

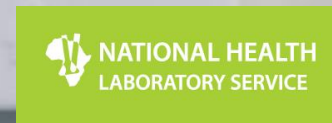
*“ Reviewing Efforts to Increase Community Access to COVID-19 Antigen Rapid Testing Services:
The South African Experience*

Lynsey Stewart-Isherwood, MSc.(med)

On behalf of:

- National Department Health
- National Health Laboratory Services (NHLS)
- National Priority Programmes (NPP) of the NHLS
- Department of Molecular Medicine & Haematology, School of Pathology, Faculty of Health Sciences, University of the Witwatersrand

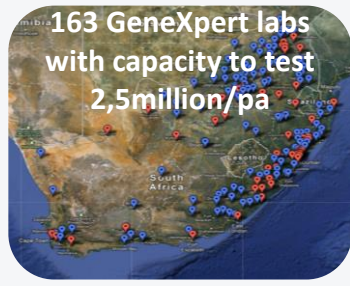
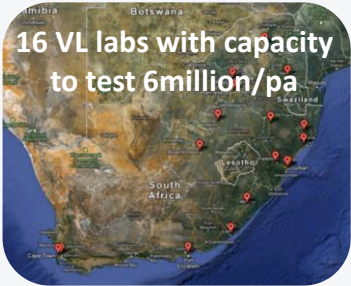
Special ECHO Session, 15 March 2022



COVID-19 Context in South Africa

National Health Laboratory Service (NHLS) has a network of 265 laboratories across the country, serving 80% of SA Population (Public Sector)

