Expansion of COVID19 diagnostics in South Africa: Rapid Antigen Testing

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- Head: iLEAD Innovation Hub

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1. Background to Testing Context of SARS CoV-2 IN SA
Temporal Considerations for SARS CoV-2 Diagnosis

Nandini Sethuraman et al1 concluded a comprehensive laboratory testing window with different technologies based on published studies. Detection sensitivity for SARS-COV-2 antibodies and virus varies significantly from the time the specimens are taken.

OVERVIEW OF SARS COV-2 ANTIGEN TESTING

- Nasopharyngeal swab PCR
- Virus isolation from respiratory tract
- Bronchoalveolar lavage/sputum PCR
- Stool PCR
- IgM antibody
- IgG antibody
Context in South Africa

NHLS has a network of 265 laboratories across the country. By 28 February 2021, the country had conducted approximately 9 million COVID 19 tests

<table>
<thead>
<tr>
<th>Virology capability</th>
<th>54%</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 VL labs with capacity to test 6 million/pa</td>
<td>32%</td>
</tr>
<tr>
<td>163 GeneXpert labs with capacity to test 2.5 million/pa</td>
<td>14%</td>
</tr>
</tbody>
</table>

Capacity for COVID 19 Testing

COVID 19 National Statistics

Tests conducted | 9,007,479
Positive cases identified | 1,513,393
Total recoveries | 1,430,259
Total deaths | 49,993
New cases | 1,168
Active cases | 33,141

Source: NHLS Portfolio Committee Presentation, June 2020; SA Department of Health, NICD, "Update on Covid-19 (28th February 2021)" Notes: 1. Tests done by NHLS (250 tests with unconfirmed location); 2. Backlog of unprocessed specimens; 3. Capacity (equipment available) as at end May 2020; 4. Number of hospitals reporting COVID 19 cases from both public and private sector
SARS-CoV-2 Testing Landscape: South Africa

**Test Pipeline**

- **Assays evaluated for SAHPRA**
  - RT-PCR: 496
  - Serology: 557
  - Antigens: 21

**Background to Testing Context of SARS-CoV-2 in SA**

**Table 1: Advantages and disadvantages of testing methods for SARS-CoV-2**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nucleic acid amplification testing (NAAT)</td>
<td>Detects active SARS-CoV-2 infection&lt;br&gt;High sensitivity and specificity</td>
<td>Turnaround time of hours to days&lt;br&gt;Labour intensive&lt;br&gt;Requires laboratory infrastructure and skilled personnel&lt;br&gt;More expensive than RDTs</td>
</tr>
<tr>
<td>Rapid diagnostic tests: Antigen-detecting tests</td>
<td>Detects active SARS-CoV-2 infection&lt;br&gt;Can be used at the point of care (outside laboratories)&lt;br&gt;Easy to perform&lt;br&gt;Quick results (typically under 30 minutes) enabling rapid implementation of infection control measures, including contact tracing&lt;br&gt;Less expensive than NAAT, e.g., RT-PCR tests</td>
<td>Variable sensitivity and specificity, generally lower than NAAT&lt;br&gt;Lower sensitivity means negative predictive value is lower than for NAAT, especially in settings with high prevalence of SARS-CoV-2&lt;br&gt;Confirmatory NAAT testing of RDT positives is advised in all low-prevalence settings and for RDT negatives in high-prevalence settings&lt;br&gt;Negative Ag-RDT results cannot be used to remove a contact from quarantine</td>
</tr>
<tr>
<td>Rapid diagnostic tests: Antibody-detecting tests</td>
<td>Ab-RDTs can be used to detect previous infection with SARS-CoV-2&lt;br&gt;Can be used at the point of care (outside laboratories) or in higher throughput formats in laboratories&lt;br&gt;Easy to perform&lt;br&gt;Quick results (typically under 30 minutes for point-of-care testing)&lt;br&gt;Less expensive than NAAT, e.g., RT-PCR tests</td>
<td>Clinical significance of a positive Ab-RDT result is still under investigation&lt;br&gt;Positive Ab-RDT results do not guarantee presence of neutralizing antibodies or protective immunity&lt;br&gt;Ab-RDTs should not be used for determining active infections in clinical care or for contact-tracing purposes&lt;br&gt;Interpretation of Ab-RDT results depends on the timing of the disease, clinical morbidity, the epidemiology and prevalence within the setting, the type of test used, the validation method, and the reliability of the results</td>
</tr>
</tbody>
</table>

