

FreshCells™ Cell Culture Media












For *in vitro* Diagnostic Use

Please contact Quidel Corporation Technical Support for technical assistance regarding this procedure.

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TurboTreat® is covered by U.S. Patent Nos. 5,891,624; 6,458,577.
R-Mix™ is covered by U.S. Patent Nos. 6,168,915; 6,376,172; 6,406,842.
R-Mix Too™ is covered by U.S. Patent No. 6,946,291.
Super E-Mix™ is covered by U.S. Patent Nos. 6,168,915; 6,573,080; 7,186,504.

Symbols Lexicon/Glossary

 In Vitro Diagnostic Medical Device	 Batch code/lot number
 Temperature limit	 Catalog number
 Consult e-labeling instructions for use	 Use by YYYYMONDD
 Patent Numbers	 Manufacturer
 Do not reuse	
 CE mark of conformity (Conformité Européen)	 Authorized representative in the European Community

Intended Use

FreshCells™ culture media products are intended for use with the Diagnostic Hybrids *FreshCells*™ and *FreshCells*™ *MixedCells*™ (R-Mix™, R-Mix Too™, Super E-Mix™ and H&V-Mix™), and *FreshFrozenCells*® cultures. They are provided as "Ready to Use" solutions in several package size volumes.

Description

The Diagnostic Hybrids *FreshCells*™ culture media are formulated to supply the cells with the required nutrients during the incubation period. Each medium also contains antibiotics to suppress the growth of bacteria and/or fungi present in specimens.

Warnings and Precautions

1. *FreshCells*™ culture media products are for *in vitro* diagnostic use.
2. As with all methods for virus identification using cultured cells, personnel must be properly trained in virus culture and safe handling techniques as described in the CDC-NIH manual¹, i.e., manipulations which present potential personnel hazards should be conducted in a Class II biosafety cabinet and gloves should be worn at all times.
3. Cultures and specimens should be autoclaved or disinfected with a solution of sodium hypochlorite (1:10 final dilution of household bleach) prior to disposal.

¹ CDC-NIH Manual, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 5th edition, 2007, CDC-NIH manual. [<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>]

Stability and Storage

1. *FreshCells*™ culture media should be stored at 2° to 8°C.
2. Upon receipt, *FreshCells*™ culture media should be visually examined for a lack of turbidity and the typical peach-to-pink color. Do not use any media exhibiting a yellow or purple color or any degree of turbidity as these are all indicators of possible contamination.

Quality Assurance

1. *FreshCells*™ culture media is analyzed prior to shipping. A Lot Specification Sheet is supplied with each order to inform the end user of its quality control status. Additionally, visual inspection for a lack of turbidity and the typical peach-to-pink color should be performed and documented upon receipt.
2. Negative cell controls should be run with each batch of specimens tested for virus or *Chlamydia*. Negative controls consist of non-inoculated monolayers that otherwise are handled the same as inoculated monolayers.
3. Positive virus controls may be run using previously identified viral agents that will produce the result desired from a positive patient sample. While not generally required by regulatory organizations, these may be useful for troubleshooting purposes or for the production of additional external staining controls.

Lot Specifications

Information beyond that provided by the Product Insert, Lot Specification Sheet, or Material Safety Data Sheet is available upon request.

Limitations

Diagnostic Hybrids culture media products are intended for use with the *FreshCells*™, *MixedCells*™, *ReadyCells*®, and *FreshFrozenCells*® cultures.

Procedure

1. Refer to the Diagnostic Hybrids cell-line-specific product insert for instructions for use.
2. *FreshCells*™ culture media products are provided in formats and formulations described in Table 1.

References

Available upon request, contact Diagnostic Hybrids Technical Support at 1-800-874-1517 or outside the US at +1(858) 552-1100.

Warranty Statement

These products are warranted to perform as described in their labeling and the Diagnostic Hybrids literature when used in accordance with their instructions. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THIS EXPRESS WARRANTY AND DIAGNOSTIC HYBRIDS DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR PARTICULAR PURPOSE. Diagnostic Hybrids sole obligation and purchaser's exclusive remedy for breach of this warranty shall be, at the option of Diagnostic Hybrids to repair or replace the products.

FreshCells, *MixedCells*, *ReadyCells*, *FreshFrozenCells*, R-Mix, R-Mix Too, E-Mix and H&V-Mix are trademarks or registered trademarks of Diagnostic Hybrids, Inc., in the United States and other countries.

