



Parsortix[®] PC1 ICT-01 Instrument Control Test Kit Instructions for Use



REF ICT-OM-F Parsortix PC1 ICT-01 Instrument Control Test Kit Instructions for Use
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Parsortix[®] PC1

Rx ONLY



Intended Use: The Parsortix[®] PC1 system is an in vitro diagnostic device intended to enrich circulating tumor cells (CTCs) from peripheral blood collected in K₂EDTA tubes from patients diagnosed with metastatic breast cancer. The system employs a microfluidic chamber (a Parsortix cell separation cassette) to capture cells of a certain size and deformability from the population of cells present in blood. The cells retained in the cassette are harvested by the Parsortix PC1 system for use in subsequent downstream assays. The end user is responsible for the validation of any downstream assay. The standalone device, as indicated, does not identify, enumerate or characterize CTCs and cannot be used to make any diagnostic/prognostic claims for CTCs, including monitoring indications or as an aid in any disease management and/or treatment decisions.

www.angleplc.com/ivd-ifu



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1. Intended Use

For *In Vitro* Diagnostic Use

The Parsortix[®] PC1 system is an in vitro diagnostic device intended to enrich circulating tumor cells (CTCs) from peripheral blood collected in K₂EDTA tubes from patients diagnosed with metastatic breast cancer. The system employs a microfluidic chamber (a Parsortix cell separation cassette) to capture cells of a certain size and deformability from the population of cells present in blood. The cells retained in the cassette are harvested by the Parsortix PC1 system for use in subsequent downstream assays. The end user is responsible for the validation of any downstream assay. The standalone device, as indicated, does not identify, enumerate or characterize CTCs and cannot be used to make any diagnostic/prognostic claims for CTCs, including monitoring indications or as an aid in any disease management and/or treatment decisions.

2. References

The following documents are referenced:

- *PC1-OM-F Parsortix PC1 Instrument Instructions for Use*
- *MBC-OM-F Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit Instructions for Use*

3. Summary and Explanation

The Parsortix PC1 instrument used in combination with the Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit (MBC-01 kit) enables the enrichment and isolation of CTCs from a peripheral blood sample drawn from metastatic breast cancer patients into K₂EDTA tubes and provides them as free cells suspended in buffer to allow a variety of subsequent downstream evaluations in accordance with **Section 1** above. The Parsortix PC1 ICT-01 Instrument Control Test Kit (ICT-01 kit) is used periodically (weekly) in conjunction with the Parsortix PC1 instrument and the MBC-01 kit to verify acceptable Parsortix PC1 instrument performance. All three of these components (the Parsortix PC1 instrument, MBC-01 kit, and ICT-01 kit) comprise the Parsortix PC1 system (device). Refer to the Instructions for Use (IFU) for the MBC-01 and ICT-01 kits for additional information. These IFUs can be found here: www.angleplc.com/ivd-ifu

4. Principle of Operation

The Parsortix PC1 instrument is intended for use by suitably trained users in a clinical laboratory setting and must be used in conjunction with the MBC-01 and ICT-01 kits. In order to verify that the Parsortix PC1 instrument is operating within pre-established acceptable limits, an Instrument Control Test (ICT) procedure must be used. This ICT-01 kit is to be used on a weekly basis in conjunction with the MBC-01 kit.

The ICT-01 kit contains single-use tubes of fixed pre-labeled cells from a breast carcinoma cell line (SKBR3), suspended in a buffer. Two cell populations, comprising a “low” number of cells and a “high” number of cells, have been pre-stained with two distinct fluorescence markers. The use of this ICT-01 kit requires access to a fluorescence microscope and a trained operator to enumerate the fluorescently labeled SKBR3 cells that are captured and harvested from the Parsortix PC1 instrument. The pass/fail criteria for the low and high cell populations are kit specific and are applied to the cell counts obtained to determine acceptable Parsortix PC1 instrument performance.



5. Materials Provided

The ICT-01 kit is provided for use with the Parsortix PC1 instrument as a control to enable the device intended use as set out in **Section 1** of this document.