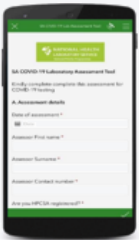
Capacity for COVID 19 Testing



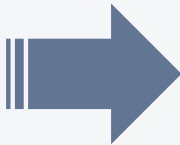
Testing access: PCR & RDT

60
Mobile
Laboratories
(GXP & RDT)

Ag-RDT
Testing sites



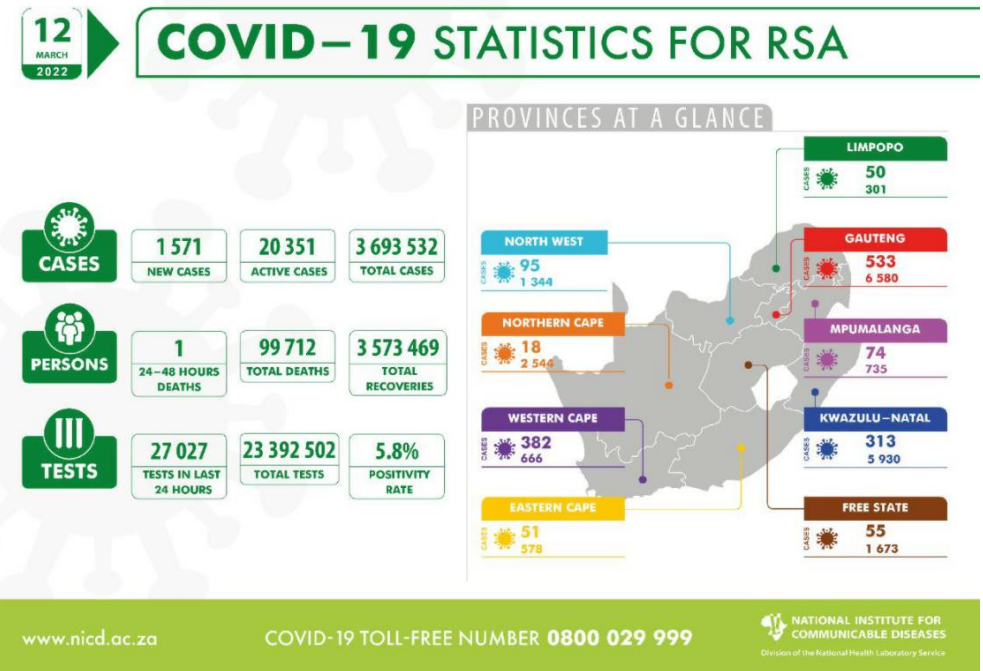
UTILISING DIGITAL
HEALTH – RAPID
ASSESSMENT
TOOL



11 Academic, 29 private and 9 tertiary laboratories

COVID 19 National Statistics

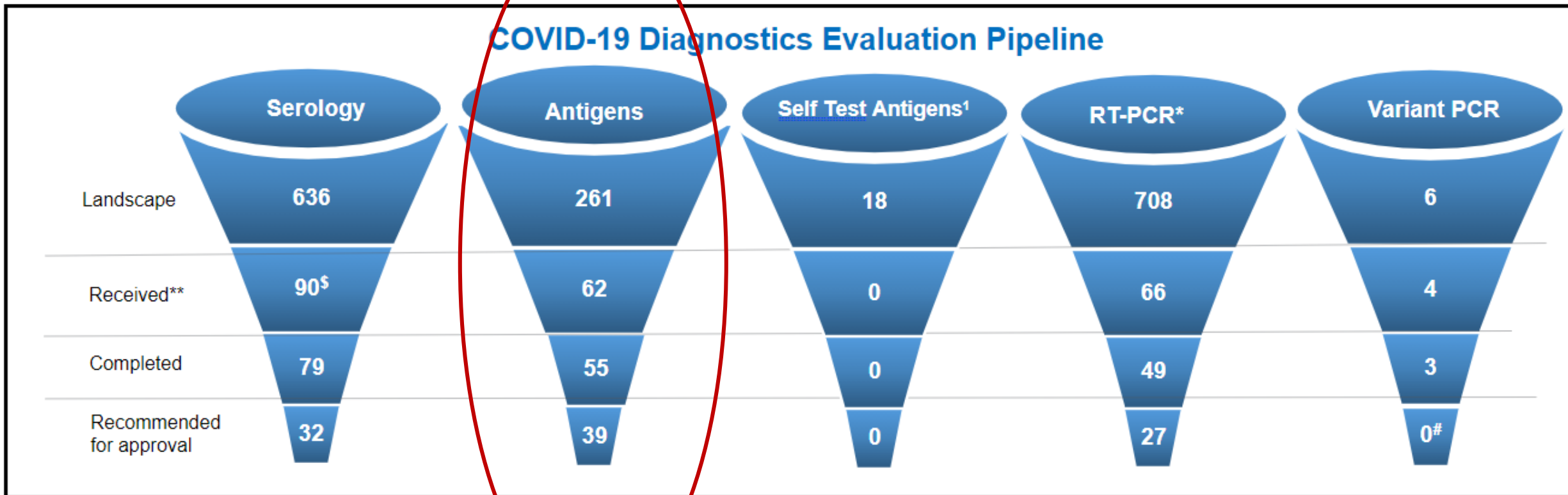
	Tests conducted	23 392 502
	Positive cases identified	3 693 532
	Total recoveries	3 573 469
	Total deaths	99 712
	New cases	1 571
	Active cases	20 351



As of 12 March 2022

www.nicd.ac.za

COVID-19 Pipeline (29 October 2021)



*Includes: Closed systems, PCR Kits, Lysis to PCR kits, front-end extractions/lysis/heating methods. **Includes "on hold", "no supplier feedback", "not feasible".

[§]Includes ELISA neutralisation assays. [#]Only two of these have been requested through SAHPRA (novel work stream). ¹ Only FDA approved



With compliments Prof Lesley Scott and R&D team

Antigen evaluation pipeline: South African (as of January 2022)

