

## VA National Combined Verification Study for Cepheid SARS-CoV-2 Assay—STUDY PLAN

This cooperative verification plan will allow individual sites to perform a minimally sized verification study while collectively producing enough data to demonstrate the performance of the assay in the VA system.

THIS PLAN HAS BEEN REVIEWED AND APPROVED BY NATIONAL VA PATH AND LAB DIRECTOR

The study will be performed as outlined below and the results of that study will be logged into the separate, standardized Excel data collection spreadsheet. Once completed, that spreadsheet will be emailed to [Mohammad.Obeidat@va.gov](mailto:Mohammad.Obeidat@va.gov) for data collation. We will be observing the data in real time to monitor for issues with the assay. If issues arise, updates will be provided back to all sites. After ~2 weeks, the collated national data report will be returned to each participating site to include in their verification folders.

### Study Plan:

1. Obtain the SeraCare AccuPlex SARS-CoV-2 Reference Material Kit (0505-0126) directly from SeraCare.
2. Pre-write your local procedure for the test, along with any pre-verification paperwork you typically prepare (will send local examples separately).
3. Fill out the left side of the standardized national data collection worksheet with info for your facility.
4. After receiving the Cepheid SARS-CoV-2 assay kits do the following:
  - a. On DAY 1, set up and run the SeraCare external Positive control 2 times and the Negative control 2 times as per the Cepheid CoV-2 package insert.
    - i. optimally, this will be performed by different operators, but that is not required
    - ii. record the results along with date of testing on the standardized data collection form
    - iii. If you received one *Invalid* result (for any test) or one *Presumptive Positive* (on a positive control sample), then repeat that particular control 1X and record in the spare spaces on the form. Make notes on the form as to exactly what you did.
      - if the repeat test now agrees with the intended result, you may move to DAY 2 plan
      - if the repeat test does not run as expected, you must repeat DAY 1 testing the next day
    - iv. If there is a fully discordant result (Neg result on a Pos control or Pos/Presum Pos on a neg control), you must repeat DAY1 testing the next day. Please record any corrective actions in the Notes section of the data form.
  - b. On DAY 2 (or DAY3 if DAY1 testing had to be repeated), run the positive and negative control 1X each.
    - i. Record results on the standardized data sheet.
    - ii. If they result as expected, Pos/Neg external controls only need to be run 1X each week or with a new lot or shipment. We will **NOT** be doing 20 consecutive days of QC at this juncture.
    - iii. If they do not result as expected, then follow your internal procedures for implementing corrective actions for failed QC. Record corrective actions on the form and repeat testing. Record repeated results in spare spaces on the form.
5. Once DAY 2 testing has been completed successfully (or DAY3 if there was a failure), you may go live with testing patients. Get your Director/Pathologist to sign off. Record Go-Live date on the data collection sheet.
8. Email the completed data spreadsheet to [Mohammad.Obeidat@va.gov](mailto:Mohammad.Obeidat@va.gov). Retain/print a copy for your files. *If the initial run had to be repeated, please fill out and submit two data sheets, one for the failed attempt and a second for the successful one.* Please record all invalid results on the sheet along with all repeat testing.

# VA National Combined Verification Study for Cepheid SARS-CoV-2 Assay

### PLEASE EMAIL COMPLETED FORM TO: MOHAMMAD.OBEIDAT@VA.GOV ###

LOCAL VERIFICATION SITE INFORMATION	
Facility Name:	
Facility Address:	
Dept/Mail Stop:	
Street:	
City, State:	
Zip Code:	
Microbiology/ Molecular Lab Contact:	
Name	
e-mail	
Phone	
Pathologist/Director:	
Name	
e-mail	
Phone	
DATE-Study Started:	
DATE-Study Completed:	

LOCAL SITE STUDY DATA USING EXTERNAL CONTROLS*:		
Cepheid Lot#: Cepheid Exp Date: SeraCare Lot#:	ASSAY RESULT (Positive/ Presumptive Positive/ Negative/Invalid )	NOTES
<b>DAY 1:</b>		
POSITIVE CONTROL Run 1		
POSITIVE CONTROL Run 2		
Negative Control Run 1		
Negative Control Run 2		
<b>DAY 2**:</b>		
POSITIVE CONTROL		
Negative Control		

**Optional: Technologists Performing the Study**

Day 1:	Day 2:

\*Most will be using the SeraCare AccuPlex™ SARS-CoV-2 Reference Material Kit. If using a different kit, please indicate the exact kit used in the notes section above.

\*\*You may go live with the assay upon successful completion of Day2 testing. Successful completion defined as all 6 control runs resulting as expected. Presumptive Pos is *not expected*.