2. Molecular Testing Update
NHLS SARS-CoV-2 molecular testing platform

~3 million laboratory test results

<table>
<thead>
<tr>
<th>Assay name</th>
<th>Assay type</th>
<th>n</th>
<th>Positive</th>
<th>Inconclusive</th>
<th>Unsuccessful</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEEGENE - CFX</td>
<td>open</td>
<td>942831</td>
<td>18.5%</td>
<td>1.1%</td>
<td>0.4%</td>
</tr>
<tr>
<td>ROCHE 6800/8800</td>
<td>closed</td>
<td>561069</td>
<td>20.0%</td>
<td>0.1%</td>
<td>0.1%</td>
</tr>
<tr>
<td>GENEXPERT</td>
<td>closed</td>
<td>472268</td>
<td>21.0%</td>
<td>0.2%</td>
<td>0.2%</td>
</tr>
<tr>
<td>THERMO MPLEX - QUANTSTUDIO</td>
<td>open</td>
<td>457681</td>
<td>18.7%</td>
<td>1.3%</td>
<td>0.2%</td>
</tr>
<tr>
<td>ABBOTT M2000</td>
<td>closed</td>
<td>247280</td>
<td>20.5%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Laboratory testing, NHLS

Number of tests:
- March-20: 6,344
- April-20: 94,157
- May-20: 273,434
- June-20: 425,515
- July-20: 525,789
- August-20: 506,777
- September-20: 218,919
- October-20: 244,114
- November-20: 253,418
- December-20: 438,527
- January-21: 596,771

Positivity:
- March-20: 0.04
- April-20: 0.44
- May-20: 2.3
- June-20: 7.66
- July-20: 19.86
- August-20: 9.69
- September-20: 3.96
- October-20: 4
- November-20: 5.44
- December-20: 18.11
- January-21: 27.36
Increase in VL: Median Ct by facility type

- Similar distribution of assays receiving specimens from “clinic” and “hospital”
- Ct lower in 2nd wave
- By January in spite of increasing positivity, the Ct trend is upward (lower viral load)

<table>
<thead>
<tr>
<th>Facility Type</th>
<th>JUL</th>
<th>DEC</th>
<th>Delta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic</td>
<td>29.9</td>
<td>28.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Hospital</td>
<td>29.7</td>
<td>28.8</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Ct= 30

Positive results (with Ct)
3. Discovery of new variant
Network for Genomic Surveillance in South Africa

Supported by the DSI and the SA MRC
Identification and tracking of novel SARS-CoV-2 lineage in South Africa

New lineage rapidly become the dominant

Since early November, the new lineage has rapidly become the dominant lineage in the sampled locations (>90% of sequences in week beginning 16 Nov)
Receptor binding domain (RBD). Some experimental data on enhanced binding and nAb resistance.