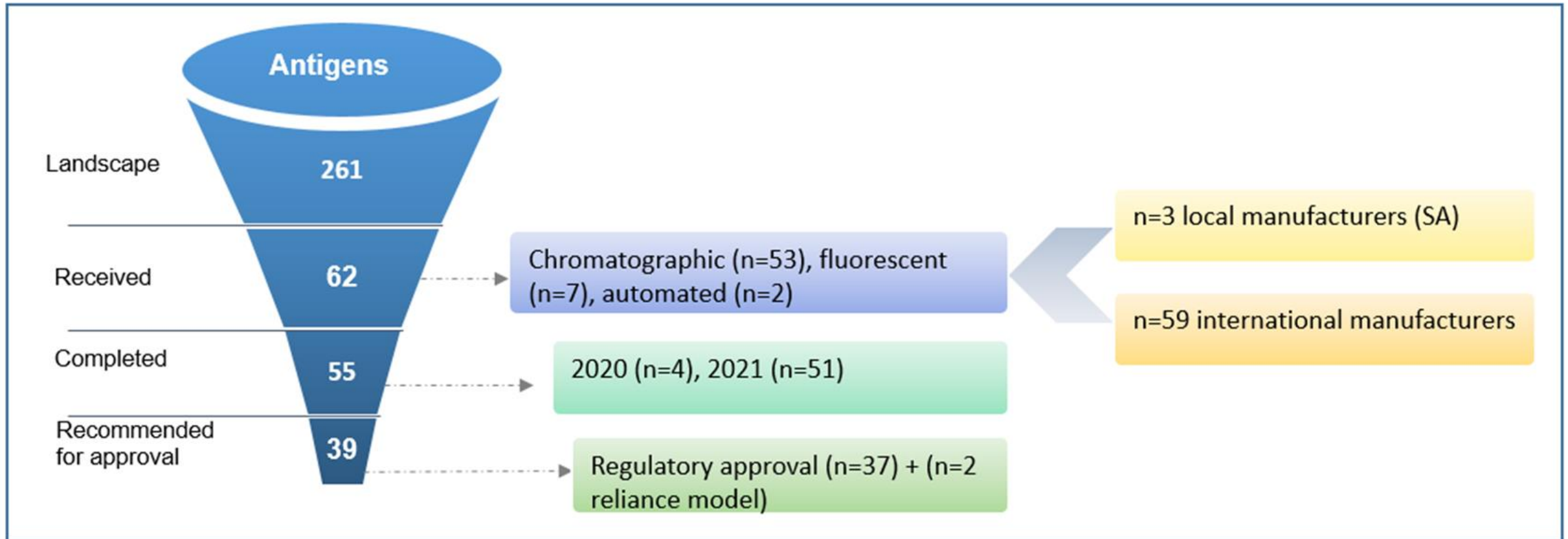
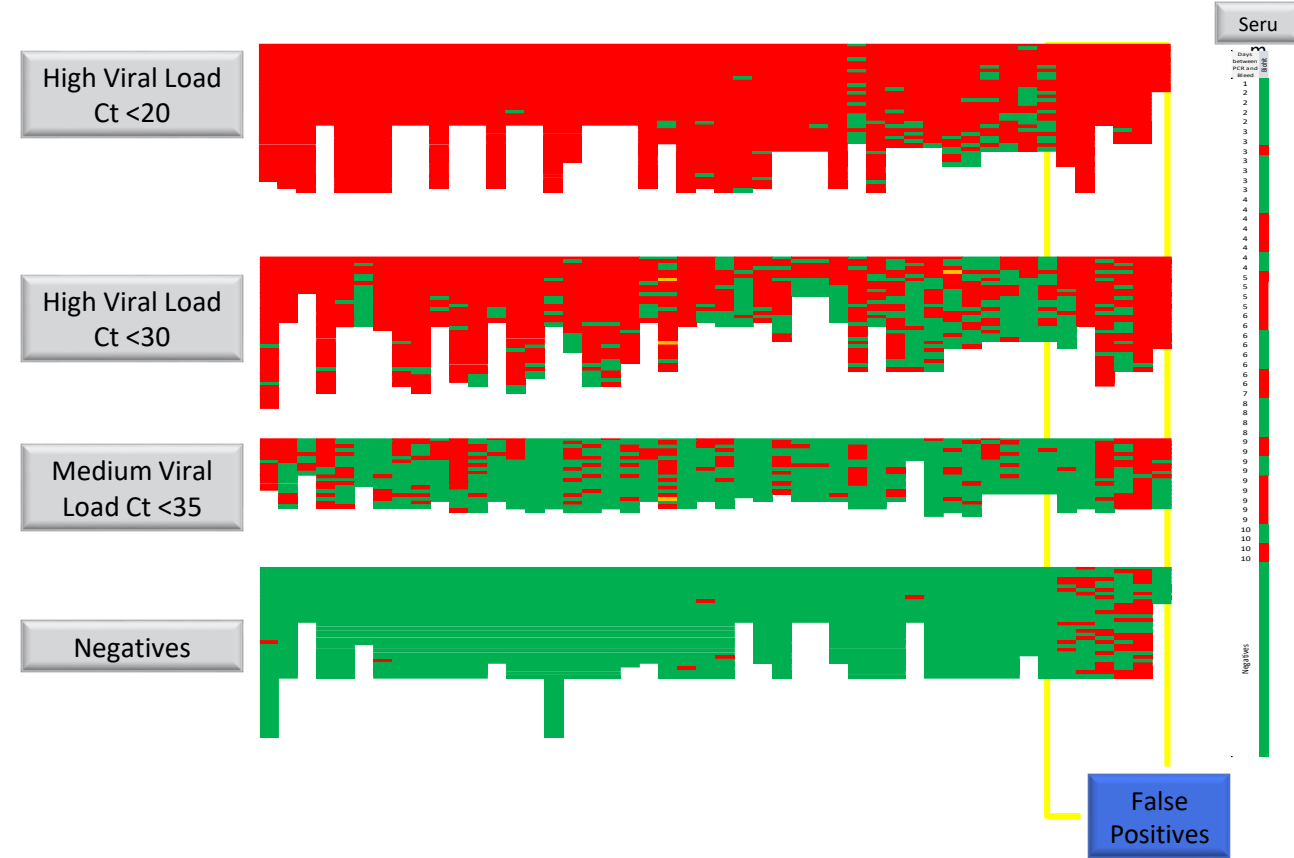
