### Molecular Tests

**Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) or Nucleic Acid Amplification**

- **Examples**: Cepheid Xpert Xpress BioFire COVID-19 panels
  - **Collected From**: Saliva, nasal, nasopharyngeal, sputum, tracheal, deep bronchial
  - **Clinical Use**: To achieve both high sensitivity (0.76-0.94) and specificity (1.00) in the detection of SARS-CoV-2 RNA
  - **Sensitivity**: Sensitivity is higher among rapid RT-PCR and standard lab-based RT-PCR platforms (0.94-1.00) compared with rapid isothermal RT-PCR platforms (approximately 0.70-0.81)
  - **Specificity**: Specificity across all PCR platforms are excellent (0.96-1.00)
  - **Pros**: Increased sensitivity among non-rapid isothermal RT-PCRs; excellent specificity
  - **Cons**: A positive result may not represent active infection or correlate with infectiousness; Sample processing and assay run-time may take longer

- **Antigen Tests**: Abbott rapid antigen home test BinaxNOW COVID-19 Ag Card
- **Antibody Tests**: Lumix xMAP Multi-Antigen IgG Assay EUROIMMUN QuantiVac ELISA

- **Antigen Tests**: Saliva or nasopharyngeal
- **Clinical Use**: To quickly (10-45 min) detect the presence of SARS-CoV-2
  - **Antibody Tests**: Serology (blood)
  - **Clinical Use**: To assist in diagnosing a previous SARS-CoV-2 infection

- **Pros**: Assays may detect IgM, IgG, or both
  - **Cons**: No obvious difference in the performance of assays designed to detect the N protein or various portions of the S protein
  - **Cons**: Timing and frequency of seroreversion to undetectable is unknown
  - **Cons**: Pooled sensitivities of IgM and IgG at 2 weeks post-infection are 0.73 and 0.68, respectively; both specificities >0.98
  - **Cons**: Pooled sensitivities of total antibody assays at 2 weeks post-infection are 0.94 with a specificity of 1.00
  - **Pros**: May assist in the diagnosis of a previous or protracted illness

### Sensitivity

- **Specificity**: Specificity is >0.97
  - **Specificity**: Specificity across all PCR platforms are excellent (0.96-1.00)
  - **Specificity**: Most RT-PCR platforms report positive results on the basis of a cycle threshold (Ct)
  - **Specificity**: The Ct is inversely proportional to viral load
  - **Pros**: Results available quickly
  - **Cons**: Sensitivity is variable depending on date of initial infection; false positives may occur in low prevalence settings
  - **Cons**: Specificity is very good
  - **Cons**: Positive results may not represent immunity

### Common Diagnostic Tests Used for SARS-CoV-2 Infection

- **Pros**: Increased sensitivity among non-rapid isothermal RT-PCRs; excellent specificity
  - **Cons**: Decreased sensitivity if not used during the period of high viral replication/early symptomatic stages of illness
  - **Cons**: Specificity is very good
  - **Cons**: False positives may occur in low prevalence settings (WHO)