



# ReadyCells<sup>®</sup>

Singles and Mixed

**Frozen cell monolayers in shell vials. Cultured cells for use in virus and/or Chlamydia isolation.**

For *in vitro* diagnostic use.

A symbols glossary can be found at [quidel.com/glossary](http://quidel.com/glossary).



## INTENDED USE

Diagnostic Hybrids ReadyCells are frozen cultured cell monolayers intended for virus and/or *Chlamydia* isolation and to aid in the diagnosis of diseases associated with infectious agents. These cultured cells should not be used for serial propagation. The laboratory must determine the cell type to be used as host for isolation of a particular virus and/or *Chlamydia*. ReadyCells are provided in the following product formats (see Table 1).

- Singles – a single cell line.
- MixedCells™ (Patented) – two cell lines mixed at approximately equal cell density.

## SUMMARY AND EXPLANATION

Specific cultured cell types provide the necessary living host systems for the identification of viruses and *Chlamydia spp.* Such cultured cells are used in the isolation, detection and identification of these infectious agents.<sup>1,2</sup> The procedure typically consists of incubating a specimen with an appropriately sensitive cultured cell type. This incubation period is variable and is dependent on the detection system used. The classic detection method is the observation of cellular changes due to infection of the cultured cells, termed cytopathic effect (CPE). The use of monoclonal antibodies against specific infectious agents to confirm an agent's identity has become widely accepted; this method has increased the sensitivity of the cultured cell system and substantially decreased the time to infectious agent detection.

Diagnostic Hybrids ReadyCells frozen cell monolayers expand the utility of cultured cells by providing laboratories greater flexibility. Cultured cell monolayers are cryopreserved at optimum confluency and sensitivity. They are supplied to the laboratory ready to thaw, reseed, and use.

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- ReadyCells **must be received frozen** and **completely covered on all sides** with dry ice. Dispose of dry ice in a safe manner according to your facility's policies.
- Thawed ReadyCells product **cannot** be re-frozen.
- Do not use components that appear to be broken or damaged.
- To avoid shell vial damage, care should be used when removing and replacing caps.
- Cultured cells should be used (inoculated) on or prior to their labeled expiration date.
- 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 manual,<sup>1,2</sup> Biosafety in Microbiological

and Biomedical Laboratories, 2007, 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.

- Cultured cells used for virus or *Chlamydia spp.* detection may also support the replication of infectious agents which are classified by the CDC as agents requiring cultivation under BSL-3 conditions. Please consult <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm> for a listing of the BSL-3 infectious agents and the CDC recommendations.
- Cultures and specimens should be autoclaved or disinfected with a solution of sodium hypochlorite (1:10 final dilution of household bleach) prior to disposal.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at [quidel.com](http://quidel.com).

## MATERIALS PROVIDED

ReadyCells products and their susceptibility to specific infectious agents are listed in Table 1.

ReadyCells are provided as single or mixed cultured cell monolayers adhered to glass coverslips contained in shell vials. They are available in a configuration of 24 shell vials per box.

The cultured cells used in ReadyCells are characterized by isoenzyme analysis and have been tested and found free of *Mycoplasma spp.* and other adventitious organisms. The current passage number of each cell type in the product is noted on the Lot Specification Report, which is supplied with each shipment of ReadyCells and which is also available upon request.

## MATERIALS REQUIRED BUT NOT PROVIDED

- It is strongly recommended that the ReadyCells dry heat block be used to thaw the frozen monolayer cultures.
- It is strongly recommended that the appropriate culture medium ("Refeed Medium," available from Quidel) is used.
- For the products, R-Mix and R-Mix Too, a wash solution ("Rinse Buffer," available from Quidel) is recommended to be used immediately after thawing the product.

## STORAGE

- Upon receipt, rapidly transfer the ReadyCells monolayers from the dry ice shipping container directly to the final storage freezer without delay.
- ReadyCells must be stored at  $-70^{\circ}\text{C}$  or colder upon receipt.
- Do not store the ReadyCells monolayers in liquid nitrogen.

## QUALITY CONTROL

The ReadyCells monolayers should be examined, upon thawing and refeeding, for integrity of the culture cell monolayer. The monolayer should be intact and cover the surface of the coverslip; it may not appear as a solid sheet.

Negative controls should be run with each batch of specimens tested for virus. Negative controls consist of non-inoculated monolayers and are handled the same as the inoculated monolayers.

