

From: Tull, Lori
Sent: Friday, February 26, 2016 3:08 PM
To: Wouter Van't Hof (wvanthof@clevelandcordblood.org)
Subject: IR for STN 125594

Hi Wouter,

We have another request for information. Can you please respond by March 1?

1. Please specify the incubation temperature(s) of the [REDACTED] DETECTION SYSTEM that you will be using for the actual HPC, Cord Blood Sterility test. Please update all respective SOPs (as needed) to indicate the incubation temperature(s) and submit them for our review.
2. Reference - Sterility test method validation study, VAL-0007: Please specify the incubation temperature(s) that you have used during your sterility test method validation study, VAL-0007.
3. Reference - Sterility test method validation study, VAL-0007: We note that the [REDACTED] (for [REDACTED] determination) were incubated at [REDACTED] – did you incubate any of the [REDACTED] media bottles at this lower incubation temperature for the method validation study? If yes, please specify which ones.

Regards,
Lori Tull
Team Lead
Regulatory Management Staff
Office of Cellular, Tissue, and Gene Therapies
Center for Biologicals Evaluation and Research
(240) 402-8361

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.