**South African variant**

<table>
<thead>
<tr>
<th>Gene</th>
<th>Nucleotide</th>
<th>Amino Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>orf1ab</td>
<td>1059C&gt;T</td>
<td>T265I</td>
</tr>
<tr>
<td></td>
<td>5230G&gt;T</td>
<td>K1655N</td>
</tr>
<tr>
<td></td>
<td>10323A&gt;G</td>
<td>K3353R</td>
</tr>
<tr>
<td>spike</td>
<td>21614C&gt;T</td>
<td>L18F</td>
</tr>
<tr>
<td></td>
<td>21801A&gt;C</td>
<td>D80A</td>
</tr>
<tr>
<td></td>
<td>22206A&gt;G</td>
<td>D215G</td>
</tr>
<tr>
<td></td>
<td>22287T&gt;A*</td>
<td>L242H*</td>
</tr>
<tr>
<td></td>
<td>22286-22294 deletion*</td>
<td>L242_244L deletion*</td>
</tr>
<tr>
<td></td>
<td>22299G&gt;T</td>
<td>R246I</td>
</tr>
<tr>
<td></td>
<td>22813G&gt;T</td>
<td>K417N</td>
</tr>
<tr>
<td></td>
<td>23012G&gt;A</td>
<td>E484K</td>
</tr>
<tr>
<td></td>
<td>23063A&gt;T</td>
<td>N501Y</td>
</tr>
<tr>
<td></td>
<td>23664C&gt;T</td>
<td>A701V</td>
</tr>
<tr>
<td>orf3a</td>
<td>25563G&gt;T</td>
<td>Q57H</td>
</tr>
<tr>
<td></td>
<td>25904C&gt;T</td>
<td>S171L</td>
</tr>
<tr>
<td>E</td>
<td>26456C&gt;T</td>
<td>P71L</td>
</tr>
<tr>
<td>N</td>
<td>28887C&gt;T</td>
<td>T205I</td>
</tr>
</tbody>
</table>

**United Kingdom variant**

<table>
<thead>
<tr>
<th>gene</th>
<th>nucleotide</th>
<th>amino acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORF1ab</td>
<td>C3267T</td>
<td>T1001I</td>
</tr>
<tr>
<td></td>
<td>C5388A</td>
<td>A1708D</td>
</tr>
<tr>
<td></td>
<td>T6954C</td>
<td>I2230T</td>
</tr>
<tr>
<td></td>
<td>11288-11296 deletion</td>
<td>SGF 3675-3677 deletion</td>
</tr>
<tr>
<td>spike</td>
<td>21765-21770 deletion</td>
<td>HV 69-70 deletion</td>
</tr>
<tr>
<td></td>
<td>21991-21993 deletion</td>
<td>Y144 deletion</td>
</tr>
<tr>
<td></td>
<td>A23063T</td>
<td>N501Y</td>
</tr>
<tr>
<td></td>
<td>C23271A</td>
<td>A570D</td>
</tr>
<tr>
<td></td>
<td>C23604A</td>
<td>P681H</td>
</tr>
<tr>
<td></td>
<td>C23709T</td>
<td>T716I</td>
</tr>
<tr>
<td></td>
<td>T24506G</td>
<td>S982A</td>
</tr>
<tr>
<td></td>
<td>G24914C</td>
<td>D1118H</td>
</tr>
<tr>
<td>Orf8</td>
<td>C27972T</td>
<td>Q27stop</td>
</tr>
<tr>
<td></td>
<td>G28048T</td>
<td>R52I</td>
</tr>
<tr>
<td></td>
<td>A28111G</td>
<td>Y73C</td>
</tr>
<tr>
<td>N</td>
<td>28280 GAT-&gt;CTA</td>
<td>D3L</td>
</tr>
<tr>
<td></td>
<td>C28977T</td>
<td>S235F</td>
</tr>
</tbody>
</table>

**Summary:**
- 15 lineage defining mutations
- 8 in spike
- 1 deletion

**Thermo Fisher assay S-target dropout**
DISCOVERY OF NEW VARIANT

501Y.V2 Structure: Tegally et al, 2021

Source: https://www.medrxiv.org/content/10.1101/2020.12.21.20248640v1
4. Antigen testing overview
### Available WHO approved COVID-19 Antigen RDTs

- **High-performance SARS-COV-2 antigen tests are flexible tests to deploy across settings to reduce COVID-19 transmission**

- **There are currently three antigen (Ag) tests for SARS-CoV-2 that are being marketed in Low- and Middle-Income Countries ("LMICs")**

- **WHO recommends use of Ag rapid tests for COVID-19 diagnosis if they meet minimum performance standards (≥97% specificity and ≥80% sensitivity)**

