

**From:** [Evans, Jill A.](#)  
**To:** [Jarvis, Candace](#)  
**Subject:** Sterility validation protocol and validation testing summary outline for LifeSouth  
**Date:** Thursday, December 13, 2012 3:59:40 PM  
**Attachments:** (b)(4) [Re-Validation Draft for FDA comments 12-13-12.doc](#)  
(b)(4) [Validation Testing Outline revised 12-3-12.xlsx](#)  
[lert.txt](#)

---

Candace,

Attached is the protocol we promised you this morning.

The FDA reviewer also asked that Tammy include her questions. They are as follows:

We have some concerns regarding the RBC waste and plasma volume required to perform the va

(b)(4)

**Jill Evans**  
Vice President of Quality



4039 Newberry Road  
Gainesville, FL 32607  
Phone: 1-888-795-2707 Ext: 41634  
[www.lifesouth.org](http://www.lifesouth.org)

### Connecting our donors to our patients

-----  
LifeSouth Community Blood Centers, Inc. is not responsible for errors or omissions in this e-mail message. This message (and any associated files) is intended only for the use of the individual or entity to which it is addressed and may contain information that is confidential, subject to copyright or constitutes a trade secret. If you are not the intended recipient you are hereby notified that any dissemination, copying or distribution of this message, or files associated with this message, is strictly prohibited. If you have received this message in error, please notify us immediately by replying to the message and deleting it from your computer. Messages sent to and from us may be monitored. Internet communications cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. Therefore, we do

not accept responsibility for any errors or omissions that are present in this message, or any attachment, that have arisen as a result of e-mail transmission. If verification is required, please request a hard-copy version. Any views or opinions presented are solely those of the author and do not necessarily represent those of LifeSouth Community Blood Centers, Inc.

-----

---

11 Pages redacted due to (b)(4)