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Abbott ID NOW COVID-19 Testing CLIA Waived Status

Corporate Responsibility & Physician Enterprise

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What you need to **Know:**

- Abbott Diagnostics has manufactured the Abbott ID Now Covid-19 test. The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) and authorizes the emergency use of this product in the following testing locations:
  - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests.
  - Patient care settings using the ID NOW Instrument
- The FDA provides guidance and clarification in defining the term “patient care setting” as a point of care (POC) test that, under the EUA, can be per performed as CLIA Waived test.
- The College of American Pathologist (CAP) and The Joint Commission for laboratory accreditation and CLIA, clarifies that for the duration of the emergency declaration, the Abbott ID NOW COVID-19 test, can be performed in a patient care setting that is qualified to have the test performed operating under a CLIA Certificate of Waiver.

What to **Do:**

- Patient Care areas outside of the laboratory that have a CLIA Certificate of Waiver that will be receiving a testing device or have begun testing using the Abbott ID NOW COVID-19 device:
  - Contact Karen Smith, Executive Lab Leader karen.smith@dignityhealth.org and Yanely Reyes-Hernandez, yanelyreyes-hernandez@catholichealth.net System Director Laboratory Compliance to inform them of testing
  - Follow CLIA regulations and manufacturer’s instructions for performing waived testing
  - Provide the Patient Fact Sheet for the Abbott ID NOW COVID-19 testing to each patient being tested. https://www.fda.gov/media/136524/download
  - Follow the CDC guidelines for use of PPE for diagnostic testing conducted outside of a BSL-2 laboratory, such as point of care. https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html#decentralized

What to **Share:**

- Please share with physician enterprise administrative leaders so they are aware of the regulatory information regarding the Abbott ID Now testing for COVID-19

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