The Parsortix PC1 ICT-01 Instrument Control Test Kit contains the following items:

- N ICT-01 Instrument Control Test (ICT) tubes corresponding to N instrument control tests, where $N = 10$ or 25
- M 12mL sample tubes corresponding to N ICT tubes, where $M = 10$ or 25
- X Parsortix PC1 GEN3P6.5IVD Cell Separation Cassettes, where $X = 10$ or 25
- Y ICT label sets (Where $Y = 10$ or 15 – e.g. Sets of labels, each set containing three individual labels to enable labeling of the ICT sample tube, separation cassette and harvest vessel);
- One package insert (per kit) containing instructions for use for the Parsortix PC1 ICT-01 Instrument Control Test Kit.

Each ICT-01 kit is sufficient to perform either 10 or 25 instrument control tests when used in conjunction with the Parsortix PC1 instrument and the MBC-01 kit, as described in this document.

6. Materials Required, Not Provided

Equipment:

- Parsortix PC1 instrument pre-loaded with the application software and the following core protocol files: **MBC01**, **PX2_CLEAN**, **PX2_LOAD** and **PX2_PRIMING**.
- Calibrated 300 μ L pipettor
- Pipette-aid
- Microcentrifuge with rotor for 1.5mL/2.0mL microfuge tubes and microcentrifuge adaptor
- Fluorescence microscope with appropriate objectives (e.g., 10X, 20X), fluorescence light source capable of 488 nm / 532 nm excitation, and filters for FITC and CY3
- Eppendorf 022636227 Adapter for fixed-angle and aerosol rotors; 0.5mL tubes and BD Microtainer tubes

Reagents and consumables:

Part Number	Manufacturer	Product
MBC-01	ANGLE	Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit
63429-04	Electron Microscopy Sciences	Hydrophobic 21 droplet printed slide
143205WR	Steris Life Sciences	ProKlenz® 120
352098	BD/Falcon	50mL Falcon Tubes
Varies	Varies	5 or 10mL sterile serological pipettes
Varies	Varies	Sterile, filtered PBS (500mL Bottles) without Ca ²⁺ /Mg ²⁺
Varies	Varies	Deionized Water (1 Liter Bottles)
Varies	Varies	200 μ L low protein binding tips

Part Number	Manufacturer	Product
Varies	Varies	Absolute Ethanol (99.5%)
Varies	Varies	Clorox® Hypochlorite Bleach
Varies	Varies	Alcohol pre-soaked wipes
Varies	Varies	Flat bottom, clear 96 well microtiter plate suitable for fluorescence microscopy

7. Warnings and Precautions



- **CAUTION:** Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the State in which he/she practices to use, or order the use of, the device.
- **WARNING:** Instructions for use and labeling for the Parsortix PC1 instrument, MBC-01 kit and ICT-01 kit must be followed at all times.
- **WARNING:** Following the Parsortix PC1 instrument, ICT-01 and MBC-01 kit Instructions for Use will ensure optimum device performance. It is the responsibility of the user to ensure instrument performance is adequate for specific downstream evaluation.
- **WARNING:** Do not use GEN3C cleaning cassettes from the MBC-01 kit in place of GEN3P6.5IVD cell separation cassettes for the processing of ICT samples on the Parsortix PC1 instrument.
- **WARNING:** Blood sample processing should not be conducted as per the MBC-01 kit Instructions for Use using a Parsortix PC1 instrument that has not undergone the weekly maintenance, including a successful ICT procedure as described in the ICT-01 kit Instructions for Use.
- **WARNING:** The Parsortix PC1 instrument together with the ICT-01 and MBC-01 kits is designed for use in a high complexity testing laboratory environment, as defined by CLIA. It must be situated and operated only in facilities with the specialized infrastructure and general equipment required for clinical laboratory operations, including those with blood disposal facilities following universal precautions. Users must follow these universal precautions and use specified laboratory safety equipment. All chemicals and all consumables that had contact with blood must be disposed of using adequate precautions and in accordance with local, state, and national regulations.
- **WARNING:** The Parsortix PC1 GEN3C cleaning cassettes and GEN3P6.5IVD cell separation cassettes (collectively cassettes) are fragile and must be handled with care. Always handle cassettes by the edges and avoid applying pressure to its surfaces.

- **WARNING:** Follow Health and Safety and Precautionary statements as described in the Parsortix PC1 Instrument Instructions for Use.
- **WARNING:** Each ICT tube contains the preservative sodium azide. If swallowed, seek medical advice immediately and show the containers or labels. Keep out of reach of children. Keep away from food and drink. Wear suitable protective clothing. Contact with acids liberates very toxic gas. Azide compounds should be flushed with large volumes of water during disposal to avoid deposits in lead or copper plumbing where explosive conditions can develop.

