

Processing Item Information Sheet (PIIS)

“Circulating Tumour Cells (CTC) Isolation and Detection” Scheme [CTC26]

This sheet contains all the information on the **CTC Processing and Testing 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/Test Item Description

- Source material: Stabilized Whole Blood from a healthy donor with spiked-in cell line.
- Packaging: Based on the Participant’s method (e.g. RareCyte, CellSave, Streck cfDNA,...).
- Date of Preparation: Cell culture start a week in advance of the day of shipment. Blood collection and spike in on day of shipment (October 2026).
- 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: No homogeneity study was performed. Cancer-ID PT CTC schemes 2016 to 2019, serve as proven evidence for fitness-for-purpose of the spike in procedure. Stability of the Processing Item depends on the blood collection tube provider and is stated in the blood collection tube instruction manual.

Instructions to Prepare the Processing Item for Extraction

- Any storage requirement between receipt and processing date: follow the recommendations of the blood collection tube provider, as written in the blood collection tube instruction manual.

Tube	Company	Temp Range (°C)	Max PCD*
RareCyte	Rarecyte	18-25	72h
CellSave	Cell Search	15-30	96h
TransFix	Cytomark	18-25	5d
Streck cfDNA for CTCs	Streck	15-30	4d

* pre-centrifugation delay

- Requirements: Proceed to CTC Isolation and Detection within the timeframe allowed by the blood collection tube provider, as written in the blood collection tube instruction manual.

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 isolate or enrich **CTC** and enumerate them from the Processing Item following your **usual routine method**.
- You will be asked to report information under the following scheme: **Circulating Tumour Cells (CTC) Isolation and Detection**.
- Please be ready to enter only the following information:
 - Enrichment (Parsortix, CellSearch, VyCAP, Siemens, ClearCell, RareCyte);
 - Enumeration (No, Microscope, CellTrack, CyteFinder)
 - Isolation (No, DEPArray, FACS, Puncher, ALS, Laser);
 - Type of tube
 - Sample volume (mL);
 - Time and day of sample processing
- Please ignore the Genome Amplification and Molecular Analysis sections.

What and How to Submit

- 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 CTC26 PT scheme as accurately as possible, adding any relevant detail and comment in the appropriate comment 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>Results submission</i>	<i>Data analysis & Report preparation</i>	<i>Reports available</i>
17 NOV 2026, <u>latest</u>	20 NOV 2026 – 31 JAN 2027	March 2027

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