

# Sterility Testing Question Tcon, July 11, 2012 - Ducord

## 125407/9 teleconference minutes

Friday, July 11, 2012 10:00 am

**Duke:** Joanne Kurtzburg, MD, PhD, Rebecca Durham, Bruce Burnett, Ph.D.

**FDA:** Mark Davidson, Joydeep Ghosh, Safa Karandish

### **Regarding:** BLA 125407 and Sterility Testing Question

Points discussed:

1. The SOP CCBB-LAB-028 still shows that the proposed incubation time for the sterility test is (b)(4) - it should be (b)(4).

Duke Response: An updated version of the SOP showing (b)(4) of incubation time will be submitted ASAP.

2. Antibiotics in mother's blood can cross the placenta and enter the cord blood. As that antibiotic could inhibit the sterility test and give false positive results, is the sponsor excluding donor mothers who are on perinatal prophylactic antibiotic?

Discussion Summary: Duke stated that they will not exclude the mothers on perinatal prophylactic antibiotic because:

- a. It is a standard OB/GYN practice to give antibiotics.
- b. As more than 50% of the mothers giving childbirth are on perinatal prophylactic antibiotic that will significantly reduce the cord blood donor pool.
- c. No other cord blood bank is excluding them.

However, they acknowledged that the antibiotic from the mother's blood can cross into the cord blood and inhibit the sterility test and give false positive result. They were also not aware of the new final rules of the 21 CFR 610.12.

FDA suggested that the sponsor submit a document stating their decision to keep the above donor pool and explaining why it will be safe to do so - the sponsor agreed to submit an unofficial document for our review by email and if acceptable submit that as an official amendment.

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