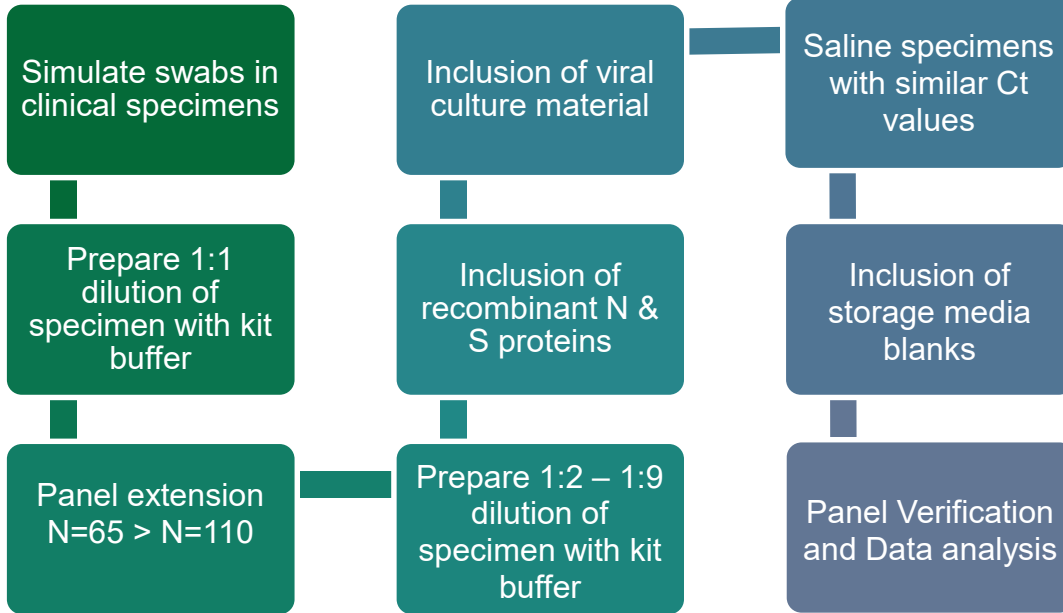


