FACT SHEET: Implementation of Abbott ID NOW COVID-19

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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.
- 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.
- Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Distribution to Public Health Laboratories (PHLs)

- 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.
- PHLs will receive weekly distributions of ID NOW COVID-19 test kits and control kits. Placing orders is not required.
- The weekly distribution is intended to supply those instruments originally deployed to PHLs. However, PHLs have the discretion to supply other sites within their state that have ID NOW instrumentation to best serve state testing priorities.
- 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

- ID NOW COVID-19 kits and controls will be automatically shipped from IRR on a weekly basis.
- Due to the high demand for this product, Abbott is able to commit kits to IRR but weekly availability is limited. PHLs 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

- It is recommended to perform a biological risk assessment prior to testing based on your laboratory and location of where the instrument will be placed. Public health laboratories should also support testing sites in conducting risk assessments to assure safety of personnel performing the test.
- Follow standard precautions when handling clinical specimens, all of which may contain potentially infectious materials. Standard precautions include hand hygiene and the use of personal protective equipment (PPE), such as laboratory coats or gowns, gloves, respiratory equipment and eye protection.
- To minimize the risk of contamination from swab package during sample collection and swab stick during testing, it is recommended to widely open the package by pulling from the top down. Carefully remove the swab and perform sample collection. If the swab is to be returned to its package for transport, carefully return to allow the swab head to come into contact with the lower portion of the packaging. Avoid touching the outside of the wrapper with the swab. If preferred, the swab may also be placed into a conical tube for storage prior to testing.
- Clean instrument and surrounding areas immediately after possible patient sample contamination using a disinfectant approved in the packaging instructions.

Considerations of the PHL When Deploying an ID NOW Instrument

- Training: Abbott has virtual training available by appointment. Contact info TBD.
- Reporting
- Restocking supplies and prioritizing which sites receive supplies
- Risk Assessment
- Establishing quality assurance processes including quality control schedules

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Association of Public Health Laboratories
8515 Georgia Ave, Suite 700
Silver Spring, MD 20910
eoc@aphl.org