### TESTING AND DIAGNOSTICS WORKING GROUP

#### LINKS OF INTEREST

### Guidance and FAQs

- 1. CDC Overview of testing for SARS-CoV-2
- 2. CSTE Case Definition
- 3. FDA FAQ <u>update</u>
- 4. CDC <u>Calculating SARS-CoV-2 Laboratory Test Percent Positivity</u>)and <u>FAQ</u>
- 5. IRR FAQ
- 6. CDC <u>Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated</u> with Coronavirus Disease 2019 (COVID-19)
- 7. CMS CLIA FAQ
- 8. CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19
- 9. CDC Common Investigation Protocol for Investigating Suspected SARS-CoV-2 Reinfection

### Back to School (Institutes of Higher Education and K-12)

- 1. CDC Operating Schools during COVID-19
- 2. CDC Indicators for Dynamic School Decision-Making
- 3. CMS <u>University testing</u>
- 4. CDC Testing, Screening, and Outbreak Response for Institutions of Higher Education (IHEs)
- 5. CDC Considerations for Institutions of Higher Education
- 6. CDC Interim Considerations for Testing for K-12 School Administrators and Public Health Officials

### Congregate Settings

- 1. CDC <u>Interim Guidance for General Population Disaster Shelters During the COVID-19 Pandemic</u> (and <a href="https://www.cdc.gov/coronavirus/2019-ncov/community/index.html">https://www.cdc.gov/coronavirus/2019-ncov/community/index.html</a>)
- 2. CDC Interim Considerations for SARS-CoV-2 Testing in Correctional and Detention Facilities
- 3. CDC Performing Broad-Based Testing for SARS-CoV-2 in Congregate Settings

### Wastewater Testing

- 1. CDC Developing a Wastewater Surveillance Sampling Strategy
- 2. CDC <u>Wastewater Surveillance Data Reporting and Analytics</u>
- 3. CDC Public Health Interpretation and Use of Wastewater Surveillance Data
- 4. CDC <u>Wastewater Surveillance Testing Methods</u>
- 5. CDC <u>Targeted Wastewater Surveillance at Facilities, Institutions, and Workplaces</u>

#### Data Reporting

- Standardized electronic laboratory reporting (ELR) flat file from CDC, APHL, CSTE, and other partners
- 2. CDC How to report COVID-19 laboratory data
- 3. HHS Laboratory Data Reporting Guidance
- 4. HHS COVID-19 Laboratory Data Reporting Implementation Specifications
- 5. HHS COVID-19 Data Reporting for Non-Lab-Based Testing
- 6. CSTE Electronic Laboratory Reporting Points of Contact
- 7. LOINC In-Vitro Diagnostic (LIVD) Test Code Mapping for SARS-CoV-2 Tests
- 8. LOINC Webinar for SARS-CoV-2/COVID-19

- 9. SARS-CoV-2 LOINC codes and Basics
- 10. CDC Healthcare Facilities That Have Implemented COVID-19 Electronic Case Reporting

# Regulatory

- 1. Prep Act <u>update</u> related to vaccines
- 2. FDA publishes comparative performance data
- 3. FDA Recommendations on Providing Clear Instructions to Patients Who Self-Collect an Anterior Nares (Nasal) Sample in a Health Care Setting for SARS-CoV-2 Testing Letter to Health Care Providers
- 4. FDA <u>announces</u> New Enforcement <u>Policy</u> for Modifications to FDA-Cleared Molecular Influenza and RSV Tests During the COVID-19 Public Health Emergency

### Additional Resources

- 1. Health Resources and Services Administration (HRSA) testing dashboard
- 2. CDC COVID Data Tracker
- 3. Flu SC2 Multiplex videos: setting up and analyzing
- 4. CLSI <u>documents</u> for COVID-19 testing
- 5. CDC Clinical Laboratory portal
- 6. CDC Division of Laboratory Systems (DLS)
- 7. APHL COVID-19 response
- 8. HHS Coronavirus (COVID-19)
- 9. Sign up for CDC email updates related to COVID-19
- 10. CDC COVIDView Weekly Summary
- 11. HHS Community-Based Testing Sites for COVID-19

# POINT OF CARE TESTING

# Regulatory

- 1. CMS rule
- 2. CMS surveyor quidance
- 3. CMS POC antigen enforcement discretion
- 4. Prep Act <u>update</u> related to congregate settings
- 5. CMS <u>Laboratory Quick Start Guide to CLIA Certification</u>
- 6. CMS How to Obtain a CLIA Certificate of Waiver
- 7. CMS Medicare payment for COVID-19 Viral Testing: Skilled Nursing Facility/Nursing Facility

### Guidance and FAQs

- 1. CDC interim guidance for rapid antigen testing <u>update</u>
- 2. APHL Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing
- 3. CDC <u>Guidance for SARS-CoV-2 Point-of-Care Testing</u>
- 4. FDA Potential for False Positive Results with Antigen Tests for rapid Detection of SARS-CoV-2 Letter to Clinical Laboratory Staff and Health Care Providers

### Abbott BinaxNOW

- 1. For BinaxNOW test training and information: BINAXNOW™ COVID-19 AG CARD AND NAVICA™ APP SET-UP AND TRAINING
- 2. HHS Site for COVID-19 Rapid test and BinaxNOW distribution: <u>COVID-19 Rapid Point-Of-Care Test Distribution</u>

# Nursing Home Program

- 1. <u>CMS site</u>, including weekly County positivity, list of facilities receiving antigen test supplies from HHS, FAQs, and toolkit
- 2. CMS Toolkit on State Actions to Mitigate COVID-19 Prevalence in Nursing Homes
- 3. HHS <u>webinar</u>
- 4. CDC Considerations for Antigen testing in nursing homes
- 5. CDC <u>Testing in Nursing Homes</u>
- 6. Sites available to nursing homes for training and reordering from <u>BD</u> and <u>Quidel</u>
- 7. BD Webinars
- 8. BD Reporting options that best fit your workflow
- 9. National Healthcare Safety Network (NHSN) Long Term Care Facility (LTCF) <u>COVID-19 Module.</u>