Risk and safety phrases: R22 (Harmful if swallowed) and S28 (After contact with skin, wash with plenty of soap).

8. Limitations

- For *In Vitro* Diagnostic Use
- The Parsortix PC1 Instrument must only be used in conjunction with a Parsortix PC1 ICT-01 Instrument Control Test Kit (ICT-01 kit) and a Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit (MBC-01 kit) and in accordance with the Intended Use set out in the instructions accompanying the equipment and kits.
- An acceptable ICT result does not guarantee that circulating tumor cells (CTCs) will be captured from a blood sample.
- Refer to the *PC1-OM-F Parsortix PC1 Instrument Instructions for Use* and *MBC-OM-F Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit Instructions for Use* for further limitations related to the device. These IFUs can be found here: www.angleplc.com/ivd-ifu

9. Storage and Handling

9.1 Storage

The ICT-01 Instrument Control Test Kit content is supplied ready for use in single use containers. The pack must be visually inspected for any sign of damage before use. The Parsortix GEN3P6.5IVD cell separation cassettes must be stored at room temperature protected from exposure to sunlight. When properly stored, cassettes are stable until the expiration date printed on the packaging. Do not use expired cassettes. The rack containing the ICT tubes at must be stored at 2-8 °C. When stored at 2-8 °C, the ICT tubes are stable until the expiration date printed on the packaging. Do not use expired ICT tubes.

9.2 Handling

For instructions on how and when to load and remove cassettes on and from the Parsortix PC1 instrument, and for reagent handling required to operate the instrument, please refer to the *PC1-OM-F Parsortix PC1 Instrument Instructions for Use*.

The **MBC01** protocol will be installed on the Parsortix PC1 instrument during instrument set-up by trained ANGLE personnel.



10. Instrument Control Test (ICT) Procedure

10.1 Parsortix PC1 Instrument Weekly Maintenance

The ICT procedure must be performed as part of the Parsortix PC1 instrument weekly maintenance procedure and as part of the instrument standard recovery procedure described in the *PC1-OM-F Parsortix PC1 Instrument Instructions for Use* document in **Sections 10.9** and **11.1**, respectively. The ICT tube, which contains fluorescently labeled cells, is dispensed into one of the 12mL sample tubes provided in the kit and is processed on a Parsortix PC1 instrument using a Parsortix PC1 GEN3P6.5IVD cell separation cassette. Captured cells are harvested and independently enumerated by a trained user, and the count is compared with pass/fail criteria provided with each ICT-01 kit to confirm acceptable performance of the Parsortix PC1 instrument.

10.2 Initial Checklist

Refer to the *PC1-OM-F Parsortix PC1 Instrument Instructions for Use* document for full instructions on how to operate the Parsortix PC1 instrument. The following conditions need to be fulfilled before performing an ICT-01 procedure:

- Visual inspection of the external instrument tubing for any signs of kinks, leaks, or damage.
- The reagents required for normal operation are in place according to *PC1-OM-F Parsortix PC1 Instrument Instructions for Use Section 10.5*.
- The Parsortix PC1 instrument must have passed the weekly maintenance procedure as per *PC1-OM-F Parsortix PC1 Instrument Instructions for Use Section 10.9*.
- The Parsortix PC1 instrument must have been cleaned after the last operation and within the past 24 hours prior to use. Refer to *PC1-OM-F Parsortix PC1 Instrument Instructions for Use Section 10.8.2* for cleaning instructions.
- The amount of liquid in the waste reagent bottle must be less than 400mL. Otherwise, follow the instructions as per *PC1-OM-F Parsortix PC1 Instrument Instructions for Use Section 10.5.1*.
- A clean 50mL Falcon tube is attached to the sample mount of the Parsortix PC1 instrument.
- A GEN3C cleaning cassette is correctly inserted in the cassette clamp. Refer to *PC1-OM-F Parsortix PC1 Instrument Instructions for Use Section 10.4* for cassette handling instructions.
- The harvest valve is turned clockwise to the "SEP" position (*PC1-OM-F Parsortix PC1 Instrument Instructions for Use Section 10.6*).
- The harvest waste line "H" is plugged into the cap of the harvest waste tube.
- A new Parsortix PC1 GEN3P6.5IVD cell separation cassette is available.
- An additional empty 50mL Falcon tube is available.

