Innovative Life Science Solutions™

PRODUCT DESCRIPTION

ZTM:A1™ Transport and Processing Media
(Supplemented with HEPES and Antibiotics: Clindamycin and Gentamycin)

INCELL CERTIFIED Chemically Defined No Animal-Derived Components

Product Names: ZTM:A1™

Product Codes: ZTMA1-100, ZTMA1-500, ZTMA1-500-6

General Use: Media to transport and process tissues and cells

Features: GMP quality; sterile; USP grade materials; no animal-derived components; no human proteins; with antibiotics

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General Description

ZTM:A1™ transport and processing media is a sterile, animal component free, chemically defined, GMP-manufactured, and ready-to-use solution to ship and process freshly isolated tissues and separated cells or tissues intended for clinical use. ZTM:A1™ is a proprietary formulation of USP and pharmaceutical grade chemicals with selected antibiotics and supplemented with a long-acting stable glutamine to support maintenance and viability of tissues during transport or processing. ZTM:A1™ media does not contain supplemental growth-promoting factors, or human or animal-derived sera or supplements, so it is not suitable for cell culture.

Formulation and Packaging

ZTM:A1™ media contains components (salts, amino acids, sugars) that are high quality USP or pharmaceutical grade chemicals from plant and microbial sources. ZTM:A1™ media helps maintain living tissue during transport, processing and short term storage. ZTM:A1™ antibiotics are clindamycin (6.5 µg/mL); and gentamicin (50 µg/mL). There is no amphotericin B, in contrast to its related media, ZTM:A2™, which has twice ("2X") clindamycin (13 µg/mL) and gentamicin (100 µg/mL); and also contains amphotericin B (2.5 µg/mL). ZTM:A1™ contains 10 mM HEPES and is packaged in 100 mL (ZTMA1-100) and 500 mL (ZTMA1-500) sizes in square PET media bottles that meet medical device quality for media storage.

Use and Methods: Transportation, Processing and Storage

ZTM:A1™ and its related media ZTM:A2™, help maintain a supportive tissue and "cell-friendly" environment during transport and subsequent bioprocessing (e.g., enzymatic and mechanical tissue disruption). Antibiotics are included to control bioburden from source tissues or that may have been introduced into the sample at harvest. Table 1 on the next page, shows tissues where ZTM™ media are suitable for use as the ZTM:A1™ or ZTM:A2™ formulas. For processing tissues, and depending on the protocol, ZTM:A1™ and ZTM:A2™ can be used from 2°C to 8°C. Note that ZTM™ solutions are NOT cryopreservation or culture media. Tissues that are to be processed for living cells, or the released cells, should NOT be stored frozen or cultured in these media.

Manufacturing

Media are manufactured by sterile 0.22 µm filtration and packaging, using cGMP standards in an ISO Class 7 clean room and ISO Class 5 biosafety cabinet. Raw materials are pre-tested, and the final product is checked by quality specifications and acceptance criteria (see below) tested by USP standards for pH, osmolality, sterility (bacteria, fungi), mycoplasma and endotoxin prior to release and preparation of the Certificate of Analysis.

ZTM:A1™

Transport and Processing Solution

Specifications	Acceptance Criteria
Visual	Colorless, clear, solution
pH (USP <791>)	6.5 to 7.0
Osmolality (USP <785>)	290 to 350 mmol/kg
Sterility: SC (USP <71>)	No microbial growth
Sterility: fTG (USP <71>)	No microbial growth
Mycoplasma (USP <63>)	None detected
Endotoxin (USP<85>)	<0.1 EU/mL
Expiration Date	24 months storage at 2°C to 8°C.

Storage

ZTM:A1™ Media shelf-life is 24 months from the date of manufacture if kept between 2°C and 8°C. Do Not Freeze.

