

Parsortix® Control Test (PCT) for Parsortix® PR1 and PR1 WICS Instruments Instructions For Use (IFU)

Version A

For Research Use Only – Not for use in diagnostic procedures

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1. Scope and Applicability

This Instructions for Use document applies to the storage, preparation and use of the Parsortix® Control Test (PCT), Product REF CTR-PCT-01, with compatible Parsortix® PR1 and PR1 WICS instruments using approved protocols. It covers instrument and PCT preparation, processing, harvest and enumeration of fluorescently labelled control cells, result interpretation, troubleshooting and disposal.

The Parsortix® Control Test (PCT) is a research-use-only control intended for use by trained laboratory personnel to verify the correct operation of compatible Parsortix® PR1 and PR1 WICS instruments in research laboratory environments. The PCT contains fixed, fluorescently labelled cells and may also be used as an alternative to contrived samples when troubleshooting instrument performance.

The PCT is intended for research use only. Not for use in diagnostic procedures.

2. References

PCT Safety Data Sheet (MSDS)

PR1-OM-C Parsortix® PR1 System Operating Manual

PR1WICS-OM-A Parsortix® PR1 WICS System Operating Manual

3. Reagents, Consumables and Equipment

In addition to the Parsortix® PR1 or PR1 WICS instrument and its standard accessory and consumables (as per PR1-OM-C Parsortix® PR1 System Operating Manual or PR1WICS-OM-A Parsortix® PR1 WICS System Operating Manual), the items below must be obtained either from CellBxHealth or external suppliers.

Materials Provided by CellBxHealth

CATALOGUE NUMBER (REF)	PRODUCT
CAS-3C-RUO-CC	Parsortix® GEN3C Cleaning Cassette
CAS-3P-RUO-65	Parsortix® GEN3P 6.5 Cell Separation Cassette
CTR-PCT-01	Parsortix® PCT-01 Instrument Control Test

Materials Required but not Provided by CellBxHealth

The following items are also required but are not provided by CellBxHealth:

CATALOGUE NUMBER (REF)	SUPPLIER	PRODUCT
352098	Corning	50 mL Falcon Tubes
165305	ThermoFisher	96 Well Black/Clear Bottom Plate, TC Surface OR alternative product below
50-292-18	Fisher Scientific	PTFE Printed Microscope Slide 21 Round wells, 4mm
N/A	N/A	Microcentrifuge with fixed rotor for 1.5 mL / 2.0 mL microfuge tubes
N/A	N/A	Fluorescence microscope with appropriate objectives (e.g. 10X, 20X, 40X), 488nm laser, and filters for FITC

Note: The PCT should be stored between +2 °C and +8 °C and can be kept until the expiration date on the label

4. Warnings and Precautions

Read and follow this IFU, the compatible instrument operating manual and the current PCT Safety Data Sheet before use.

For professional laboratory use by appropriately trained personnel. Use only for the approved intended purpose.

Wear laboratory coat, suitable chemical-resistant gloves and eye protection. Avoid splashes and generation of aerosols or mists.

Do not discharge the product or residues to drains. Collect product, spills and contaminated materials in a compatible, clearly labelled waste container for authorised disposal.

Do not use if the container is damaged, leaking, incorrectly labelled, expired or has been stored outside the specified conditions.

Do not mix lots, pool residual material or reuse single-use material unless expressly authorised by CellBxHealth Technical Support.

5. Limitations

The PCT must be used only with the compatible instrument, software, protocol, consumables and accessories specified in the approved labelling.

A passing PCT result demonstrates only the performance characteristic(s) covered by the validated PCT procedure. It does not guarantee performance outside those characteristics or the validity of unrelated sample results.

A failed, invalid or incomplete PCT must be investigated and resolved before affected instrument use is resumed. Contact CellBxHealth Technical Support, where appropriate (support@cellbxhealth.com).

Modified volumes, incubation times, storage conditions, acceptance criteria or procedures have not been validated unless expressly stated.

6. Storage and Handling

6.1. Storage

Store PCTs at 2-8 °C.