<table>
<thead>
<tr>
<th>Approved COVID-19 diagnostics¹</th>
<th>Test type</th>
<th>Test characteristics²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>Ag-RDT</td>
<td>Spec: 99.8%, Sen: 91.4%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TAT³: ~15 min/test</td>
</tr>
<tr>
<td>SD Biosensor</td>
<td>Ag-RDT</td>
<td>Spec: 97.6⁸ - 99.3³⁶ Sen: 76.6³⁶ - 88.7³⁶</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TAT: ~15 min/test</td>
</tr>
<tr>
<td>Lumira</td>
<td>Ag POC device</td>
<td>Spec: 96.6%, Sen: 97.6%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TAT: ~12 min/test</td>
</tr>
<tr>
<td>Various suppliers</td>
<td>NAAT (PCR)</td>
<td>Gold standard, but high TATs limit usefulness of results⁵</td>
</tr>
</tbody>
</table>

---

1. Includes COVID-19 tests approved by a stringent regulatory authority (WHO, US FDA, and/or CE) as of Sept-2020.
2. Source: Data from manufacturer IFU.
3. TAT = turnaround around time.
4. Ranges represent data from Germany (low-prevalence) and Brazil (high-prevalence), respectively; performance expected to fall within this range.
5. Data suggests that TATs >2 days have little to no impact on reducing transmission, however in many SSA countries average turnaround times are 2-5 days or more (further detail on slide 10).
5. Antigen RDT Validations
Lab Antigen Testing Validation Streams for SAHPRA

**ANTIGEN RDT VALIDATIONS**

- Positive and Negative SARS-CoV-2 residual clinical specimens (PBS/VTM/UTM)
  - HVL n=80 (CT <30)
  - MVL n=20 (CT >30 <35)
  - Negatives n=30

- Simulate swabs - follow IFU
  - Rapid Ag test
  - Positive - record results
  - Negative - repeat results
  - Perform precision data on positive and negative specimens
  - Re-analyse false negative - using 1:1 ratio of specimen to kit buffer

- SARS-CoV-2 viral culture panels
  - 1:10^5 (Log 5.0) n=3
  - 1:10^4 (Log 4.7) n=3

- Purified Recombinant SARS-CoV-2 proteins – insect cells
  - N protein (50 nM)
  - S protein (50 nM)

- Prepare serial dilution (10 nM to 2.4 pM)

- RNA Extraction – RT-PCR
  - Rapid Ag test
  - Obtain Ct values
  - Determine LoD
  - Record results

- Rapid Ag test
  - Determine LoD
  - Record results

**Result Interpretation Type**

- Visual
- Analyser

- Chromatographic
- Colorimeter
- Fluorescent

**Antigen RDT Regulatory Approvals (n=17 RDTs)**

- WHO (EUA)
- FDA (EUA)
- Australia TGA
- Health Canada
- Singapore HSA
- Brazil
- Philippines
- Korea - Export
- Korea MDFS
- CE-IVD
- SAHPRA
- Unknown

**Abbreviations**

- HVL – high viral load
- MVL – medium viral load
- CT – cycle threshold
- IFU – instructions for use
- LFA – lateral flow assay
- LoD – limit of detection
- nM – nano molar
- RT – PCR – reverse transcriptase polymerase chain reaction
# Antigen test evaluations in progress

## Antigen testing evaluations conducted at NHLS

<table>
<thead>
<tr>
<th>Reports completed and submitted to SAHPRA (n=7)</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>• SD Biosensor</td>
<td></td>
</tr>
<tr>
<td>• Rapigen (Biocredit)</td>
<td></td>
</tr>
<tr>
<td>• Abbott Panbio</td>
<td></td>
</tr>
<tr>
<td>• PCL Antigene</td>
<td></td>
</tr>
<tr>
<td>• Nowcheck COVID-19 Ag test</td>
<td></td>
</tr>
<tr>
<td>• BD Veritor Ag assay</td>
<td></td>
</tr>
<tr>
<td>• Camtech COVID-19 Ag test</td>
<td></td>
</tr>
</tbody>
</table>