Table 1. ZTM:A1™ and its Related Media* ZTM:A2™ are Suitable for Transport and/or Processing of Surgically Resected Human and Animal Tissues for Use in Various Clinical or Research Applications

Tissue Types	Primary Cell Type(s) Derived
Adipose (Fat)	Mesenchymal Stem Cells; Stromal vascular fraction regenerative cells; adipose cells
Bone Marrow* Bone	Hematopoietic and mesenchymal stem cells; various types of renewable progenitor cells; Endothelial cells; entire population; bone and cartilage progenitors; other cells
Brain and Neural (Spinal)	Progenitors; Induction of differentiation
Breast	Primary epithelial cells and/or mesenchymal support cells
Cartilage	Chondrocytes and Progenitors
Colon; Gastrointestinal, incl. oral; esophageal	Primary epithelial and/or mesenchymal support cells or complex tissues in organ-like cultures
Dental Pulp	Hematopoietic and mesenchymal stem cells; Various types of renewable progenitor cells; like bone marrow
Heart	Primary muscle and mesenchymal cells
Kidney	Primary epithelial cells and/or mesenchymal support cells
Liver	Primary epithelial cells and/or mesenchymal support cells
Lung	Primary epithelial cells and/or mesenchymal support cells
Lymph Node*	Lymphocytes and mesenchymal support cells
Muscles (Peripheral; Heart; Smooth)	Pericytes; Mesenchymal or Stromal Stem Cells; other regenerative cells
Pancreas and Other Neuroendocrine Organs	Pancreatic islet beta and acinar cells; other organs (e.g., adrenal)
Parathyroid*	Adenoma cells isolated and stored for potential autologous re-transplantation
Peripheral or apheresis Blood*	Various types of white blood cells, including lymphocytes, macrophages, etc.; Circulating or mesenchymal cells; Endothelial cells.
Placenta	Trophoblasts; Syncytiotrophoblasts; Endothelial cells; Hematopoietic and mesenchymal stem cells; Various renewable progenitor cells
Prostate	Primary epithelial cells and/or mesenchymal support cells
Skin (adult; newborn)	Epidermal keratinocytes; biopsies; hair follicles Dermal Fibroblasts; Mesenchymal cells
Spleen*	Lymphocytes and mesenchymal support cells
Tumors	Epithelial, mesenchymal, lymphoid
Umbilical cord*	Hematopoietic and mesenchymal stem cells; various types of renewable progenitor cells; Endothelial cells

Choice of ZTM™ media type is based on risk assessment of the donor tissue source. ZTM:A2™ has twice the concentration of antibiotics than ZTM:A1™ and also has amphotericin B (anti-fungal). Choice of ZTM:A2™ depends on amount of bioburden and if fungal organisms might be an expected risk. Also, antifungals should not be used with blood derived cells.
*Asterisks next to tissue type recommend ZTM:A1™; remaining tissue types can be either ZTM:A1™ or ZTM:A2™.

Master Files Applications Note

ZTM™ media (ZTM:A1™ and ZTM:A2™) are in FDA Drug and Device Master Files but the media has not been tested by INCELL for any specific diagnostic or therapeutic use. To request use of any product's Master File call, fax, or send an email to info@incell.com.

Animal Component Free. INCELL certifies that these media have no "animal-derived components" per the following criteria:

- No animal-derived components are added by INCELL or come from raw materials supplied as components of the Product.
- Product does not come into contact with animal-derived material during manufacturing, processing, handling, or packaging.
- Our Products are manufactured on dedicated animal free equipment in animal free clean rooms.
- This certification applies only to the condition of the above-described Product in its unopened package, and INCELL assumes no responsibility for a Product failing to meet this Statement after handling or use after opening the package.
- Signed "Animal Origin Statement" can be provided on request.

Ordering: Contact INCELL Corporation

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Technical Assistance

The scientists at INCELL are available to discuss the media or special needs of your cells, and to assist you in your cell culture applications. Call 1-800-364-1765 or e-mail info@incell.com.