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From: Suraj Saksena
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Hi Elizabeth & Sunny,

I wanted to update you on the different tasks that have been completed in preparation for the CLIA Audit on 12/03:

- SOPs for the 4 LDT assays have been reviewed and signed (Adam, Daniel, Michelle and myself have all signed off on the final SOPs; Based on your recommendation, I signed as the reviewer in Sharada and Ran's absence)
- Hardcopies of the SOPs for the 4 LDTs have been handed over to Li
- SOP for Periodic QC of CLIA Edisons has been prepared (by Jared) and signed by Sam (I need to get Daniel and Adam's signature on Monday; they have electronic copies of this SOP to review until Monday). This SOP will be handed over to Li on Monday once all the signatures are obtained
- Hard copies of Periodic QC data will be provided to Li (if required)
- MOPs for Edison cartridge production (CAPSYS) have been reviewed and signed (Li mentioned that these will not be required for the audit, but it is good to have these)
- Logs of Daily assay QC for the 4 LDTs will be accessible to Li so that she can pull them up on demand during inspection

Thanks,

Suraj

Suraj Saksena

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