

**From:** Hutchins, Beth  
**Sent:** Monday, June 11, 2001 8:55 AM  
**To:** Amine Kamen (E-mail); Andrew Byrnes (E-mail); Bryan Butman (E-mail); Charla Andrews (VRC) (E-mail); Charles Buck (ATCC); Christopher Murphy (E-mail); Chuck Prussak (E-mail); Dale Gruber (E-mail); Daniel MALARME (E-mail); David Venables (E-mail); Deb Stutz (Molecular Medicine) (E-mail); Dick Sublett (E-mail); Dominick Vacante (E-mail); Elisabeth Lehmberg (E-mail); Eric Cornavaca (E-mail); Erno Pungor (E-mail); Estuardo Aguilar-Cordova (E-mail); Flavia Borellini (E-mail); Gary Vellekamp (E-mail); Geoff Sharpe (E-mail); Heike Nesbit (E-mail); Jeff Beecham (E-mail); Jesse Keegan (E-mail); Jim (Panlabs old email) Gilbert (E-mail); Joe Senesac (E-mail); Keith (direct) Carson (E-mail); Larry Couture (E-mail); Manisha Trivedi (E-mail); Maria Croyle (E-mail); Mark Bowe (E-mail); Mark D'Andrea (E-mail); Mark Plavsic (E-mail); Matthias Schweizer (E-mail); Meg Casais (E-mail); Merribeth Morin (E-mail); Michael Kadan (E-mail); Michel Koehl (E-mail); Nancy (ncsajjadi@aol.com) Sajjadi (E-mail); Nancy Sajjadi (E-mail); Paul Shabram (E-mail); Peter Harris (E-mail); Phillip Gomez (VRC) (E-mail); Rene Lardenoije (E-mail); Rukmini Pennathur-Das (E-mail); Shawn Gallagher (E-mail); Stephanie Simek (E-mail); Steven Bauer (E-mail); Tony Meager (E-mail); Tracy Lawhon (E-mail); Victoria Sluzky (E-mail)  
**Cc:** Ken Timmons (E-mail); Ken Timmons (E-mail 2); Jim Gilbert (E-mail); Jim Gilbert (E-mail 2); Frank Flagge (E-mail); Sugarman, Barry  
**Subject:** Summary of Telecon for Ad Ref Mat 293 Testing Phase Cell Bank

This morning Dale Gruber, Joe Senesac, Keith Carson, and I discussed production, testing, and timeline for production of a 50 vial 293 testing phase cell bank to be made from the Master Cell Bank donated by UAB. Invitrogen will make the 293 testing phase cell bank. They are charged with producing at least 50 x 1 mL vials containing approximately  $1 \times 10^7$  cells/mL in a suitable freezing medium (containing DMSO), and to provide assurance of sterility and freedom from mycoplasma, as well as to provide % viability, and viable cell number upon thaw in the form of a characterization summary or CofA. The timeline for production of the reference material virus bank, purified reference material, and testing phase cell bank now look like this:

- Virus bank fill - 6/11 and 6/12
- Virus bank testing begins 6/18 week
- Virus bank material transfer to Introgen as soon as mycoplasma/sterility and Canji in-house testing results available; release to Introgen on an interim CofA: Mycoplasma test is the pacing item, a 28-day test with report to follow. Anticipated interim release, 3rd or 4th week of July.
- Introgen will initiate production of the reference material at the end of July.
- In order to ensure that the virus bank is fully released prior to vialing of the purified reference material, Introgen will hold at a specific holding step (post-chromatography purification) until the virus bank is released. The pacing item for release of the virus bank is the completion of the in vivo adventitious virus agent test. Canji, MDS PharmaServices, and Introgen will keep in close contact to ensure coordination.
- Invitrogen to deliver the tested 293 Testing Phase Cell Bank by the 1st week of September to ensure its availability for the T-zero stability test points.
- Introgen to fill purified reference material after virus bank is released.
- T-zero testing will be initiated as soon as possible after the purified reference material is filled based on an Introgen-provided interim CofA to include an unofficial particle concentration.
- Introgen to complete release testing of the purified reference material and characterization to be initiated as soon as reasonable after fill.

Keith Carson will contact ATCC regarding provision of a couple of MCB vials to Invitrogen for production of the 293 Testing Phase Cell Bank and whether ATCC can store this cell bank after it has been made. Beth Hutchins to provide a copy of the MCB cell bank package to Invitrogen

along with the exact freeze medium detail for their use in making the testing phase cell bank.

The current thought is that, pending agreement with ATCC, ATCC will store the 293 Testing Phase Cell Bank as it is the other materials for the Adenovirus Reference Material project. Invitrogen will include the appropriate ATCC ascension number on the 293 Testing Phase Cell Bank on its labels. Beth will provide a copy of the virus bank labels as an example to Invitrogen. Testing phase participants will have to pay for shipping from ATCC to themselves for materials received from the Working Group.

Submitted 06/11/2001 by Beth Hutchins