Figure 1a SARS-CoV-2 diagnostic evaluation pipeline for rapid antigen tests as of January 2022

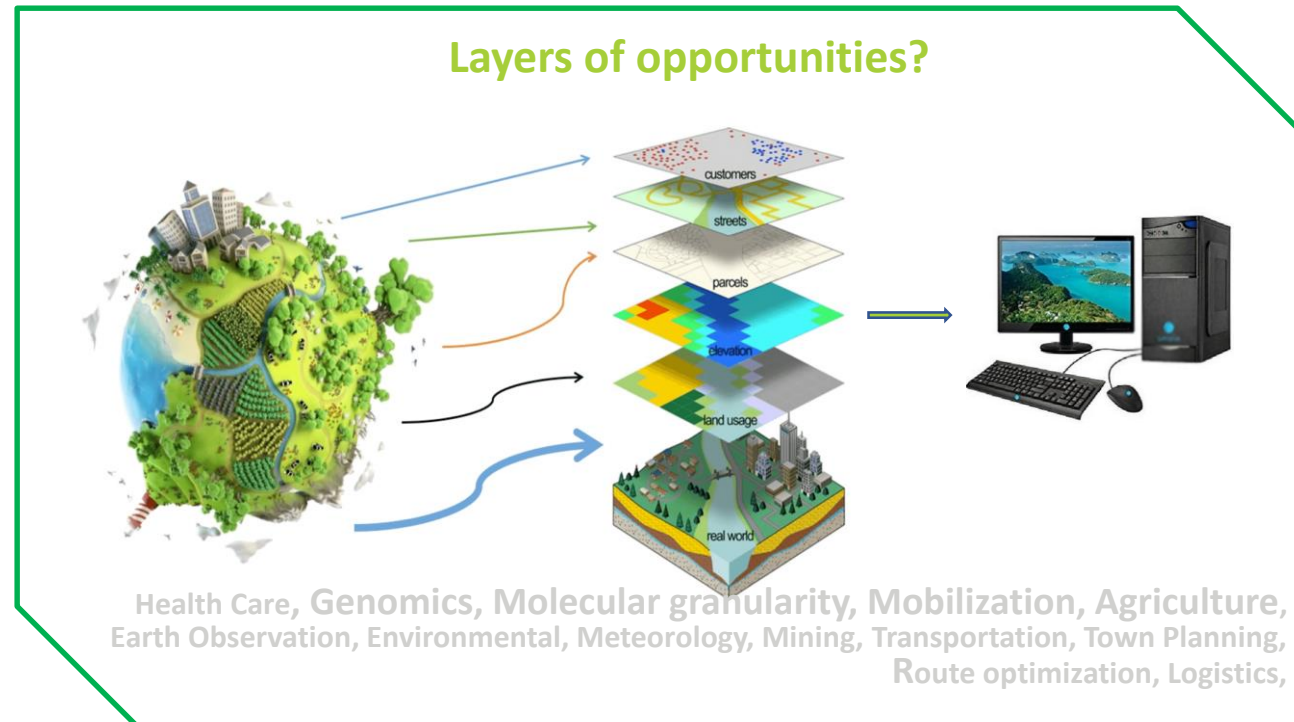