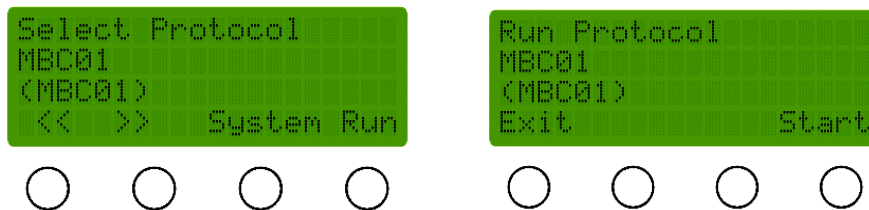
10.3 ICT Sample Preparation

1. Remove an ICT tube from the refrigerator.
2. Appropriately label a new Parsortix PC1 GEN3P6.5IVD cell separation cassette (separation cassette) by placing one of the provided labels in the middle of the new separation cassette on the "smooth" film side.

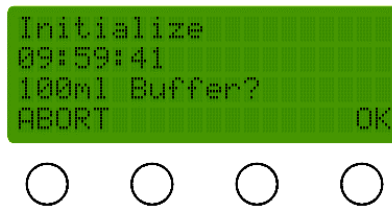
3. Appropriately label a 12mL sample tube using one of the provided labels and place it into a test tube rack.
4. Dispense 3mL of PBS buffer into the 12mL sample tube.
5. Pulse-spin the ICT tube that was removed from the refrigerator for 5 seconds using a microcentrifuge and the appropriate tube adapter.
6. Without agitating or shaking the contents, carefully remove the ICT tube from the microcentrifuge, and remove the cap.
7. Using a new low binding tip and a 300µL pipette set to 230µL, transfer the entire contents of the ICT tube (total volume of ~220µL) into the 12mL sample tube containing the 3mL of PBS, and rinse the tip by pipetting the PBS in the 12mL sample tube up and down three times.
8. Rinse the ICT tube as follows:
 - a. Using a new low binding tip, pipette 40µL of PBS into the ICT tube;
 - b. Gently pipette the PBS up and down three times in the ICT tube;
 - c. Transfer the 40µL of PBS into the 12mL sample tube;
 - d. Repeat the above rinse step **once** more.

10.4 ICT Sample Processing

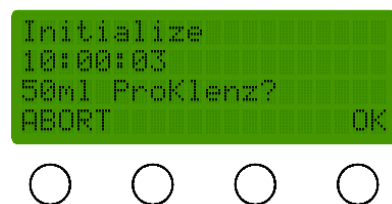
1. In the main menu screen, select the protocol "**MBC01**" and press [Run] then [Start] and follow the on-screen instructions.



2. At prompt "100mL Buffer?" check that the buffer reservoir (250mL bottle connected to the line labeled "B") contains >100mL of PBS. Press [OK].



3. At prompt "50mL ProKlenz?" check that the cleaning reagent reservoir (250mL bottle connected to the line labeled "C") contains >50mL of 10% ProKlenz solution. Press [OK].



4. At prompt "10mL EtOH?" check that the priming reagent reservoir (100mL bottle connected to the line labeled "P") contains >10mL 100% (absolute) ethanol. Press [OK].

```
Initialize
10:00:26
10ml EtOH?
ABORT OK
```



5. At prompt "Waste empty?" ensure that the waste reservoir (500mL bottle connected to the line labeled "W") has <400mL of liquid. If the level of the waste fluid is \geq 400mL, change the waste reservoir as detailed in *PC1-OM-F Parsortix PC1 Instrument Instructions for Use* **Section 10.5.1**. Press [OK].

```
Initialize
10:02:43
Waste Empty?
ABORT OK
```



