

PRODUCT SHEET

1. **Intended Use:** This product is intended for preclinical application. It is not intended for any therapeutic or diagnostic use
2. **Storage Temperature:** -150°C or below
3. **Biosafety level to be used while formulating:** 1
4. **Description & Certificate of Analysis**

Product Information:

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|------------------|--|
| Product Name | HuSu-TRANS-TR-O |
| Source | Provided on Demand |
| Special Handling | Minimize exposure to non-liquid nitrogen temperatures, especially room temperature transfers |

Required Testing & Results:

| Test | Specification | Result |
|-----------------------------------|---|--|
| Mycoplasma | Negative | Negative |
| Appearance, Container Integrity | Conforms | Conforms |
| Appearance, Suspension Appearance | Conforms | Conforms |
| Cell Count | > 0.5x10 ⁶ viable cells/vial | >0.5x10 ⁶ viable cells/vial |
| Cell Viability | >92% | >92% |
| Biomarker CA125 | >95% positive | 100% |
| Biomarker HE4 | >95% positive | 100% |
| Clonogenicity | Positive | Positive |
| Endotoxin | <3 EU/mL | <3 EU/mL |
| Bio Burden - Sterility | Negative | Negative |

Supporting Data:

| | |
|---------------------|--|
| Safety Data | Representative Final Product lots were found non-tumorigenic and non-toxic |
| Donor Specimen (DS) | This DS has met all release criteria including donor selection criteria, consent for donation, virus testing (HIV1/2, HBV & HBC) |

General Information:

| | |
|----------------|-----------------------------|
| Organism | Homo sapiens, human |
| Disease | Cancerous – Malignant tumor |
| Ethnicity | Indian |
| Product Format | Frozen |

5. Safety Precaution

Recommending protective gloves, apron, face mask be worn when handling frozen vials

6. Unpacking & Storage Instructions

- Check all containers for leakage or breakage
- Remove the frozen vial from the dry ice packaging and immediately place at a temperature below -150°C, until ready for use

7. Handling Procedure for Frozen Cells

- Refer to the batch specific information for the total number of viable cells recovered from this lot
- Remove one vial at a time from storage and thaw the vial by gentle agitation in a 37°C water bath. Thawing should be rapid (1 to 2 minutes)
- Remove the vial from the water bath as soon as the contents are thawed, and decontaminate by dipping in or spraying with 70% ethanol under aseptic conditions
- Add the appropriate volume (5 mL) of medium into a sterile conical tube. Using a sterile pipette, transfer the cells from one cryo vial to the conical tube and gently tap the tube to mix the suspension for 5 min at room temperature
- Centrifuge the cells at 150 x g for 3 to 5 minutes
- Remove the supernatant and the pellet is to be re-suspended in the volume for desired next step

8. Human Material Precaution

All tissues used for isolation are obtained under informed consent and concerned regulatory ethics approval to conform to handling biological samples standards; to protect the privacy of the donor’s personal health information

9. Transtoxbio Warranty

The viability of the product is warranted for 25 days from the date of shipment, and is valid only if the product is stored and handled according to the information included in



10. Disclaimer

- This product is intended for preclinical research purposes only and not for use in humans. While Transtoxbio uses realistic efforts to include support information on this product sheet, makes no warranties or representations as to its accuracy
- This product is sent with the condition that you are responsible for its safe storage, handling, and use. Transtoxbio is not liable for any damages or injuries arising from receipt and/or use of this product