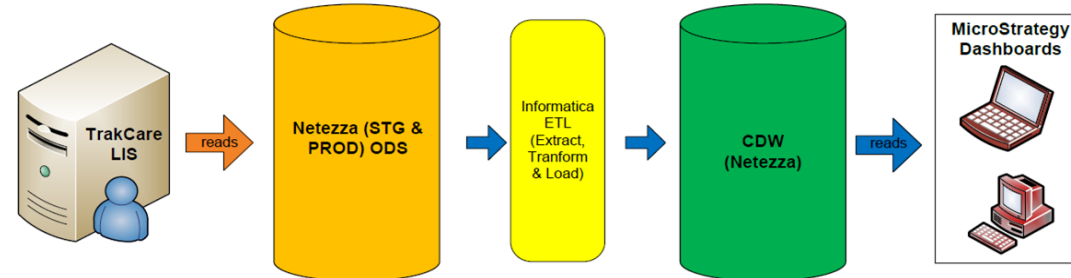
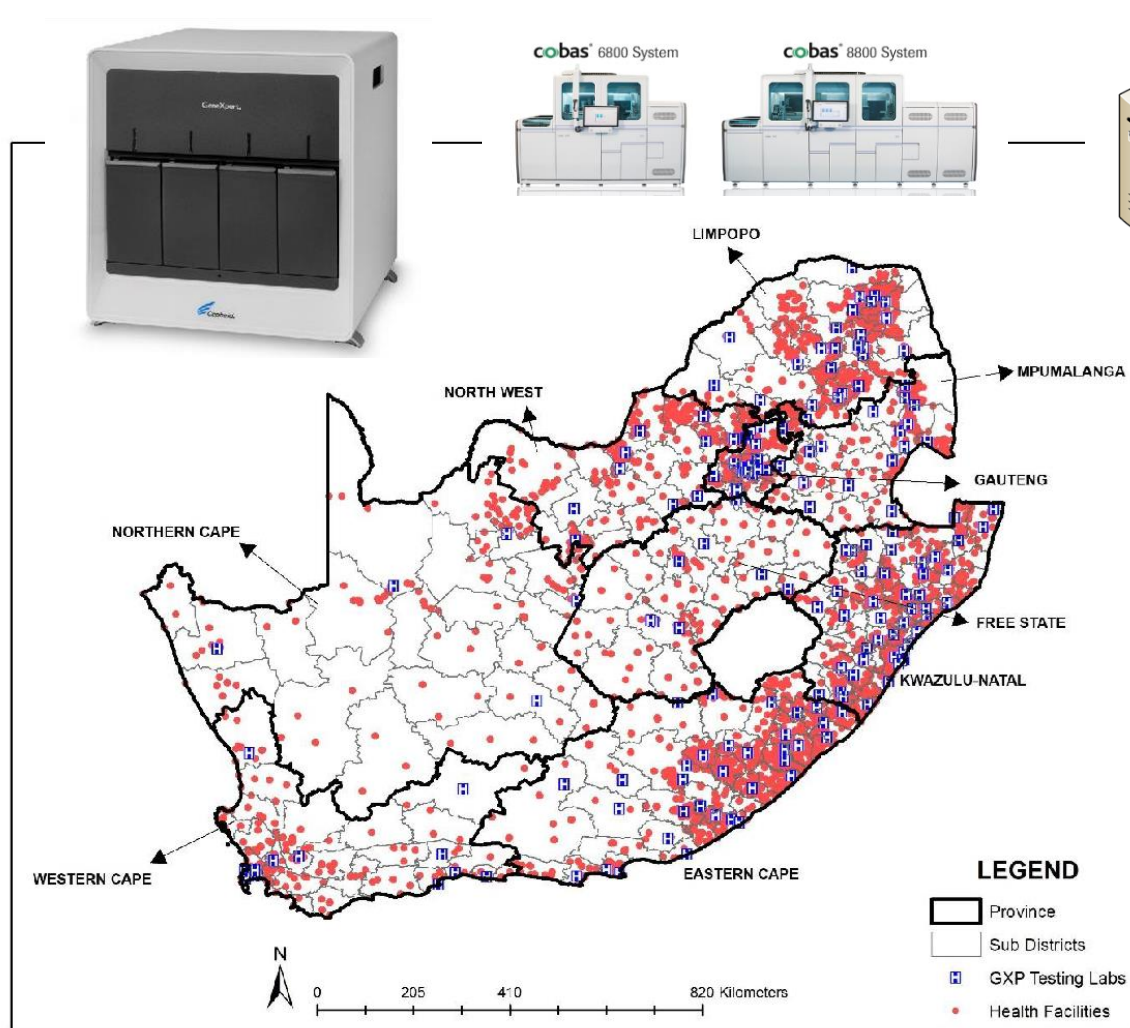
SARS-CoV-2 antigen diagnostics

