NONWAIVED Lab Name:

Verification of Performance for EUA Methods

TEST___COVID-19/SARS CoV-2_____ INSTRUMENT_____Abbot ID Now_____

DATE_____ PERFORMED BY_____

Must be performed by laboratory staff.

1. **Accuracy verification**

Test control material positive and negative for qualitative methods.

DAY	Ref Lab Accession #	Ref Lab Results	ID Now Analyzer Results
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Correlation data is added to the boxes above. If results fall within shaded areas, then it indicates acceptable correlation. Once all data is added for each correlation event, the total number of events that fall within the shaded boxes is divided by the total number of events. The percentage is written on the line by the test being correlated. At least 90% agreement is acceptable.

Positive		
Negative		
	Negative	**Positive**

% Agreement Observed:_____

2. Precision verification

Verify precision by recording the results of 5 positive control runs and 5 negative control runs.
Lot Numbers and Expiration Date of QC:

Positive Control:_____

Negative Control:_____

Day	Pos Ctrl	Neg Ctrl
1		
2		
3		
4		
5		

Acceptable limits:

95% agreement for qualitative results

Positive		
Negative		
	Negative	**Positive**

NONWAIVED Lab Name:

3. Reportable range verification – Not applicable at this time, Emergency Use Authorization Test

4. Reference interval verification – Not applicable at this time, Emergency Use Authorization Test

COMMENTS:

1. Contact the FDA about your intent to use this test under the EUA, by reaching out to them at CDRH-EUA-Reporting@fda.hhs.gov
2. Notify your Laboratory Accreditation Organization that you have validated this test and to add to your current test menu.
3. Enroll in a proficiency test program such as API or CAP.
4. Please e-mail Sarah Vu at sarah.vu@abbott.com when your facility has gone live with COVID-19 testing. This step is in addition to your FEMA and IHS reporting requirements.
5. Complete written test procedure and obtain Laboratory Director Signature of Approval.
6. Complete Testing staff training and initial competency assessment.
7. File the Safety Data Sheet in SDS Binder and send a copy to Safety Officer.
8. An IQCP is not required for tests released under an EUA. Follow manufacturer's instructions for QC frequency.

Approved Date: _____

Lab Director or designee signature of approval: _____