

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:

Product Name	TRANS-TR-H&N
Source	Provided on Demand
Special Handling	Minimize exposure to non-liquid nitrogen temperatures, especially room temperature transfers

Quality 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 CDKN2A	>95% positive	100%
Biomarker PI6NK4A	>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

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