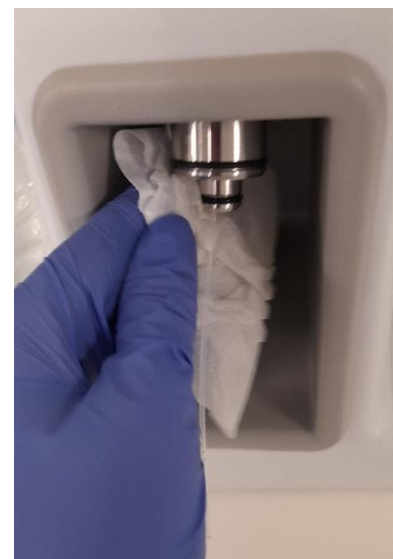
6. At prompt "Insert New Cassette" "Ready?", open the cassette clamp and remove the GEN3C cleaning cassette, keeping it safe. Insert a new, properly labeled, Parsortix GEN3P6.5IVD separation cassette into the cassette clamp. Close the clamp and press [OK].

```
Insert New Cassette
10:03:18
Ready?
ABORT OK
```



7. At prompt "Rinse Vacutainer" "Start?", pull the currently mounted 50mL Falcon tube off of the sample mount, keeping the sample line inside the tube. Press [OK] to start the rinse procedure and collect the fluid dispensed by the instrument inside the tube. At the end of the rinse procedure, fully remove the 50mL Falcon tube and use an alcohol-soaked wipe to carefully wipe the outside of the sample line and the O-rings on the sample mount.

```
Rinse Vacutainer
10:03:58
Start?
ABORT OK
```



8. At prompt "Preparing sample" "Attach Vacutainer..." attach the 12mL sample tube containing the ICT tube contents and 3mL of PBS onto the sample mount of the instrument. A twisting action will help to push the mouth of the tube over the O-ring. Secure the sample tube by pushing it into the vertical position and press [OK].

```
Preparing Sample
10:04:22
Attach Vacutainer...
ABORT OK
```



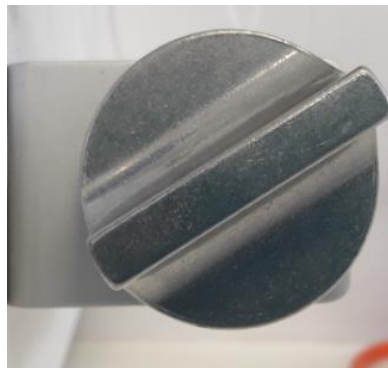
9. At prompt "Preparing Sample" "Start?" press [OK] to start separation of the ICT sample.

```
Preparing Sample
10:04:44
Start?
ABORT OK
```



10. At prompt "Rotate Valve..." "Counterclockwise", rotate the harvest valve counterclockwise into the HAR position. Press [OK]. Check that the sample tube is empty.

```
Rotate Valve...
10:06:28
Counterclockwise
ABORT OK
```



11. At prompt "Cell recovery" "Start?", remove the harvest line from the harvest waste tube and clean it with an alcohol-soaked wipe. Place the harvest vessel (either a 21-droplet slide or the empty well of a flat bottom 96 well microtiter plate) beneath the harvest line and press [OK] to harvest the control cells captured from the separation cassette onto/into the collection vessel.

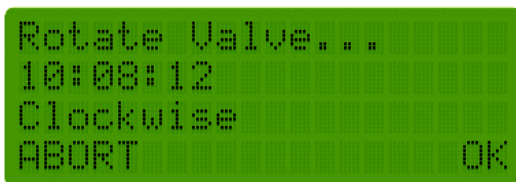


If a 96 well plate is the harvest vessel, collect the entire harvest into one well of the plate. If a 21-droplet hydrophobic slide is the harvest vessel, collect one 'drop' of harvest onto each 'well' of the slide. Ensure an adequate range of motion with the harvest line to reach each droplet location or the targeted empty well.



Enumerate the harvested cells as instructed in **Section 10.5** below.

12. At prompt "Rotate Valve..." "Clockwise", place the harvest line back into the harvest waste tube and rotate the harvest valve clockwise to the SEP position. Press [OK].