Evaluating out of scope: *Laboratory versus clinical*



Data sharing and feedback loops are critical

South Africa's NHLS single LIS successfully provides central data, but requires horizontal access for **surveillance**, **operations** and **logistics**



Health Care, Genomics, Molecular granularity, Mobilization, Agriculture, Earth Observation, Environmental, Meteorology, Mining, Transportation, Town Planning, Route optimization, Logistics,

ASLM Antigen Testing Training Programme Overview

SARS-COV-2 antigen **rapid diagnostic tests** are an alternative option for diagnosing active infection through detection of viral proteins. Rapid antigen tests revolutionize the response to COVID-19 by providing **accurate test results in 10 to 20 minutes** instead 24 hours, allowing tests to be performed at **point of care (POC)** and dramatically lowering the price of the tests.

Objective

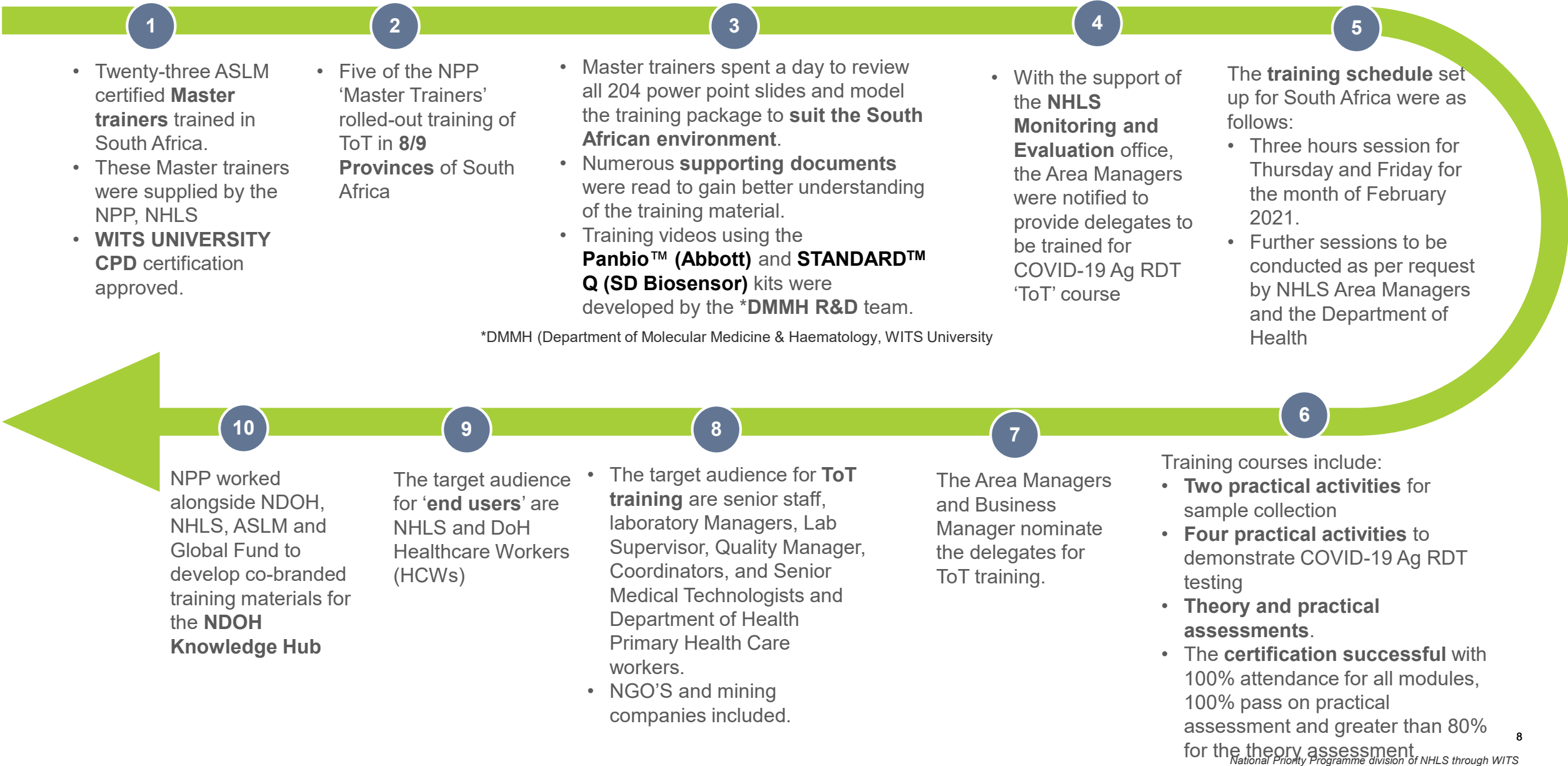
Proper training on the safe use and implementation of antigen tests are vital to ensuring quality testing. A comprehensive training package around safety, sample collection, testing, reporting and management of the COVID-19 antigen RDT tests are packaged to ensure standardization in the African continent as per WHO guidelines.

