CellPro Labs
CELL LINE EXPERTS

Cell Line Product Information

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INTENDED USE

For *in vitro* Diagnostic Use

Cell Line products are used in the isolation and detection of viruses to diagnose infectious disease or for cytotoxicity testing. They can also be used for the assay of viral antibodies, production of viral antigens to be used in serologic testing, and the propagation of viruses for characterization and analysis by molecular biology methods. The presence of cytotoxins in clinical specimens may also be determined by their induction of cytopathic effects (CPE) on culture cells. These techniques depend upon the selection of appropriate cells lines, inoculation of an appropriate specimen, maintenance of the inoculated cells, and the testing of the inoculated cells for the presence of the virus or cytotoxin and they may include culture confirmation using immunologic reagents.

Routinely Available Cell Lines

Primary Cell Line		Maximum Passage #	Shelf Life*
RK	Rabbit Kidney, New Zealand White	Primary	1 week
RMK	Rhesus Monkey Kidney, *Mucaca mulatta*	Primary	1 week
RMKa	Rhesus Monkey Kidney w/ SV5 & SV40	Primary	1 week
Continuous Cell Line		**Maximum Passage #**	**Shelf Life***
A549	Human Lung Carcinoma	100	1 week
BGMK	Buffalo Green Monkey Kidney	125	1 week
HEp-2	Human Cervix Carcinoma	400	1 week
McCoy	Mouse Fibroblast	75	1 week
MRC-5	Human Lung Fibroblast	25	1 week
HFF	Human Foreskin Fibroblast	10	1 week
Vero	African Green Monkey Kidney	180	1 week
WI-38	Human Lung Fibroblast	25	1 week
MDCK	Madin-Darby Canine Kidney	80	1 week

*Shelf life is approximate and based on original scheduled ship date.

Primary Cell Line	Virus Isolation								
	Coxsackie A	Coxsackie B	Echovirus	Herpes Simplex	Influenza A, B, C	Measles	Mumps	Parainfluenza	Polio
RK				●					
RMK	●	●	●		●	●	●	●	●
RMKa	●	●	●		●	●	●	●	●

Cont. Cell Line	Virus Isolation															
	Adenovirus	Coxsackie A	Coxsackie B	Cytomegalovirus	Echovirus	Enteroviruses	Herpes Simplex	Influenza A, B, C	Mumps	Norovirus	Parainfluenza	Polio	Rhinovirus	Respiratory syncytial virus	Varicella zoster	*Chlamydia trachomatis*	*Chlamydia pneumonia*
A549	●						●								●		
BGMK			●			●				●		●				●	
HEp-2	●		●				●					●		●			●
McCoy																●	
MRC-5	●	●		●	●		●					●	●	●	●		
HFF	●	●		●	●		●					●			●		
Vero			●				●		●			●					
WI-38	●	●		●	●		●					●	●	●	●		
MDCK								●									

WARNINGS AND PRECAUTIONS

- Cell culture products can transmit infectious agents. Products should be handled in accordance with the CDC-NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, 2007.
- Manipulations should be conducted in a Class II biosafety cabinet with gloves.
- Cell cultures should be inactivated via disinfection or by autoclaving.
- Primary cells may contain hazardous microorganisms; simian viruses, adenoviruses, foamy viruses, Herpes B virus, bacteria or parasites. Herpes B can infect humans and cause death.

CARE AND MAINTENANCE OF CELL LINES

Storage:

- Aging of cell culture products may affect their sensitivity to viruses.
- It is recommended that cell culture products be incubated at least 2 hours after delivery and before use.
- Maintain cells at incubator temperatures (35°C to 37°C) for maximum shelf life.
- If the cells are incubated in a CO_2 environment, the cap should be loosened to facilitate gas exchange.
- Tubes should be stored in a slanted position with the bottom of the tube slightly downward and tube marking positioned upward.
- Shell vials should be stored upright.
- Multi-well plates should be stored flat, facing upward.
- Flasks should be stored flat with media covering the cells.