Keep the container tightly closed and protected from light.

Do not use after the expiry date printed on the label.

Do not use material that has leaked, changed appearance or been stored outside the labelled conditions.

6.2. Handling

Mix or resuspend using the method stated in this document.

Use each container once unless the approved design specifies otherwise. Record lot number and expiry date, where appropriate.

Dispose of residual material and contaminated consumables as described in the current Safety Data Sheet.

7. Performing a PCT

- Prior to running the PCT, ensure that the instrument has undergone either a cleaning cycle within the last 24 hours or its weekly maintenance as per *Parsortix® PR1 System Operating Manual (PR1-OM-C)* or *Parsortix® PR1 WICS System Operating Manual (PR1WICS-OM-A)*.
- Ensure the buffer reservoir contains at least 100 mL PBS.
- Ensure the priming reservoir contains at least 10 mL pure ethanol.
- Ensure a primed cleaning cassette is present inside the clamp.
- Ensure that a clean 50 mL Falcon tube is attached to the sample/vacutainer mount.
- Ensure that the harvest valve is turned 'clockwise' and is in "SEP" position before proceeding. Correct position for the harvest valve to be in the "SEP" position is shown in Figure 1 below:

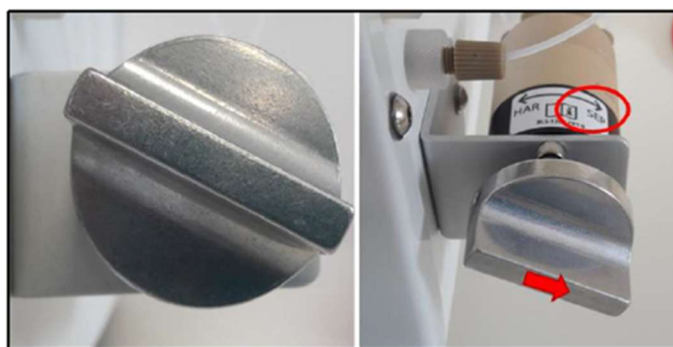


Figure 1 - Harvest/Separation valve in "SEP" position

- Select the **CTC01** protocol. Press [Run] then [Start].
- When prompted, "check Buffer", verify that the buffer reservoir bottle contains >100 mL PBS. Press [OK].
- When prompted, "check Cleaning rgt", verify that the cleaning reservoir contains >25 mL of 10% cleaning solution. Press [OK].
- When prompted, "check Priming rgt", verify that the ethanol reservoir contains >10 mL of 100% Ethanol. Press [OK].
- When prompted, "Waste empty?", verify that the waste reservoir bottle contains <400 mL of fluid and that the harvest waste tube is empty. Press [OK].
- When prompted "Insert New Cassette" / "Ready?", open cassette clamp, remove the Cleaning Cassette and keep it safe. Place a new Parsortix® Cell Separation Cassette into the clamp. Press [OK].

- While the new Separation Cassette is priming, prepare the PCT sample as follows:
 1. Remove a PCT vial from the refrigerator.
 2. Dispense 2.5 mL PBS buffer into a 50 mL Falcon tube.
 3. Pulse-spin the PCT vial using a microcentrifuge for ~5 seconds.
 4. Without agitating or shaking the contents, carefully remove the cap of the PCT vial.
 5. Using low binding pipette tips and a 200 µL pipette, transfer the entire contents of the PCT vial into the 50 mL Falcon tube containing the 2.5 mL of PBS. **Do not discard the pipette tip.**
 6. Fill and empty the pipette tip with the Falcon tube's PBS three times. **Do not discard the pipette tip.**
 7. Rinse the PCT vial as follows:
 - Pipette 200 µL of PBS into the PCT vial.
 - Gently pipette the buffer up and down three times in the vial ensuring the liquid runs down the walls of the vial.
 - Transfer the 200 µL of PBS into the Falcon tube.
 - Repeat this rinse procedure one more time.
- When prompted “Rinse Vacutainer” / “Start?”, pull the empty 50 mL Falcon tube off from the sample mount, keeping the sample line inside the tube. Press [OK] to start the rinse and collect the fluid inside the empty 50 mL Falcon tube.
- At the end of the rinse, fully remove the 50 mL tube and use an alcohol-soaked wipe to carefully wipe the outside of the sample line and the O-rings on the sample connection.
- When prompted “Preparing Sample” / “Attach Vacutainer...”, attach the vacutainer containing the PCT sample onto the sample mount. A twisting action will help in pushing the tube over the O-ring. Secure the sample tube by pushing it into the vertical position, then press [OK].
- When prompted “Preparing Sample” / “Start?”, press [OK] to start separation.
- A typical separation for a PCT sample will take approximately 40 minutes to complete. When prompted “Rotate Valve...” / “Anticlockwise”, verify that no liquid remains in the vacutainer.
- Rotate the harvest valve anticlockwise to “HAR” position. Correct position for harvest valve to be in the “HAR” position is shown here:

