

**From:** [Rosendorff, Adam](#)  
**To:** [Eleco, Elsa@CDPH](mailto:Eleco_Elsa@CDPH)  
**Subject:** Request to extend the deadline for LDT re-validation, LFS condition level deficiencies.  
**Date:** Saturday, July 3, 2021 6:56:05 AM

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Dear Elsa

We are requesting a further extension to complete the LDT re-validation, of another 7 weeks, which would bring the new deadline to September 7th, 2021. This timeline is based on details given below and could change based on receipt of controls and materials. We will continue to actively communicate with LFS.

Here is where we currently stand with our plan:

1. **Validation plan (complete)**
2. **Procurement of validation materials and execution of validation**

Validation of Ct cutoff values

- a. Complete

Accuracy

- a. We have currently requested the 30 positive samples and 30 negative samples from Dr Kimsey (original request made via email on June 17<sup>th</sup>), with assay LoDs comparable to the PerkinElmer assay (LoD 120 copies/mL) . We are waiting for these to be sourced. Target date est. 2 weeks ( target date 7/16)
- b. Once we receive the samples it will take 3-4 days to complete the accuracy studies ( target date 7/19)

Sensitivity (LoD finding and confirmation):

- a. We are still waiting for Heat-Killed Virus (VR-1986HK) from ATCC, as well as TWIST viral SARS-CoV2-RNA for quantitating the HKV. We had originally intended to obtain these material from BEI in early June but encountered numerous difficulties. (target date 7/16)
- b. Once we receive the material, it will take 5 days to complete the sensitivity study (target date 7/24)

Precision (reproducibility)

- a. Since early June we began sourcing samples from the lab in each CT range (negative, CT <37, CT 37-42)- due to the lower volume of samples coming through the lab (~5000/day) and the low prevalence of positive samples (~2.5%) sourcing these samples is expected to take 2-3 weeks (target date 7/23)

- b. Once we collect these samples, it will take 4 days to complete the study (target date 7/28)

Analytical sensitivity

- a. In Silico study will take 2-3 days (target date 7/31)

Analytical specificity (pathogen cross-reactivity)

- a) We are in the process of procuring ~50 pathogens from ATCC, however they require lead time to prepare the specimens, approve the order and ship the specimens to us (target date for receiving specimens: 7/16)
- b) In silico study will take 2-3 days (target date 8/3)
- c) Wet-lab study will take 2 weeks (target date 8/17)

Analytical specificity (interfering substances)

- a. We are in the process of procuring ~14 substances from a variety of sources, some requiring MD prescriptions. (Target date 7/16)
- b. Execution of interfering substances studies will take at least 1 week (target date 8/24)

Verification of sample stability (RNA stability)

- a) Since early June, we began the process of sourcing samples from the lab in each CT range (Ct 10-10, Ct19-37 and Ct37-42)- due to the lower volume of samples coming through the lab (~5000/day) and the low prevalence of positive samples (~2.5%) sourcing samples is expected to take 2-3 weeks (target date 7/23)
- b) Wet-lab study will take 1 week (target date 8/31)

Writing up the validation report, QA and laboratory director review, edits, final approval as a controlled document.

- a. This is expected to take a week (target date 9/7)

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