13. At prompt "End of Harvest" "Insert Cleaning Cass", open the cassette clamp, remove the GEN3P6.5IVD separation cassette and dispose of it safely. Insert the GEN3C cleaning cassette into the clamp, close the clamp assembly and press [OK]. The cleaning cycle will take approximately 45 minutes to complete.

```
End of Harvest
10:08:28
Insert Cleaning Cass
ABORT OK
```



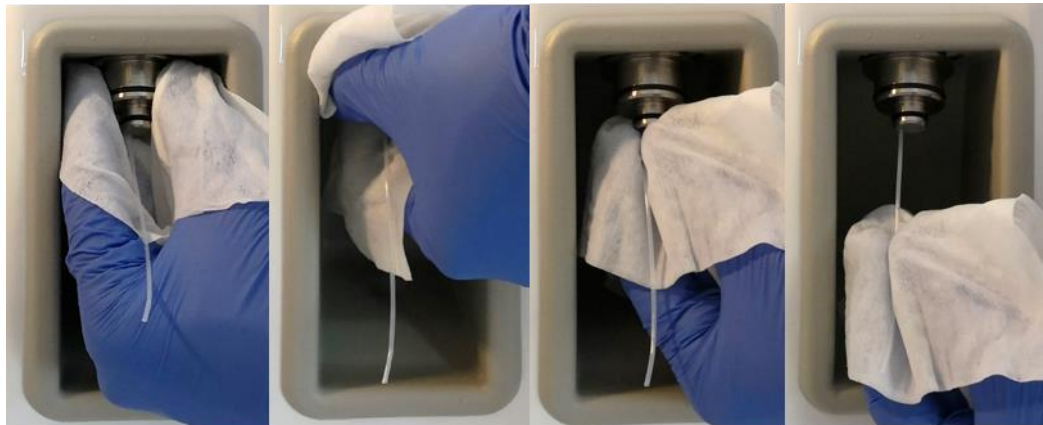
14. At prompt "Remove Vacutainer", carefully remove and properly dispose of the mounted sample tube and press [OK]. A twisting motion will help with the removal of the sample tube.

```
Finished
10:12:21
Remove Vacutainer
ABORT OK
```



15. At prompt "CleanVacutainer-line", clean the O-rings on the sample mount and the outside of the sample line using an alcohol-soaked wipe. Press [OK].

```
Finished
10:12:57
CleanVacutainer-line
ABORT OK
```



16. At prompt "Attach newVacutainer", place a clean 50mL Falcon tube onto the sample mount. Empty the fluids from the harvest waste tube and reattach the tube to the harvest line. Press [OK].

```
Finished
10:13:17
Attach newVacutainer
ABORT OK
```



17. At prompt "Finished MBC01", press [OK] then [Continue] to return to the main menu screen.

```
Finished MBC01
10:13:35
Back to Main menu?
ABORT OK
```

```
Protocol finished
Continue
```



10.5 Enumeration of Harvested ICT Cells

If a 96-well microtiter plate was used as the harvest vessel, the plate must be allowed to sit for a minimum of one (1) hour before counting the number of cells as indicated below to allow the cells to settle to the bottom of the well. If enumeration of the harvested cells cannot be performed within 2 hours after harvest, cover the plate with a light protective covering and store in the dark at 4°C for up to 24 hours. Avoid any shaking when handling the plate, as for proper visualization and enumeration, the cells must lay in a monolayer at the bottom the well.

If a 21-droplet hydrophobic slide was used as the harvest vessel, the slide must be allowed to sit in a covered slide holder for a minimum of 15 minutes before counting the number of cells as indicated below. The cells in each of the droplets on the slide must be enumerated within 30 minutes after harvest to avoid evaporation of the droplets and the formation of crystals. **NOTE:** Cells are not expected to be seen in the first nine drops of the harvest. To enable efficient counting, it is recommended to start counting wells 10-21 and then follow-up, checking that wells 1-9 do not have cells present.

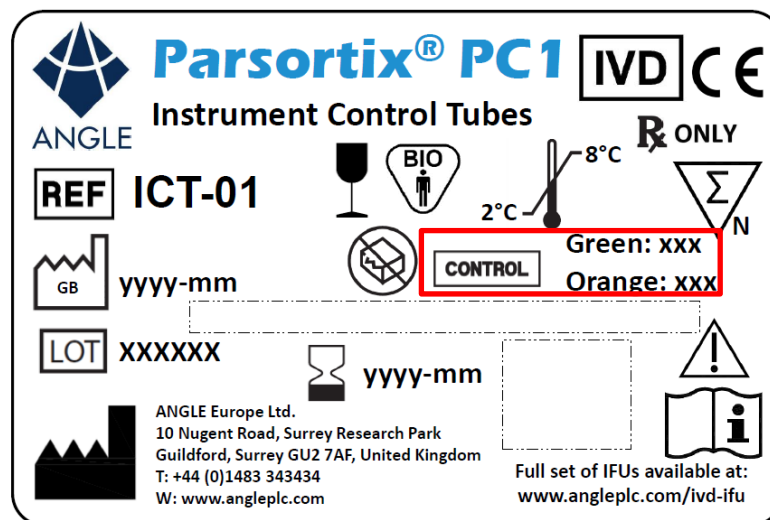
Using a fluorescence microscope set to the FITC channel, count the number of green cells present and record the result. Changing to the Cy3 channel, or using a fluorescence microscope set to the CY3 channel, count the number of orange cells present and record the result.