## PROCEDURE

### Preliminary Comments and Precautions

1. Warm refeed medium to 25°C to 37°C before adding to cultures.
2. Do not disturb the cell monolayers during the thawing process.
3. Cells must not be allowed to dry at any stage during the cultivation process.
4. Use a fresh, sterile pipette for each specimen to avoid cross contamination.
5. When inoculating a specimen into a culture, be careful to not splash the residual liquid from the pipette, since it could contaminate adjacent cultures.

### Thawing and Refeeding Cell Cultures

1. Verify that the ReadyCells heat block has reached a steady temperature of 37°C.
2. Remove appropriate number of ReadyCells shell vials from the freezer and **immediately** transfer to the heat block.  
**NOTE:** The heat block should be in close proximity to the freezer. If the distance is excessive (greater than 45 seconds transit time), the ReadyCells should be transported to the heat block on dry ice.
3. Incubate shell vials for 4 minutes.  
**NOTE:** Incubation greater than 4 minutes may cause monolayer deterioration.
4. Aspirate the freeze medium, taking care not to damage the monolayers, and collect the medium in a disinfectant-containing trap. **Do not let cells dry.**  
**NOTE 1:** For the products R-Mix/R-Mix Too ReadyCells, perform steps a-d below.  
**NOTE 2:** For all others, go directly to step e.
  - a) Add 0.5 mL of R-Mix™ ReadyCells Rinse Buffer to each shell-vial.
  - b) Incubate at room temperature for 4 minutes.
  - c) Aspirate the rinse solution, taking care not to damage the monolayers, and collect the solution in a disinfectant-containing trap. **Do not let cells dry.**
  - d) Add 1.0 mL of R-Mix ReadyCells Refeed Medium to each shell-vial and proceed with inoculation procedure.**For all other products: (NOTE 2)**
  - e) Add 1.0 mL of the appropriate Refeed Medium to each shell-vial.

### Inoculation Procedure

1. Add 0.2 to 0.4 mL of prepared specimen or control to an appropriately labeled shell-vial.
2. Centrifuge inoculated shell vials at 700xg for 60 minutes.
3. Remove shell vials from the centrifuge and place in a 35°C to 37°C incubator.
4. Incubate the shell vials for the laboratory's established period of time (24 to 72 hours).
5. Determine the presence or absence of infectious agents with the appropriate monoclonal antibody staining kit/procedure.

## RESULTS

Refer to appropriate reference material for expected results and reporting suggestions.

## LIMITATIONS

- ReadyCells should be thawed for use on or before their labeled expiration date.
- ReadyCells, once thawed, should be refeed according to these instructions, and maintained at 35°C to 37°C until used, but not longer than 8 hours.

**Table 1. ReadyCells and Their Virus Susceptibility Profiles**

Cell Type	Infectious Agents
<b>Hs27</b> (human foreskin fibroblast)	Intended use: For the cultivation and detection of adenovirus, CMV (cytomegalovirus), echovirus, Herpes simplex (HSV), mumps, poliovirus, rhinovirus, Varicella-zoster (VZV).
<b>McCoy</b> (mouse fibroblast)	Intended use: For the cultivation and detection of <i>Chlamydia</i> and HSV.
<p><b>Super E-Mix™:</b> BGMK with hDAF and A549</p> <p>Buffalo green monkey kidney (derived from African green monkey) with Decay Accelerating Factor</p> <p><i>and</i></p> <p>human lung carcinoma</p>	<p>Intended use: For the cultivation and detection of enteroviruses from patient specimens, especially coxsackievirus A, coxsackievirus B, echovirus, and poliovirus.</p> <p>Virus susceptibility profiles of each individual cell type in Super E-Mix: HSV, coxsackievirus B, coxsackievirus A, echovirus, and poliovirus</p> <p><i>and</i></p> <p>Adenovirus, HSV, influenza, measles, mumps, parainfluenza, poliovirus, RSV, rotavirus, VZV.</p>
<p><b>R-Mix™:</b> Mv1Lu and A549</p> <p>mink lung</p> <p><i>and</i></p> <p>human lung carcinoma</p>	<p>Intended use: For the cultivation and detection of respiratory viruses from patient specimens, especially influenza virus types A and B, adenovirus, respiratory syncytial virus (RSV), metapneumovirus (MPV) and parainfluenza virus types 1, 2, and 3.</p> <p>Virus susceptibility profiles of each individual cell type in R-Mix: HSV, CMV, influenza A and influenza B</p> <p><i>and</i></p> <p>Adenovirus, HSV, influenza, MPV, measles, mumps, parainfluenza, poliovirus, RSV, rotavirus, VZV.</p>
<p><b>R-Mix Too™:</b> MDCK and A549</p> <p>Madin-Darby canine kidney</p> <p><i>and</i></p> <p>human lung carcinoma</p>	<p>Intended use: For the cultivation and detection of respiratory viruses from patient specimens, especially influenza virus types A and B, adenovirus, RSV, MPV and parainfluenza virus types 1, 2, and 3.</p> <p>Virus susceptibility profiles of each individual cell type in R-Mix Too: influenza A, influenza B, some types of adenovirus, reoviruses, coxsackievirus</p> <p><i>and</i></p> <p>Adenovirus, HSV, influenza, MPV, measles, mumps, parainfluenza, poliovirus, RSV, rotavirus, VZV.</p>

