

Processing Item Information Sheet (PIIS)

“Circulating Tumour Cells (CTC) Isolation and Detection” 2020_R1 Scheme

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 with spiked in cell line.
- Packaging: Dangerous Good class 6.2 Category B UN3373, shipped in Saf-T-Pak 309 SYS, following the manufacturers packaging instruction.
- Date of Preparation: Cell culture start a week in advance of the day of shipment. Blood collection and spike in on 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: 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: 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 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 results must be submitted online to 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 “Circulating Tumour Cells (CTC) Isolation and Detection” Scheme.
- Please complete the questionnaire as accurately as possible, adding any relevant detail and comment in the appropriate comment 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>
<u>Immediately</u> after extraction <u>Before</u> 20 NOV 2020	20 NOV 2020, <u>latest</u>	23 NOV 2020– 22 JAN 2021	26 FEB 2021

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