

From: [Evans, Jill A.](#)
To: [Jarvis, Candace](#)
Cc: [Ghosh, Joydeep](#); [Heidaran, Mohammad](#); [Dollins, Eric](#)
Subject: RE: Revised (b)(4) sterility validation plan for FDA second review - LifeSouth
Date: Thursday, January 03, 2013 5:37:28 PM
Attachments: [emfalert.txt](#)

Will do – thank you all!
Happy New Year

Jill Evans
Vice President of Quality



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Connecting our donors to our patients

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From: Jarvis, Candace [mailto:Candace.Jarvis@fda.hhs.gov]
Sent: Thursday, January 03, 2013 3:25 PM
To: Evans, Jill A.
Cc: Ghosh, Joydeep; Heidaran, Mohammad; Dollins, Eric
Subject: RE: Revised (b)(4) sterility validation plan for FDA second review - LifeSouth
Importance: High

Hi Jill,

Thank you for your email of the revised stability protocol draft. After further review, it has been noted that the changes are acceptable; however, the only thing that needs to be changed is the current methods using (b)(4) and not (b)(4) of the final Buffy coat (For the current sterility testing of cord blood samples, (b)(4) culture bottles are each inoculated with (b)(4) µL of the final buffy coat (post DMSO addition) cord blood sample per current LifeSouth SOP (b)(4).1.1 *Inoculate the Culture Bottles*).
Please update this.

Thank you,

*Candace N. Jarvis
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From: Evans, Jill A. [<mailto:JAEvans@lifesouth.org>]
Sent: Thursday, December 20, 2012 5:23 PM
To: Jarvis, Candace
Subject: Revised (b)(4) sterility validation plan for FDA second review - LifeSouth

Hi Candace,

Attached are the revised (b)(4) validation documents for FDA review. Changes were made to the validation plan per our FDA conference call discussion this week. The sections that are highlighted in yellow (in the attached documents) reflect the changes that were made to the original validation plan.

Jill

Jill Evans
Vice President of Quality



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