

Assay Validation Protocol Telecon, Ducord

Hi Amanda,

The ---(b)(4)--- assay validation protocol looks sufficient given that it is a qualitative test.

In the validation report it would be helpful if you also included a discussion/results of the ---(b)(4)----- and CAP proficiency testing, since it doesn't appear to be that much data to coordinate.

There was also a discussion of SOP COMM-QA-044, but I am not sure that this refers to? Please explain or provide more info in the validation study report.

If you have further questions please let me know.

Thank you,

Denise

Mark please record this communication in the EDR. Thanks, denise

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