TABLE 1: Cell Culture Media Products

REF	Product	Size	Description
10-200100	Cell Planting Medium	100-mL	<ul style="list-style-type: none"> Developed for use in cell culture planting (<i>FreshCells</i>[™] single cell lines and <i>FreshFrozenCells</i>[®]). EMEM with EBSS (Earle's Balanced Salt Solution), 10% FBS, 25 mM HEPES, Glutamine, and Gentamicin at 50 µg/mL. Sterile.
10-200100EU1	Supplement for Cell Planting Medium Base (10-200100EU2)	11-mL tube	<ul style="list-style-type: none"> Supplement contains FBS, and Gentamicin sufficient for 100-mL bottle of Cell Planting Medium Base (10-200100EU2). Sterile.
10-200100EU2	Cell Planting Medium Base	100-mL bottle	<ul style="list-style-type: none"> EMEM a buffered salt solution with HEPES and other necessary sugars, amino acids and vitamins. Sterile.
10-210125	MRC-5 Cell Growth Medium	125-mL bottle	<ul style="list-style-type: none"> DMEM, 10% FBS, Glutamine, and Gentamicin at 50 µg/mL. Sterile.
10-220100 10-220500	ELVIS [®] Replacement Medium	100-mL 500-mL	<ul style="list-style-type: none"> Developed for use with <i>FreshCells</i>[™] ELVIS[®] HSV Cells. EMEM with EBSS, 7% FBS, 25 mM HEPES, Glutamine, Penicillin at 100 units/mL, Streptomycin at 100 µg/mL and Amphotericin B at 1.25 µg/mL. Sterile.
10-290030	TurboTreat [®] A Mink Lung Cell Pretreatment Medium	30-mL	<ul style="list-style-type: none"> Recommended for use only with Mink lung CMV cell cultures. EMEM with EBSS, without phenol red, 10% FBS, 25 mM HEPES, Glutamine, and Gentamicin at 50 µg/mL. Sterile.
10-310100	RM-01 Refeed Medium (Zero-Serum Refeed Medium)	100-mL	<ul style="list-style-type: none"> A defined medium with EMEM with EBSS, and Glutamine. Sterile.
10-320100 10-320500	RM-02 Refeed Medium (Standard 2% FBS Refeed Medium)	100-mL 500-mL	<ul style="list-style-type: none"> Recommended for use with most cell cultures, for subsequent detection of viruses other than Influenzae. EMEM with EBSS, 2% FBS, 25 mM HEPES, Non-essential amino acids (NEAA), Glutamine, Gentamicin at 10 µg/mL, Penicillin at 50 units/mL, Streptomycin at 50 µg/mL, and Amphotericin B at 1.25 µg/mL. Sterile.
10-330100 10-330500	RM-03T R-Mix [™] Refeed Medium	100-mL 500-mL	<ul style="list-style-type: none"> Developed for use with <i>R-Mix</i>[™] cultures (<u>not for use</u> with <i>ReadyCells</i>[®] cultures). A defined medium with NEAA, Penicillin at 100 units/mL, Streptomycin at 100 µg/mL, and Trypsin (bovine origin) at ~0.5 µg/mL. Sterile.
10-340100 10-340500	<i>Chlamydia</i> Isolation Medium*	100-mL 500-mL	<ul style="list-style-type: none"> Recommended for use with <i>Chlamydial</i> cell cultures. EMEM with EBSS, 10% FBS, 25 mM HEPES, 22 mM Glucose, NEAA, Gentamicin at 10 µg/mL, Streptomycin at 50 µg/mL, Amphotericin B at 2 µg/mL and Cyclohexamide at 1 µg/mL. Sterile.
10-350100 10-350500	RM-05 Refeed Medium (Standard 10% FBS Refeed Medium)	100-mL 500-mL	<ul style="list-style-type: none"> Recommended for use with most cell cultures, for subsequent detection of viruses other than <i>influenzae</i>. EMEM with EBSS, 10% FBS, 25 mM HEPES, NEAA, Glutamine, Gentamicin at 10 µg/mL, Penicillin at 50 units/mL, Streptomycin at 50 µg/mL, and Amphotericin B at 1.25 µg/mL. Sterile.
10-360100	Zero-Serum Refeed Medium – PS	100-mL	<ul style="list-style-type: none"> A defined medium with NEAA, Penicillin at 100 units/mL and Streptomycin at 100 µg/mL. Sterile.
10-380100 10-380500	Super E-Mix [™] Refeed Medium	100-mL 500-mL	<ul style="list-style-type: none"> Developed for use with Super E-Mix[™] (<i>MixedCells</i>[™] and <i>ReadyCells</i>[®]) cultures. A defined medium with 0.1% FBS, NEAA, Penicillin at 100 units/mL, and Streptomycin at 100 µg/mL. Sterile.
10-390100 10-390500	Zero-Serum Refeed Medium – PSGA	100-mL 500-mL	<ul style="list-style-type: none"> Recommended for use with RhMK cultures when used for cultivation of respiratory viruses, i.e., <i>influenzae</i>. A defined medium with NEAA, Penicillin at 100 units/mL, Streptomycin at 100 µg/mL, Gentamicin at 50 µg/mL, and Amphotericin B at 1.25 µg/mL. Sterile.
05-360075	R-Mix [™] Rinse Buffer (<i>ReadyCells</i> [®])	75-mL	<ul style="list-style-type: none"> Developed for use with <i>R-Mix</i>[™] <i>ReadyCells</i>[®] cultures. A defined medium with, NEAA, Penicillin at 100 units/mL and Streptomycin at 100 µg/mL. Sterile.
05-370100	R-Mix [™] Refeed Medium (<i>ReadyCells</i> [®])	100-mL	<ul style="list-style-type: none"> Developed for use with <i>R-Mix</i>[™] <i>ReadyCells</i>[®] cultures (<u>not for use</u> with <i>FreshCells</i>[™] cultures). A defined medium with NEAA, Penicillin at 100 units/mL, Streptomycin at 100 µg/mL, and Trypsin (bovine origin) at ~0.33 µg/mL. Sterile.

*Annex II, List B associate products; McCoy (*Chlamydia*)