



Today's Agenda

- New antigen tests
- CLIA Waivers
- Training
- What results mean

Types of tests

Types of Tests

- PCR
- Antigen
- Antibody

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Abbott BinaxNOW Antigen Test

- FDA emergency use authorization
- Symptomatic (first 7 days of onset)
- Results in 15 minutes
- \$5 per test

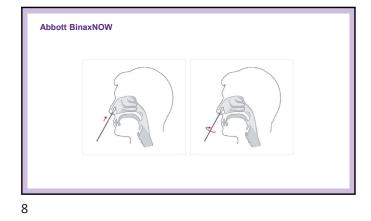


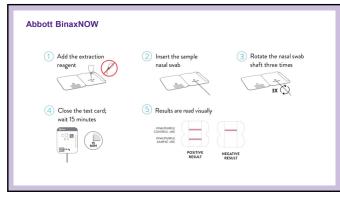
Abbott BinaxNOW Antigen Test

COVID-19 Ag CARD

- Federal government bought 150 million tests
- Sending to skilled nursing and assisted living communities
- Through December

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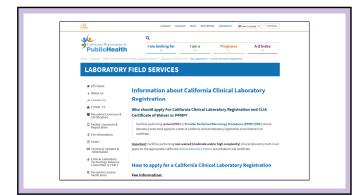
CLIA Waivers

- CMS and state agencies regulate laboratories
- CLIA Waiver allows non-complex tests outside a "laboratory"
- Waives many lab qualifications/requirements

In California

- CDPH Laboratory Field Services
- CLIA Waiver Application
- Laboratory Registration
- · Laboratory "Director"

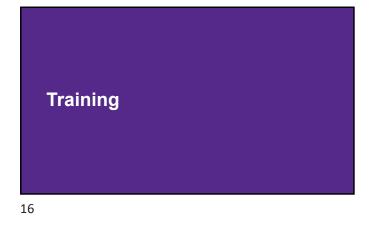
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Lab Director

- Physician or similarly qualified
- Signs of on application and registration
- · Can oversee multiple waivers



Training

- Licensed medical professional
- Complete Abbott training modules
- Document

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Performing Tests

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Performing Tests

- Wear PPE
- Follow manufacturer instructions
- **<u>Do not</u>** diagnose or order treatments!
- Report results

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Results

- CMS and FDA have provided guidance allowing use for asymptomatic persons
- Generally for exposure or outbreak response

