

Telecon, March 9, 2012 - HPC Cord Blood

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125391/0 Office: OCTGT

Product:

Hematopoietic Progenitor Cells, Cord (HPC-C)

Applicant:

Clinimmune Labs

Telecon Date/Time: 09-March-2012 1:45 PM Initiated by FDA? Yes

Telephone Number: 303 724 1307

Communication Category(ies):

Sterility data clarifications

Author: RAMANI SISTA

Telecon Summary:

Sterility data clarifications

FDA PARTICIPANTS

Ramani Sista

Joydeep Ghosh

NON-FDA PARTICIPANTS:

Sharon Miller

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

The Sponsor emailed sterility information and the reviewer requested clarification on some points:

FDA Revised sterility SOP - proposed time for incubation

Sponsor - In processing SOP, microlab SOP

2. # pg 22 on 29 - Organisms

Why a range for some and # for some

Sp. Processed in triplicate, several different ---(b)(4)---, run a control plate a test was ran. Individual information available will be sent.

FDA - not all assays done on same day, but as CB was available

3. pg 21 -(b)(4) - no org detected Day 14. (b)(4) - day not included, that too Day 14?

Sp. Yes.

4. Pg. 19 - 1st Bacteria. Incubate without (b)(4), minimum detection time was (b)(4), when (b)(4) was added the time reduced to (b)(4), is this correct?
Sponsor. Yes.

5. What incubation time in SOP?

Sp. (b)(4)

FDA. Possible that sample did not contain bacteria.

Sp. Exactly.

FDA - --(b)(4)--, what is detection time?

Sp. See in ind. Data sheet.