## Validations in progress (n=5)

<table>
<thead>
<tr>
<th>Validations in progress (n=5)</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sienna COVID-19 Antigen Rapid Test Cassette</td>
<td></td>
</tr>
<tr>
<td>• Vivacheck SARS CoV-2 rapid antigen test</td>
<td></td>
</tr>
<tr>
<td>• LumiraDx</td>
<td></td>
</tr>
<tr>
<td>• Nanjing Norman Biological Technology Co., Ltd</td>
<td></td>
</tr>
<tr>
<td>• Zhejiang Orient Gene Biotech</td>
<td></td>
</tr>
</tbody>
</table>

## Pending evaluations (using existing panels) n=8

<table>
<thead>
<tr>
<th>Pending evaluations (using existing panels) n=8</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>• BIOHIT Healthcare (Heifei)</td>
<td></td>
</tr>
<tr>
<td>• GENEDIA W COVID-19 Ag</td>
<td></td>
</tr>
<tr>
<td>• AMP SARS CoV-2 Rapid antigen test</td>
<td></td>
</tr>
<tr>
<td>• Boson Biotech</td>
<td></td>
</tr>
<tr>
<td>• Humasis COVID-19 Ag Test</td>
<td></td>
</tr>
<tr>
<td>• Nadal Covid-19 Antigen rapid test</td>
<td></td>
</tr>
<tr>
<td>• OnSite ® COVID-19 Ag Rapid Test</td>
<td></td>
</tr>
<tr>
<td>• Rapigen (SAHPRA requested evaluation)</td>
<td></td>
</tr>
</tbody>
</table>
6. Antigen testing use cases and testing algorithms
### Ag Testing Use Cases

Use cases with the greatest impact on epidemic management goals should be prioritized.

#### Algorithms in place

<table>
<thead>
<tr>
<th>Testing Scenario</th>
<th>Diagnosis in populations with known risk or exposure</th>
<th>General population screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant WHO scenarios</td>
<td>Confirmed outbreaks, suspected outbreaks, regions of widespread community transmission, asymptomatic contacts</td>
<td>Low-prevalence / general population screening, monitoring disease incidence, points of entry, etc.</td>
</tr>
<tr>
<td>Location of Testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health facilities (clinics, hospitals, treatment centers, etc.)</td>
<td></td>
<td>Ports of entry (e.g. land borders, airports, etc.)</td>
</tr>
<tr>
<td>Contact tracing (community or home)</td>
<td></td>
<td>Schools and workplaces</td>
</tr>
<tr>
<td>Closed / semi-closed settings (care homes, prisons, etc.)</td>
<td></td>
<td>Targeted population screening</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Surveillance</td>
</tr>
<tr>
<td>Target populations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with severe presentation</td>
<td></td>
<td>Travelers</td>
</tr>
<tr>
<td>Frontline HCWs and essential workers (symptomatic &amp; asymptomatic)</td>
<td></td>
<td>Teachers, students, and administrative staff</td>
</tr>
<tr>
<td>Symptomatic cases w/ high transmission risk</td>
<td></td>
<td>Factory workers, government employees, etc.</td>
</tr>
<tr>
<td>Contacts of confirmed cases (symptomatic &amp; asymptomatic)</td>
<td></td>
<td>Non-COVID inpatients (e.g. elective surgeries, hospitalized non-COVID patients, etc.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other general populations (e.g. random community screening, surveillance)</td>
</tr>
</tbody>
</table>
Algorithm - Populations with known risk or exposure

Algorithm for populations with known risk or exposure in suspected or confirmed outbreak (health facilities, contact tracing, and closed / semi-closed settings)

**Symptomatic cases**
Frontline HCWs and essential workers¹, Contacts of confirmed cases¹,² High-risk populations in confirmed outbreaks³

- **Antigen negative result**
  - High degree of continued clinical suspicion?
    - **No**
      - Manage as negative result
      - Work up cases for all other causes of illness
    - **Yes**
      - Isolate AND manage as positive result
        - (Repeat Antigen test or preferably confirm with RT-PCR where possible)

- **Antigen positive result**
  - Manage as positive result:
    - Negative
      - Manage as negative result
    - Positive
      - Implement infection prevention and control measures

¹. Symptomatic & asymptomatic
². Follow local guidelines on isolation of contacts
³. Includes elderly, people with co-morbidities, populations in closed-settings (prisons, care homes, etc.)

