 environment.
- Homogeneity and Stability Information: Homogeneity of the Processing Item was controlled and confirmed in September 2019. Stability of the Processing Item is up to 7 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: Exempt of infectious risk.
- Individual protection equipment required: Standard laboratory equipment (laboratory coat, gloves).
- In case of puncture or cuts: Abundantly wash with water and then disinfect during 10 minutes.
- In case of projection in the eye: Abundantly wash with water or physiologic serum during 5 minutes.
- In case of projection on the mucous membranes and skin: Wash with water.
- Measures to take in case of accidental dispersion: Pulverise disinfectant and clean the concerned 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); 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) cfDNA 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 (cfDNA19). **Make sure to properly close the tube to avoid evaporation.**
- As soon as extracted, the DNA tube must **immediately** be shipped, **at room temperature**, to the following address:

IBBL, PT Programme
Biorepository
1 Rue Louis Rech
L-3555 Dudelange
LUXEMBOURG

- For the shipment, use at least a **padded envelope** and send your aliquot back to IBBL by **registered mail** or using the **courier** of your choice.
- Please note that IBBL cannot receive your sample on Saturdays nor Sundays.
- Your data must be submitted online on the PT website <http://biospecimenpt.ibbl.lu/> using the login information (Laboratory Number and Password) provided to you via email after the registration to the "Cell-Free DNA (cfDNA) Extraction from Whole Blood" Scheme.
- Please complete the questionnaire as accurately as possible, adding any relevant detail and comment in the appropriate section.

Timelines

<i>Shipment of the extracted DNA to IBBL</i>	<i>Data Submission</i>	<i>Data analysis & Report preparation</i>	<i>Reports available</i>
Immediately after extraction Before 15 NOV 2019	15 NOV 2019, latest	15 NOV 2019– 17 JAN 2020	28 FEB 2020

In case of doubts in the completion phase, please contact IBBL at ISBERPT@ibbl.lu