

WAIVED Lab Name:

### **Verification of Performance for EUA Methods**

TEST COVID-19/SARS CoV-2 INSTRUMENT Abbot ID Now

Once approved by the Laboratory Director will delegate a responsible person for the CLIA waived testing and will gather the following information:

- a. Ordering of supplies and controls for the test method.
- b. Work with the manufacturer in creating a written procedure to reflect a CLIA-waived test environment.
- c. Create a documentation log for quality control testing to be completed upon receipt of a new shipment or a new tester, check with the manufacturer on their recommendations and do not deviate from their instructions.
- d. Signature approval of written procedure by the Laboratory Director.
- e. Run QC materials and make sure it is acceptable before running patient tests and reporting test results.
- f. Make sure the clinic E.H.R. CAC has created the test name in RPMS, along with reference ranges and an internal procedure QC result, if applicable.
- g. Traditional verification methods and proficiency test enrollment are not required for tests performed under a CLIA Certificate of Waiver or Provider Performed Microscopy Certificate.

### **Complete the following Steps:**

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](mailto:CDRH-EUA-Reporting@fda.hhs.gov)
2. Notify your Clinic Accreditation Organization that you have validated this waived test under an EUA.
3. Please e-mail Sarah Vu at [sarah.vu@abbott.com](mailto: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.
4. Complete written test procedure and obtain Laboratory Director Signature of Approval.
5. Complete Testing staff training and initial competency assessment form.
6. File the Safety Data Sheet in SDS Binder and send a copy to the Safety Officer.

**Approved Date:** \_\_\_\_\_

**Lab Director or designee signature of approval:** \_\_\_\_\_