COVID-19 TESTING

MICHIGAN PHARMACISTS ASSOCIATION

Overview of CLIA Waived COVID-19 Tests

In part I of the COVID-19 series we addressed the steps to take to apply for a CLIA waiver and we provided resources and an overview about the FDA and the current testing environment. In part II of the COVID-19 series we have compiled a comparative chart of the FDA, Emergency Use Authorized (EUA) tests and an explanation of the use and applicability of the tests in a community pharmacy setting, including business planning, logistics and future reimbursement considerations.

As new tests are given Emergency Use Authorization (EUA), it is imperative to verify that the test is deemed to be authorized for the CLIA-waived setting by checking the list of test kit manufacturers with an FDA EUA. There must be a **"W"**-identifying CLIA WAIVED tests- in the column titled "Authorized Settings" for any test to be performed in a CLIA-waived laboratory. Pharmacies that purchase antibody test kits in anticipation of the product becoming authorized for use in CLIA-waived settings do so at their own risk.

These are the tests currently available that meet the "W" criteria:

Test/Manufacturer	Method	Time to analysis	Instrument required	Specimen	Site	Notes regarding test
ID Now-Covid 19 (Abbott) Qualitative Test www.abbott.com	Molecular	A few hours - 2 days	ID Now Instrument	Respiratory	**NP**	• Gold standard for sensitivity • Must be analyzed by certified lab • Detects pathogen presence
AcculaSARS COV-2 Test (Mesa Biotech Inc.) Qualitative www.mesabiotech.com/products	Molecular	15-30 mins	Accula Dock or Silaris Dock	Respiratory	**Nasal**	• Can be conducted at point-of-care • Detects pathogen presence
Xpert Xpress SARS-CoV-2 Test (Cepheid) Qualitative www.cepheid.com/coronavirus	PT-PCR	45 mins	Gene Xpert DX and Gene Xpert infinity	Respiratory	**Nasal**	• Can be conducted at point-of-care • Detects pathogen presence

- **(NP)** nasopharyngeal, nose and throat SWAB- most common in current pharmacy testing sites.
- **(OP)** oropharyngeal SWAB-Nasal and throat.
- **SEROLOGY** - finger prick of blood. Can detect active infection and acquired immunity because they are designed to detect the different antibody types that someone has made in response to the antigens.
  gM-antibodies made first response to a new antigen, and when present without IgG-represents early and acute infection.
- IgG-antibodies that protect against antigens the body has already been exposed to –like the body's memory. IgG antibodies typically persist after the infection resolves, at which point they are a key element to convalescent serum-
  represents current or prior infection.

Qualitative - indicates if the sample is positive or negative for what it's trying to detect.
Quantitative - only way to determine if a person definitely has COVID or a lasting immunity to it.
Currently there are no CLIA WAIVED serology tests available.

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