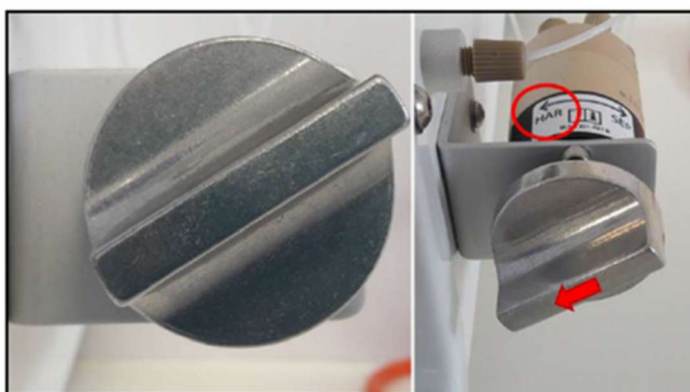


Figure 2 - Harvest/Separation valve in “HAR” position

- Press [OK].
- When prompted “Harvest” / “Start?”, remove the harvest line from the harvest waste container and clean it with an alcohol-soaked wipe.
- Place a well from a 96-well microtiter plate, or a 21-droplet slide beneath the harvest line and press [OK] to harvest the captured control cells from the cassette. See Figure 3 for recommended droplet harvesting onto a 21-droplet slide.



Figure 3 - Recommendation for harvest droplets on 21-droplet slide

- When the harvest is finished, place the 96-well microtiter plate, or 21-droplet slide on a flat surface at room temperature (18°C to 25°C), protected from dust and light (well plate - with foil), until enumeration as described below.
- When prompted “Rotate Valve...” / “Clockwise”, place the harvest line back into the harvest waste tube and rotate the harvest valve clockwise to “SEP” position. Correct position for the harvest valve to be in the “SEP” position is shown here:



Figure 4 - Harvest/Separation valve returned to “SEP” position

- Press [OK].
- When prompted “End of Harvest” / “Insert Cleaning Cass”, open the cassette clamp, remove the Separation Cassette, and dispose of it safely.
- Insert a new Cleaning Cassette into the clamp, close the assembly, and press [OK]. The cleaning cycle will take approximately 45 minutes to complete.

- When prompted “Remove Vacutainer”, remove and properly dispose of the mounted Vacutainer and press [OK].
- When prompted “CleanVacutainer-line”, use an alcohol-soaked wipe to carefully wipe the outside of the sample line and the O-rings on the sample connection. [Press OK].
- When prompted “Attach newVacutainer”, place a new 50 mL Falcon tube on the sample/vacutainer port, empty the fluids from the harvest waste tube and reattach the tube to the harvest line. Press [OK].
- When prompted “Finished CTC01” / “Back to Main Menu”, press [OK] and then [continue].

