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Sent: Sat 12/15/2012 2:35:34 AM (UTC)

Subject: R&D device build/bring-up status

As of today, **19 Monos** have been brought up. 16 of those are in the BSL lab, and 1 each with software, Karan, and shipping. We would like to keep the remaining devices down in R&D for testing purposes.

As far as minilabs, all **46 blades** will be completed by tomorrow. The blades have been checked out and all pipettes have been calibrated. We have also trained a couple of associate engineers who will be over in Newark on how to do pipette calibration (most involved part of bring-up).

Here is what is remaining for the minilab bring-up.

- 1. Finish centrifuges, remaining pipettes (if any), and fix some minor assembly issues.
- 2. Personalization We have personalized 1 minilab manually using the personalization tool (in addition to some of our scripts). We are still working on some issues with the new personalization tool. We want to be able to use this tool for personalization since it saves us a lot of data entry time. We have not rolled out personalization to the manufacturing team since we are close to developing an automated method. The current personalization method is slightly subjective and not amenable to bring-up after the blades have been placed in the chassis. We think we can finalize the fully automated method by the end of the year. This will also make the transfer over to manufacturing really simple, since personalization will be reduced to a software tool. The thought is to integrate the new method into Shekar's personalization tool. The method has been tested on a few blades and was used for personalizing all the pipette calibration cartridges.
- 3. QC/System verification test We have defined a QC/System Validation cartridge, and the different components which go into it. We have started to run these on the Monos (primarily to establish satisfactory performance on the Spec and PMT, in conjunction with the gantry and pipette). This cartridge (and the associated protocol) will serve as the QC/System Verification cartridge. This will have to be extended to include the NAA and cytometer, but for now, it covers the Spec and the PMT.
- 4. Documentation The knowledge transfer on bring-up (except personalization) is mostly complete since the manufacturing AEs were involved in the bring-up process. We have to formally document the process which we can do in the following week. Daniel P. is in the loop and will come up with some formats. We would like to hold off on the personalization documentation until the new tool has been complete (which will significantly simplify the documentation).

I would like to acknowledge the entire AE team, Daniel N., and Nick for pushing through the builds/bring-up in a short time.

Sam