Refeeding Protocol:

- Cells are shipped with fresh medium. The medium may be changed upon receipt, but this is not required. Do not let the cells dry.
- Change medium when the color changes from pink-orange (pH7.2) to yellow (acid) or purple (alkaline).
- Change medium if uninoculated cell morphology changes (increased rounding, increasing spindle-shaped, or increasing granularity)
- Using a sterile pipet, remove and discard the old medium into an appropriate disinfectant.
- Using a sterile pipet, add 1 mL to 2 mL of fresh, pre-warmed (25°C to 37°C) medium to each culture.

Indication of Instability of Deterioration:

- Cell morphology changes (rounding, sloughing, etc.).
- Failure to detect viral strains known to replicate within a specific cell type.
- Turbidity due to microbial contamination.

PROCEDURES

A large number of procedures exist for the use of cell cultures for the in vitro diagnosis of virus, *Chlamydia,* and cytotoxicity. It is important that any laboratory using cell cultures for virus and *Chlamydia* isolation or cytotoxicity testing perform and document their own validation study of the methodology they use.

General Inoculation Protocol:

- Examine cell monolayer for proper morphology.
- Appropriately label the cell culture.
- Remove all of the shipping medium from the cells. Fetal Bovine Serum can potentially inhibit influenza virus isolation.
- Add 0.2 to 2 mL of refeed medium to each tube. Do not let the cells dry.
- Transfer 0.2 to 0.5 mL of specimen to each cell culture.
- Cap the inoculated cultures and Incubate at 35° to 37°C.
- Observe cell cultures for a period of 1 to 28 days. The culture medium should be replaced if the pH changes drastically (pink-orange to yellow-purple). Cell cultures that exhibit signs of toxicity should be re-inoculated onto new cell cultures.

Quality Control:

Negative cell controls should be run with each batch of specimens tested for virus or *Chlamydia*. Negative controls consist of uninoculated monolayers that otherwise are handled the same as inoculated monolayers.

INTERPRETATION OF RESULTS

The presence of viruses and/or cytotoxins are most often observed as cytopathic effect (CPE). CPE is the morphological change induced in cells by viral replication or the presence of toxins. Observed CPE is dependent upon the infectious agent or the particular cell line. CPE usually develops in localized areas or foci that spread to involve the entire monolayer. *Chlamydia* and some other viruses do not cause CPE. For this reason, culture confirmation should be required using specific immunological reagents or hemadsorption, hemagglutination procedures.

The use of cell cultures for *in vitro* diagnosis of virus or *Chlamydia* or for toxicity testing should result in positive confirmation of the presence of the infectious agent as evidenced by CPE and specific identification of the replicating agent within the cells using a culture confirmation procedure (e.g. immunological reagent, hemadsorption, etc.).

The presence of any identifiable agent should be reported as “Agent isolated”. Specimens containing no identifiable agent should be noted and reported as “Agent not isolated; however, absence of the agent does not necessarily mean absence of disease”. A culture positive for CPE but not confirmed by immunohistochemical or other means should be reported as “Presumptive”.

Culture confirmation

Results based solely upon the presence of CPE without the use of specific culture confirmation by immunologic reagents, hemadsorption, etc. are presumptive only.

LIMITATIONS

CellPro Labs maintains strict quality control to ensure the highest level of quality and consistency in its cell culture products. However, clients should be aware that with some primary cell cultures a variation in sensitivity might be found from lot to lot.

CELLPRO LABS QUALITY CONTROL

- CellPro Labs Cell Lines are passaged a limited number of times. Passage number is based on documented loss of viral sensitivity or senescence, periodic viral susceptibility testing, and consistency of cell growth characteristics and morphology.
- Cell Lines are monitored for proper pH, morphology, growth and density characteristics.
- Cell Lines are monitored for the absence of viral, bacterial, and fungal contamination. Representative samples of each cell line are tested for mycoplasma contamination.
- Monolayer cell cultures are routinely shipped at 85% to 100% confluency.
- Cell Lines are maintained with Eagle’s minimal essential medium (MEM), supplemented with heat-inactivated fetal bovine serum, antimicrobials, and HEPES buffer, unless otherwise noted or requested by the customer.
- Cell cultures are shipped with adequate MEM to maintain the cell monolayer.