Overview of the Test

- The ID NOW COVID-19 assay is a qualitative, rapid molecular test that utilizes an isothermal nucleic acid amplification technology to detect nucleic acid from the SARS-CoV-2 viral RNA.
- Each Abbott ID NOW COVID-19 test cartridge comes with a swab and all the necessary reagents.
- The swab included in the test kit is the preferred collection device for optimal tests results.
  - Alternative approved specimen types include direct nasal, nasopharyngeal or oropharyngeal (throat) swabs and nasal, nasopharyngeal or throat swabs eluted in viral transport media, liquid Amies media, or phosphate buffered saline (PBS).
- Sample to result time is 13 minutes according to the Instructions for Use.
- Each kit contains 24 tests.
- Per the Instructions for Use, Abbott requires positive and negative external controls with each new shipment received and once for each untrained operator. The Instructions for Use also state that further controls may be tested in order to conform with local, state and/or federal regulations, accrediting organizations or your lab’s standard Quality Control procedures.

Distribution to Public Health Labs

- As part of the federal government’s response to COVID-19, HHS provided ID NOW instruments and tests to Public Health Laboratories (PHLs), the Indian Health Service and other key partners to support the response.
- In April 2020, PHLs began to receive their allotment of instruments and tests to begin the process of training and evaluating for implementation.
- IRR stock is intended to supply those instruments originally deployed to public health laboratories. It is NOT intended to supply testing sites that may have already had an ID NOW instrument even if that test site is supporting the public health response.
- Due to the high demand for this product, PHLs should consider the limited availability of kits going forward when making decisions about the best use of this resource.

Regulatory Requirements

- Testing sites performing the ID NOW COVID-19 test must have a current CLIA Certificate.
- During the COVID-19 public health emergency, CMS will permit a Certificate of Waiver laboratory to extend its existing CLIA Certificate of Waiver to operate a COVID-19 temporary testing site in an off-site location, such as a long-term care facility. The temporary site is only permitted to perform waived tests, including the Abbott ID NOW system, consistent with the laboratory's existing Certificate, and would be under the direction of the existing lab director.
Ongoing Availability of Test Kits

• Public Health Laboratories may order new ID NOW COVID-19 kits through the International Reagent Resource (IRR).

• IRR stock is only intended to supply those instruments originally deployed to public health laboratories. It is NOT intended to supply testing sites that may have already had an ID NOW instrument even if that test site is supporting the public health response.

• Due to the high demand for this product, Abbott is able to commit kits to IRR but weekly availability is limited. Public health laboratories should consider the limited availability of kits going forward when making decisions about the best use of this resource.

Potential Public Health Uses

• Any use requires CLIA certification as well as consideration of the feasibility of standing up testing, including training staff, assuring safety and establishing reporting mechanisms.

• Examples of uses for the Abbott ID NOW system include:
  ○ Deployment to rural hospitals or other critical care sites where testing is not widely available.
  ○ Deployment to local public health department testing sites currently performing CLIA waived testing for other analytes.
  ○ Deployment to test health care workers or first responders in order to reduce transmission and PPE use.
  ○ Deployment to long term care facilities or prisons. However, the regulatory requirements and the necessary CLIA documentation will need to be considered when deploying instruments to these settings if they are not currently performing other point of care testing.
  ○ Rapid deployment to aid in the investigation of a newly identified cluster. This potential use would require careful consideration to ensure the feasibility of rapidly standing up testing in this scenario including training staff, assuring safety and establishing reporting mechanisms.
  ○ Placement in public health laboratories to test high priority specimens requiring a rapid result.

Biosafety Considerations

• The Abbott ID NOW system contains an open well and is subject to generation of aerosol and splash/splatter.

• Public health laboratories should support testing sites in conducting risk assessments to assure safety of personnel performing the test.

• Testing should be conducted in a biosafety cabinet if available.

• If a biosafety cabinet is not available testing sites should consider use of biohazard shields or splash guards and appropriate PPE including gloves, face shields and respiratory protective equipment.

Responsibilities or Considerations of the PHL When Deploying an ID NOW Instrument

• Training
• Reporting
• Restocking supplies and prioritizing which sites receive supplies
• Risk Assessment
• Establishing quality assurance processes including quality control schedules