“Continued clinical suspicion can, for example, be the absence of another obvious etiology, the presence of an epidemiological link, or suggestive clinical finding (e.g. typical radiological signs).”
Algorithm - General population screening

Algorithm for general population screening where there is no suspected or confirmed outbreak (schools, workplaces, ports of entry, churches, etc.)

**General population screening**
(schools, workplaces, ports of entry, churches, etc.)

- **Antigen negative result**
  - Manage as **negative result**
  - Further isolation may not be required, however infection prevention and control measures should be followed

- **Antigen positive result**
  - Manage as **negative result**
  - Isolate AND manage as positive result and confirm with RT-PCR test if available

  - **Manage as positive result**
    - Initiate appropriate treatment
    - Implement infection prevention and control measures

- **Negative**
  - Manage as **negative result**

- **Positive**

---

**Notes:**

1. More evidence is needed in support of serial testing for antigen tests and maybe an option. Follow country guidelines.
Antigen testing at open border posts

NHLS COVID Mobile Laboratory

- 72 ports of entry in the country (land, sea and air) that open and close according to lockdown restrictions.
- Mobile laboratories are used for testing at all open ports: agile system
  - Of 53 land ports, 20 are currently open with mobile laboratories deployed to provide on-site antigen testing.
  - Of 11 airports, 2 are currently open with both PCR and antigen provided by the mobile laboratories.
    - 3 airports are reopening and being brought online.
- ALL mobile laboratory results (PCR and antigen) are reported in real time
- Travelers receive results immediately via Short Message System (SMS)
Approach to Antigen testing beyond PCR

NHLS COVID Mobile Laboratory

Coronavirus (COVID-19)

NHLS Testing Station
National Health Laboratory Service

LIS Registration Station

PCR Testing – GeneXpert and BioFire

Antigen Testing – SD Biosensor and Panbio

AG TESTING USE CASES

All mobile laboratories have full connectivity

Mobile staffing: driver-clerk and two nurses per van. Mobiles with PCR testing also have a technologist.
SARS-CoV-2 Testing: South Africa
SARS-CoV-2 diagnostic tests: June 2020-March 2021

<table>
<thead>
<tr>
<th>Province</th>
<th>No. tests</th>
<th>Percentage tested</th>
<th>No. positive</th>
<th>Percentage test positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>EASTERN CAPE</td>
<td>68 479</td>
<td>14%</td>
<td>7 570</td>
<td>11.1%</td>
</tr>
<tr>
<td>FREE STATE</td>
<td>23 081</td>
<td>5%</td>
<td>1 877</td>
<td>8.1%</td>
</tr>
<tr>
<td>GAUTENG</td>
<td>46 366</td>
<td>10%</td>
<td>3 613</td>
<td>7.8%</td>
</tr>
<tr>
<td>KWAZULU-NATAL</td>
<td>221 325</td>
<td>46%</td>
<td>24 440</td>
<td>11.0%</td>
</tr>
<tr>
<td>LIMPOPO</td>
<td>6 889</td>
<td>1%</td>
<td>408</td>
<td>5.9%</td>
</tr>
<tr>
<td>MPUMALANGA</td>
<td>38 973</td>
<td>8%</td>
<td>938</td>
<td>2.4%</td>
</tr>
<tr>
<td>NORTH WEST</td>
<td>22 496</td>
<td>5%</td>
<td>2 624</td>
<td>11.7%</td>
</tr>
<tr>
<td>NORTHERN CAPE</td>
<td>4 415</td>
<td>1%</td>
<td>205</td>
<td>4.6%</td>
</tr>
<tr>
<td>WESTERN CAPE</td>
<td>35 817</td>
<td>8%</td>
<td>5 999</td>
<td>16.6%</td>
</tr>
<tr>
<td>UNKNOWN</td>
<td>9 286</td>
<td>2%</td>
<td>447</td>
<td>4.8%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>477 127</td>
<td>100%</td>
<td>48 081</td>
<td>10.1%</td>
</tr>
</tbody>
</table>

