

SARS-CoV-2 TESTING

1-15-2021 *Denotes tests currently performed at RML

| Method: Molecular Standard PCR | Sensitivity | Specificity | Limit of Detection (LOD) copies/mL |
|--------------------------------|-------------|-------------|------------------------------------|
| Abbott M2000* | 93% | 100% | 100 cp/mL |
| Hologic Panther Aptima* | 97% | 100% | 125 cp/mL |
| DiaSorin Simplexa* | 96% | 98% | 500 cp/mL |
| Abbott Alinity m* | 100% | 96% | 100 cp/mL |

| Method: Molecular Rapid PCR or isothermal amplification | Sensitivity | Specificity | Limit of Detection (LOD) |
|---|-------------|-------------|--|
| Abbott ID NOW | 73-80% | 98-100% | 125 genome equivalents/mL |
| Mesa Biotech Accula | 53-81% | 92-100% | 150 cp/mL |
| SAMBA II | 94-100% | 90-99% | 250 cp.mL |
| Cepheid XpertXpress | 98-100% | 92-99% | 0.0200 PFU/mL PFU=plaque forming unit |

ALERT: Specimens for Abbott's ID Now **MUST be tested within 1 hr of collection.** The ID NOW only has the ability to perform 3 tests per hr. Beyond 1 hr, the specimen **MUST** be recollected.

NOTE: Rapid tests should **NOT** be used to screen asymptomatic individuals. Sensitivity estimates for patients with a high viral load (generally 3-7 days after symptom onset) was 80-100% and lower for those with low viral loads, thus Negative results in highly suspicious patients should be retested with a non-rapid molecular test.

| Method: Antigen Tests | Sensitivity | Specificity | Limit of Detection (LOD) |
|--|-------------|-------------|--|
| Abbott Binax Now Perform within 7 days of symptom onset | 97% | 98% | 140.6 TCID ₅₀ /mL |
| Quidel Sofia Perform within 5 days of symptom onset | 97% | 100% | 1.13 x10 ² TCID ₅₀ /mL |

NOTE: These tests are NOT recommended for testing of asymptomatic individuals. Negative results are recommended to reflex to PCR testing.

| Method: Antibody Test | Sensitivity (PPA on days post onset) Interpret with caution neg < 14 days onset | Specificity | LOD |
|---|--|-------------|-----|
| Abbott IgG anti-SARS-CoV-2 Nucleocapsid IgG Antibody* | 3-7 days post onset 50% 8-13 days post onset 91% ≥ 14 days 100% | 99% | N/A |