Department of Public Health
CITY OF PHILADELPHIA

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Division of COVID Containment

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COVID-19 Rapid Point-of-Care Diagnostic Testing Considerations

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Testing options to diagnose SARS-CoV-2 infection continue to expand as new platforms receive FDA emergency use authorizations. Rapid point-of-care (POC) tests can limit spread of COVID-19 by reducing the time between sample collection and result notification enabling rapid clinical and public health responses. It can be challenging for healthcare providers to determine when to use rapid POC molecular and antigen tests. While POC tests typically have very high specificity, their sensitivity is moderately lower than the current gold standard real-time polymerase chain reaction (RT-PCR) assays (Table 1).

SUMMARY POINTS

- All COVID-19 testing must be reported to PDPH.
- Consider local transmission and test characteristics when using rapid POC tests and interpreting results.

Table 1. Performance of Available Rapid Point-of-Care Platforms (as of September 21, 2020)

Device Name	Test Type	Reported Sensitivity+	Reported Specificity++
Abbott ID Now	Molecular	94%	98%
Abbott BinaxNOW	Antigen	80%	95%
BD Veritor	Antigen	84%	100%
LumiraDX	Antigen	97%	96%
Quidel Sofia/Sofia2	Antigen	80%	100%

+ Sensitivity = True Positive / (True Positive + False Negative)
++ Specificity = True Negative / (True Negative + False Positive)

When to Consider Rapid Point-of-Care Testing

Despite the moderate loss of sensitivity, the Philadelphia Department of Public Health recommends POC testing in specific clinical scenarios (Table 2). Current knowledge about rapid POC test performance:

- Suited to detect virus during **acute symptomatic infections** (symptoms for < 7 days) rather than asymptomatic infections or after 6 days of symptoms, **and particularly so at low positivity (<2%)**
- Can be used on **asymptomatic persons with known recent exposure** to individual(s) with COVID-19 (including clusters or outbreaks) or in areas with high COVID-19 positivity (≥2%)
- Can be used on **asymptomatic individuals** when a test result would initiate an immediate clinical or public health action, including patient isolation, return to school or work, or outbreak investigation; **RT-PCR is still the preferred test**
- A negative rapid POC result can be help rule out infection in individuals less likely to be positive (asymptomatic/minimal exposure) as local disease transmission declines (<2% positivity).

Table 2. PDPH Rapid Point-of-Care COVID-19 Test Use Recommendations (as of September 21, 2020)

Local Positivity	COVID-like Symptoms *	Recent Exposure^	Pre-test Probability	RT-PCR	POC
≥2%	Y	Y	High	Can use	Can use
	N	Y	High	Can use	Can use
	Y	N	High	Can use	Can use
	N	N	**Low**	**Preferred**	**Do NOT use**
<2%	Y	Y	High	Can use	Can use
	N	Y	Intermediate	**Preferred**	Can use
	Y	N	Intermediate	**Preferred**	Can use
	N	N	Low	**Preferred**	**Confirm w/ PCR**

*: COVID-like symptoms defined below ^: recent exposure OR linked to cluster or identified high risk setting

Pre-test probability of infection depends on multiple factors including duration and type of exposure, presence of symptoms, and the local positivity rate.

Additional Considerations

- **False Positive Results:** When the **pre-test probability of disease is low**, the likelihood of a false positive result increases. Clinicians should carefully consider the current local positivity along with the probability of the patient having a COVID-19 infection (symptoms and exposure) before using a rapid POC test. False positives are also more likely to occur if testing procedures are not carefully followed, leading to specimen contamination. Staff must receive adequate training to reduce usage errors. **If a false positive result is suspected:**
  - Confirm the result via RT-PCR
  - Report to FDA through MedWatch, using the following link: https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500
  - Report the result to the test manufacturer
- **False Negative Results:** When **pre-test probability of disease is high**, the likelihood of false negative results increases. If an unexpected negative rapid POC result is received (e.g. symptomatic and exposed patient), clinicians should:
  - Instruct the patient to isolate until a confirmatory test is completed AND
  - Collect a specimen for RT-PCR testing OR
  - Repeat rapid POC testing 24-48 hours after the initial unexpected negative result
- **Specimen Source and Quality:** Poor quality specimens are more likely to result in a false negative. Be sure to obtain sample correctly, visit https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html for more details
- **Monitor Virus Activity:** Visit www.phila.gov/COVID-19 to view the most recent data and consult with PDPH if you are unsure of the current local burden of disease

Reporting Positive and Negative Rapid Test Results to PDPH

The Coronavirus Aid, Relief and Economic Security (CARES) Act mandates reporting of all COVID test results to a public health agency. It is important that PDPH receive all results of POC tests on individuals residing in Philadelphia, including students, to effectively monitor the COVID-19 epidemic.

- Inform PDPH (COVIDTesting@phila.gov) **at least two weeks before initiating rapid POC testing**.
  - PDPH will assist in establishing a reporting format and answer questions regarding the POC machines, test administration techniques, and testing algorithms
- **Only start testing with rapid POC devices** after establishing a mechanism to report results from rapid POC machines to PDPH (COVIDTesting@phila.gov).
  - The following information must be reported with COVID test results: patient's full name, date of birth, current residential address in **Philadelphia** and phone number, race/ethnicity, sex, testing device/test name, test result, sample collection date, and test result date.
- **If you are already testing with a rapid POC device, please email** COVIDTesting@phila.gov **immediately**.

eCaseReporting (eCR): Sites can establish eCR from your electronic health record to report all COVID results (and soon results for other notifiable conditions) to the correct public health agency. Onboarding takes time, so an alternative reporting method is needed in the interim. More info: ecr@cdc.gov; http://bit.ly/ahimacovideCR;

***NOTE: COVID-like illness is defined as:**

At least **ONE** of these symptoms		At least **TWO** of these symptoms
new or persistent cough, shortness of breath, new loss of sense of smell, new loss of sense of taste	OR	fever, chills, muscle pain, headache, sore throat, nausea/vomiting, diarrhea, fatigue, congestion/ runny nose

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