

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  
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