8. Enumerating Green Cells in the Harvest

- Leave the harvest vessel (96-well microtiter plate **or** 21-droplet slide) at room temperature (18°C to 25°C), on a flat surface, protected from light, and allow it to sit for a minimum of 1 hour (96-well plate) or 15 minutes (21-droplet slide) before counting the number of green cells as indicated below. If cell enumeration cannot proceed within 2 hours after harvest, store the plate, covered, at 2-8°C until enumeration, 21-droplet slides must be enumerated after 15 minutes to avoid evaporation. Refrain from shaking the plate, as the cells must settle on the bottom of the well to allow accurate visualisation and enumeration.
- Using the fluorescence microscope set on the Fluorescein isothiocyanate (FITC) or equivalent, such as Green Fluorescent Protein (GFP) channel, count the number of green cells observed in the harvest and record the total number.
- Compare the number of green cells counted in the harvest to the expected number of green cells for that batch of PCT tubes. **The PASS number for green cells will be 46% of the total cells within the vial, recorded on the included QC sheet, per individual rack.**
- For the PR1 or the PR1 WICS instrument to PASS, the number of green cells present in the harvest must meet or exceed the expected pass percentage.
- If the PCT does not pass with the specified percentage, consult Section 9 of this document for troubleshooting steps.
- If troubleshooting does not improve the PCT recovery, consult CellBxHealth Support (support@cellbxhealth.com).

9. Troubleshooting

OBSERVATION	POSSIBLE CAUSE	RECOMMENDED ACTION
Damaged, leaking or abnormal PCT container	Transport/storage damage or deterioration	Do not use. Quarantine the item, document the condition and contact CellBx Health Technical Support.
Instrument does not recognise or start CTC01 protocol	Incorrect software/protocol, instrument state or operator selection	Stop. Verify approved configuration and instrument status. Do not select a substitute protocol.
Unexpected volume or incomplete transfer	Pipetting, container retention or preparation error	Treat the run as invalid. Do not estimate or top up without authorisation from CellBx Health Technical Support
Failed result	Instrument, consumable, reagent, preparation or control issue	Check harvest valve position and ensure the SEP position is engaged for processing not HAR. Check expiry dates of all reagents and consumables. Ensure all on board reagents have sufficient volumes. Check for precipitation in the reagent bottles. If visible contamination, change for clean glassware. Perform a PX2_C or PX2_CT, and process 2 more consecutive PCT's. If both pass the instrument can be used for further work. If 1 fails, contact CellBx Health Technical Support.
Spill or exposure	Container or handling incident	Follow the SDS and local emergency procedure. Collect waste appropriately.

10. Symbols Used

SYMBOL	TITLE	MEANING
	Catalogue Number	Identifies the manufacturer's catalogue or product reference number. The catalogue number for this product is CTR-PCT-01.
	Batch Code	Identifies the manufacturer's production lot or batch for traceability.
	Use-by-date	Indicates the date after which the product must not be used. The date is expressed as YYYY-MM-DD.
	Country of manufacture	Identifies the United Kingdom as the country of manufacture.
	Date of manufacture	The adjacent date identifies the date of manufacture and is expressed as YYYY-MM-DD.
	Counter indication	Indicates the total number of tests that can be performed using the contents supplied. The applicable number appears adjacent to the symbol.
	Temperature limit	Store and transport the product between 2 °C and 8 °C.
	Do not use if package is damaged and consult	Do not use the product if its packaging is damaged, opened or otherwise compromised. Consult the instructions for use for further information.

SYMBOL	TITLE	MEANING
	instructions for use	
	Do not re-use	Indicates that the product is intended for one use only and must not be reused.
	Fragile, handle with care	Indicates that the product or its packaging is fragile and must be handled carefully.
	Keep away from sunlight	Indicates that the product must be protected from sunlight and other direct light sources.
	Contains biological material of human origin	Indicates that the product contains biological material or derivatives of human origin.
	Manufacturer	Identifies the legal manufacturer. The manufacturer's name and address appear adjacent to the symbol.
	Consult electronic instructions for use	Indicates that the user must consult the electronic instructions for use. The eIFU is available at www.cellbxhealth.com .

11. Technical Support

CONTACT FIELD	DETAILS
Company	CellBx Health Technical Support
Address	10 Nugent Road, Surrey Research Park, Guildford, GU2 7AF, United Kingdom
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