**Table 2. ReadyCells part numbers**

F-54-0102-24	ReadyCells McCoy frozen cell culture (24 shell-vial box)
F-87-0102-24	ReadyCells Hs27 frozen cell culture (24 shell-vial box)
F-92-0102-24	ReadyCells Super E-Mix™ frozen cell culture (24 shell-vial box)
F-96-0102-24	ReadyCells R-Mix frozen cell culture (24 shell-vial box)
F-97-0102-24	ReadyCells R-Mix Too™ frozen cell culture (24 shell-vial box)
99-610-009 (110 volt)	ReadyCells Dry Heat Block, 110 volt
99-610-024 (230 volt)	ReadyCells Dry Heat Block, 230 volt
05-360075	R-Mix Rinse Buffer (ReadyCells)
05-370100	R-Mix Refeed Medium (ReadyCells)
10-320100	RM-02 Refeed Medium (Standard 2% FBS Refeed Medium)
10-340100	<i>Chlamydia</i> Isolation Medium
10-380100	Super E-Mix Refeed Medium

## ASSISTANCE

To place an order or for technical support, please contact a Quidel Representative at 800.874.1517 (in the U.S.) or 858.552.1100 (outside the U.S.), Monday through Friday, from 8:00 a.m. to 5:00 p.m., Eastern Time. Orders may also be placed by fax at (740) 592-9820. For e-mail support contact [customerservice@quidel.com](mailto:customerservice@quidel.com) or [technicalsupport@quidel.com](mailto:technicalsupport@quidel.com).

For services outside the U.S.A., please contact your local distributor. Additional information about Quidel, our products, and our distributors can be found on our website [quidel.com](http://quidel.com).

## REFERENCES

1. Viral Culture; Approved Guideline M41-A. Vol. 26, No. 7. Clinical and Laboratory Standards Institute, Wayne, PA. 2006.
2. McAteer J.A., W.H.J. Douglas. Monolayer culture techniques in: W.B. Jakoby (ed): Cell culture Methods in Enzymology, 1979, Vol. 58, p 132-140, Academic Press.
3. Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition, 2007, CDC-NIH manual. [<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>]
4. Biosafety Manual, 3rd edition, 2004. World Health Organization [Manual is available in additional languages; refer to WHO web page [[http://www.who.int/csr/resources/publications/biosafety/WHO\\_CDS\\_CSR\\_LYO\\_2004\\_11/en/](http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/)]]

**REF**

F-87-0102-24 Hs27 ReadyCells Shell Vials (with coverslip)  
F-54-0102-24 McCoy ReadyCells Shell Vials (with coverslip)  
F-96-0102-24 R-Mix Ready Cells Vials (with coverslip)  
F-97-0102-24 R-Mix Too ReadyCells Vials (with coverslip)  
F-92-0102-24 Super E-Mix ReadyCells Shell Vials (with coverslip)

**IVD**



**EC REP**

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## GLOSSARY

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**REF**

Catalogue number



CE mark of conformity

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**EC REP**

Authorized Representative  
in the European Community

**LOT**

Batch code

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Use by



Manufacturer

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Temperature limitation



Intended use

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Consult e-labeling  
instructions for use



Biological risks

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**IVD**

For *In Vitro* diagnostic use



Contains sufficient for 24 determinations

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