SARS-CoV-2 Ag tests: October 2020-March 2021

- Private 15%
- Public 85%

AG TESTING USE CASES

11 Oct 2020: Rollout of Ag testing at points of entry to SA
11 Dec 2020: SA-NDoH Ag testing guidelines
21 Dec 2020: WHO-FIND Ag testing implementation guidelines

SARS-CoV-2 diagnostic tests: June 2020-March 2021

AG TESTING USE CASES

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SARS-CoV-2 Ag tests: October 2020-March 2021

- Private 15%
- Public 85%
7. Challenges with Antigen Testing
## Implementation

### Stakeholder Engagement
- Delays at CLI phase; responsibility/re-imbursement

### Training
- Alignment on Used TOT ASLM modules: 23 certified, >160 master trainers
- Modified to local context, videos

### Quality Indicators
- Understanding training requirements and implementing the training programmes across all sites nationally

### Supply chain
- Challenges getting materials and reagents into the country due to movement restrictions and logistics issues
- Regulatory delays

### HR
- Critical staff (lab technical and supporting) contracting COVID-19, amidst the current shortages of people
- Data admin issues delay

### Scaling up and capability
- Different lab /clinical groups may need assistance in scaling up and building capabilities required
Future-proofing testing: digital patient-centric care

- Self-registration
- Self-sampling
- Self-testing
- Result return
- Health messaging

- Self-monitoring
- Wearables
- Biometrics
- Radio frequency ID for specimen tracking
- RDT readers

- eLABs patient management module developed
- eLABS Ag-testing module developed
- eLABS scale up in over 1500 facilities in SA and 900 facilities in Zambia
- RDT reader study published
- MVP for COVID-19 self-registration and self-sampling scoped with BMGF
Future of testing

1. Remain agile and flexible with testing profiles
2. Rapid Expansion of testing: through public and private sectors
3. Use of spare capacity for HPV, STIs, oncology: Improved agility
4. Expansion of POCT strategy: Best use case
5. Maintenance of laboratory sites: Multi-disciplinary testing
6. Ongoing quality monitoring: Real-time
7. Re-evaluation of certain assays as variants emerge
8. Rapid PCR development as variants emerge
9. Increased genomic testing capacity
10. Patient centric, own data, own monitoring, O₂ sats monitoring
Acknowledgements

- National Department of Health
- Ministerial Advisory Committee
- NHLS and the National Priority Program
- NHLS QAD
- Department of Molecular Medicine and Haematology, Wits University,
- Virology and TB Expert working groups
- Funders
- Clinical partners
- Commercial collaborators
- Innovators
SARS-CoV-2 B.1.351 (501Y.V2)

**Molecular**
- Variant isolates to be sent from AHRI (mid-February) and will be cultured at CBTBR
- 2 variants
  - 001 with the full complement of mutations including L18F
  - 002 with a deletion in the Furin site from Vero E6 passage
- Culture panels (dilution: original and novel variants) will be shared with testing laboratories
- Impact of variants on diagnostic assays in use will be assessed
  - Novel assay evaluations will include original and novel culture isolates
- CQM of Ct values and gene-dropout
- Sharing of patient specimens for genomic studies

**Serology**
- Assess approved tests using residual serum/plasma (vaccine group)
- Increase serology specimen biorepository (national)

**Antigen**
- Currently no Ag tests use the S-protein
- Discussions with PATH re use of protein panels