Outstanding Issues Email, August 8, 2012 - Ducord

From: Gavin, Denise K
To: "Rebecca Durham"; Davidson, Mark
Cc: Bruce Burnett, Ph.D.; Joanne Kurtzberg, M.D.
Subject: Duke BLA-outstanding issues--CMV assay
Date: Wednesday, August 08, 2012 6:02:00 PM

Becky,

Based on the further review of SOP CCBB-LAB-040 I have a few questions. Can you please have the technician that performs the (b)(4) assays at Friday's t-con?

Thank you, Denise

1. Please clarify how CBU ID numbers are uploaded into the -------(b)(4)--------. CCBB LAB-040 section 8.1.1 states to print daily the CMV Screen Positive Results (PROD) (b)(4)_results.1825 (any CBU with pending CMV (b)(4) testing), and 8.1.2 stated to add new CBU with pending CMV (b)(4) testing barcodes to the O:\CMVdatabase. Is this done by hand off the printed (b)(4) record? How is accuracy verified?
2. CCBB LAB-040 FRM1 is used for recording CMV results to the CBU file, it doesn't appear as though data is saved on the ---(b)(4)---. In LAB-040 section 8.8 it indicates that test date, sample tested (i.e. UCB (b)(4)) and results are recorded while online, however the sample ID barcode is not affixed until “all sheets (hardcopies) are printed.” Please clarify how FRM1 results and sample ID barcodes are verified as the correct set of results on FRM1. How are mix ups prevented? Since up to 20 forms might be printed at one time, one can conceive of an opportunity for error, even with the most careful personnel.
3. Please clarify why positive samples are tested at least twice before results reported. Reported to the file? the Maternal donor? Logically, you might want to confirm a negative result as the sample was associated with a positive MID, and especially since CBU with positive (b)(4) results are excluded. Please comment.
4. Are any components of the -------(b)(4)---------- assay for CMV approved by the FDA?

If so please provide PMA or 510K numbers.

5. Clinical CMV infection is generally associated with copy numbers in the range of 50,000-2,000,000 copies/mL of the CMV virus in whole blood, How does this compare to the --(b)(4)-- sample.
6. Please modify the CMV assay validation report to reflect that a CV of (b)(4) is considered acceptable for the assay to be valid.

From: Rebecca Durham [mailto:rebecca.durham@duke.edu]
Sent: Monday, August 06, 2012 9:53 AM
To: Gavin, Denise K
Cc: Bruce Burnett, Ph.D.; Joanne Kurtzberg, M.D.
Subject: RE: Duke BLA-outstanding issues

Denise,
We have received the list of outstanding issues and will work to respond by 09Thursday. I will work with Mark to schedule a meeting on Friday.
Becky

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From: Gavin, Denise K [mailto:Denise.Gavin@fda.hhs.gov]
Sent: Monday, August 06, 2012 9:47 AM
To: Rebecca Durham; Joanne Kurtzberg, M.D.
Cc: Bruce Burnett, Ph.D.; Amanda Parrish, Ph.D.; Davidson, Mark; Gavin, Denise K
Subject: Duke BLA-outstanding issues

Becky,
Please find the attached list of outstanding review items that need clarification.
Please response by Thursday Aug 9, 2012. We would like to schedule a follow up phone call for Friday August 10, 2012 between 1-3 pm (2-3 pm preferred) to discuss outstanding items.
Please contact Mark to set up time.
If you have additional questions, please feel free to contact me.
Thank you,
Denise

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