**TurboTreat®**

(A Mink Lung Cell Pretreatment Medium)

REF: 10-290030

For *in vitro* Diagnostic Use

Please contact Diagnostic HYBRIDS Technical Services for technical assistance regarding this procedure.

US Patent Nos.: 5,733,720 and 5,958,676; and patents pending

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**Intended Use**

TurboTreat®, developed¹ by Diagnostic Hybrids, Inc. (DHI), is intended to be used as a pretreatment medium for Mv1Lu (mink lung) cell culture prior to inoculation with specimens when looking for CMV (cytomegalovirus) or with specimens.

**Description**

TurboTreat® is formulated to supply the cells with the required nutrients during the pre-incubation period. Contains: EMEM with EBSS, without phenol red, 10% FBS, 25 mM HEPES, and Gentamicin at 50 μg/mL. Sterile.

**Warnings and Precautions**

1. TurboTreat® culture medium is for *in vitro* diagnostic use.
2. Recommended for use only with Mv1Lu CMV cell cultures.
3. Personnel working with cell culture must be properly trained in virus culture and safe handling techniques.²
4. Manipulations which present potential personnel hazards should be conducted in a Class II hood with gloves worn at all times and in accordance with the guidelines presented in the CDC-NIH Manual.
5. Cultures and specimens should be autoclaved or disinfected with a solution of sodium hypochlorite (1:10 final dilution of household bleach) prior to disposal.

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**Stability and Storage**

1. TurboTreat® should be stored at 2°C to 8°C.
2. Upon receipt, TurboTreat® should be visually examined for color and for signs of turbidity. TurboTreat® should be clear-to-light straw/yellow in color, and there should be no signs of turbidity. Do not use TurboTreat® if it exhibits any degree of turbidity as this is an indicator of possible contamination.

**Quality Assurance**

1. TurboTreat® 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 clear-to-light straw/yellow color should be performed and documented upon receipt.
2. Negative cell controls should be run with each batch of specimens tested for virus. Negative controls consist of monolayers treated with TurboTreat® but not inoculated with specimen or virus; otherwise, negative cell controls 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 or Lot Specification Sheet is available upon request (e.g., Material Safety Data Sheet).

**Limitations**

Diagnostic HYBRIDS TurboTreat® is intended for use with the FreshCells™ Mv1Lu cultures. Performance of other cell lines has not been evaluated using TurboTreat®.

**Procedure (for shell vial culture format)**

1. Determine the number of Mv1Lu shell-vials needed. It is recommended that specimens be run in duplicate shell-vials.
2. Examine the monolayers with a microscope to ensure that they are greater than 90% confluent. If not, place them in a 35°C to 37°C incubator for several hours or until the desired degree of confluence is achieved.
3. Aseptically aspirate the cell culture medium from the Mv1Lu shell-vials.
4. Transfer 0.3-mL of TurboTreat® into each Mv1Lu shell-vial. Replace caps.
5. Incubate at 35°C to 37°C for 16- to 24-hours.
6. When ready to use, aseptically aspirate the TurboTreat® from each shell-vial.
7. Inoculation: Select one of the following two methods based on your laboratory's experience.
   • Inoculate 0.2-mL of patient specimen into each shell-vial to be tested or,
   • Add 1-mL of cell culture medium (EMEM; various media available from DHI) to each shell-vial. Inoculate 0.2-mL of patient specimen.
8. Replace caps and centrifuge the inoculated shell-vials at 700xg for 45- to 60-minutes at room temperature (18°C to 30°C).
9. After centrifugation, based on the procedure used above, either:
   • Add 1-mL of cell culture medium or,
   • If specimen was inoculated through the cell culture medium.
10. Stopper each shell-vial and place in 35°C to 37°C incubator.
11. Stain at 24- and/or 48-hours post-inoculation, based on your laboratory's experience.

**NOTE:** Mv1Lu cells should not be treated with TurboTreat® for more than 24-hours since prolonged treatment may induce toxicity in the cells. If Mv1Lu cells are treated with TurboTreat®
for 16- to 24-hours but not used, the cells may be used at a later date by carefully aspirating the TurboTreat® and replacing it with 1-mL of cell culture medium. After a minimum of 24-hours are allowed for recovery, the cells should be examined to confirm confluence and may be re-treated with 0.3-mL of TurboTreat® and incubated at 35° to 37°C for 16- to 24-hours prior to performing Step 6, above. Cells are to be treated no more than two (2) times. Additional treatment will cause damage to the cells and render them unsuitable for testing. Cells not used after the second treatment with TurboTreat® should be discarded.

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.

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