11. Output and Interpretation of Result

For each batch of ICT tubes, the pass/fail criteria are provided for the cells present in the FITC (Green) and Cy3 (Orange) channels on the packaging label, as circled in red below.

To determine acceptable Parsortix PC1 instrument performance (pass), the number of pre-labeled cells present in the harvest must be equal to or exceed the values indicated for both the Green (FITC) and Orange (Cy3) cell populations.

If the Parsortix PC1 instrument fails, an instrument cleaning procedure must be performed (refer to *PC1-OM-F Parsortix PC1 Instrument Instructions for Use Section 10.8.2*) and the ICT procedure (**Section 10** above) must be repeated on the cleaned instrument. If the Parsortix PC1 instrument passes the second ICT procedure, the instrument is considered to have acceptable performance. If the Parsortix PC1 instrument fails the second ICT procedure, contact the ANGLE Technical Support. **No blood sample processing should be conducted using a Parsortix PC1 instrument that has not passed the weekly ICT procedure.**






















12. Troubleshooting

Potential problems and recommended actions related to Parsortix PC1 instrument operation are described in *PC1-OM-F Parsortix PC1 Instrument Instructions for Use* **Section 11**. Contact ANGLE Technical Support if further advice is required (see **Section 14** below).

13. Symbols Used

The ICT-01 Instrument Control Test Kit carries the following hazard, warning and operational labels:

SYMBOL	MEANING	
	READ INSTRUCTIONS	Read the instruction manual for a description of principles of operation and details of potential hazards
	CE MARK	Indicates compliance with a range of European Directives as set out in an accompanying EU Certificate of Conformity
	MANUFACTURER	Name and address of the instrument manufacturer
	DATE AND COUNTRY OF MANUFACTURE	Indicates the country of manufacture and the manufacturing date, by year and month
	LOT NUMBER	Manufacturer's lot number for traceability of components
	CONTAINS BIOLOGICAL MATERIAL OF HUMAN ORIGIN	Product contains biological material of human origin: biological tissue, cells, or their derivatives
	DO NOT USE IF PACKAGING IS DAMAGED	Do not use the labeled component if the packaging is already open in order to avoid the risk of contamination
	KEEP AWAY FROM SUNLIGHT	Parts labeled are sensitive to sunlight and should be stored away from sunlight
	CAUTION	Consult the instructions for use for important warning or cautionary information

SYMBOL	MEANING	
	FRAGILE	Indicates that the contents of a package or container are fragile and should be handled with care
	CONTENTS SUFFICIENT FOR N TESTS	Indicates the number (N as displayed) of tests (or related consumable items) supplied
	IN VITRO DIAGNOSTIC DEVICE	The device is designated as an In Vitro Diagnostic Device and is for in vitro diagnostic use in accordance with the intended use statement
	EXPIRATION DATE USE BY YYYY-MM	Indicates the expiration date, use by year and month
	CONTROL	Indicates a control material that is intended to verify the performance characteristics of another medical device
	SINGLE USE ONLY	The components must not be used more than once to avoid the risk of cross-contamination
	TEMPERATURE LIMIT	Indicates the maximum and minimum temperature limits at which the item shall be stored
	Rx ONLY	Prescription only - Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the State in which he/she practices to use, or order the use of, the device.
	CATALOG NUMBER	Indicates the manufacturer's catalogue number of the device to aid identification.
	EC REP	Indicates the European Union Authorized Representative for the Parsortix system.



14. Technical Support

Contact ANGLE Technical Support if further advice is required.

Authorized manufacturer's representative in North America:

ANGLE North America Inc
5100 Campus Drive
Suite 120
Plymouth Meeting, PA 19462
Email: us-support@angleplc.com
www.angleplc.com

Device manufacturer:



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