<p>Engaging Training</p> <p>Facilitate engaging training sessions that equip End Users (lab techs, HCWs, etc.) to successfully conduct COVID-19 Antigen testing at local facilities</p>	<p>Best Practices</p> <p>Convey theoretical best practices for COVID-19 Antigen testing, using the South African specific testing algorithm</p>	<p>Practical Exercises</p> <p>Offer practice exercises in a safe environment including videos on practical activities.</p>
<p>Competency Assessment</p> <p>Prepare participants for Competency Assessment (proficiency testing) at the end of workshop and award WITS CPD points on successful completion of assessments.</p>	<p>Review protocols</p> <p>Review helpful ongoing protocols provided by WHO, ASLM and the NHLS.</p>	<p>COVID-19 Precautions</p> <p>Introduce COVID-19 precautions and process-changes .</p>

SARS-COV-2 Ag Testing Training Strategy

- 1 **ASLM >> Master Trainers**
ASLM to train COVID-19 Ag RDT Master trainers in South Africa
- 2 **Master Trainers >> Trainer-of-Trainers (ToT)**
The Master Trainers to train 'Trainer of Trainers' (ToT) in all Provinces in South Africa
- 3 **Trainer-of-Trainers (ToT) >> End users (NHLS & DoH)**
The ToT in turn to train 'end users' within the NHLS and the Department of Health
- 4 **Training Certification and CPD points**
All training to be ASLM certified so that proper order is maintained and monitored
- 5 **Supervision Visits**
Supervision visits to be conducted for 'end user' training so that the quality for COVID-19 Ag RDT testing is maintained

Preliminary Preparation Process for ASLM/NDOH/NHLS training: January – December 2021



1

- Twenty-three ASLM certified **Master trainers** trained in South Africa.
- These Master trainers were supplied by the NPP, NHLS
- **WITS UNIVERSITY CPD** certification approved.

2

- Five of the NPP 'Master Trainers' rolled-out training of ToT in **8/9 Provinces** of South Africa

3

- Master trainers spent a day to review all 204 power point slides and model the training package to **suit the South African environment.**
- Numerous **supporting documents** were read to gain better understanding of the training material.
- Training videos using the **Panbio™ (Abbott)** and **STANDARD™ Q (SD Biosensor)** kits were developed by the ***DMMH R&D** team.

**DMMH (Department of Molecular Medicine & Haematology, WITS University)*

4

- With the support of the **NHLS Monitoring and Evaluation** office, the Area Managers were notified to provide delegates to be trained for COVID-19 Ag RDT 'ToT' course

5

The **training schedule** set up for South Africa were as follows:

- Three hours session for Thursday and Friday for the month of February 2021.
- Further sessions to be conducted as per request by NHLS Area Managers and the Department of Health

10

NPP worked alongside NDOH, NHLS, ASLM and Global Fund to develop co-branded training materials for the **NDOH Knowledge Hub**

9

The target audience for '**end users**' are NHLS and DoH Healthcare Workers (HCWs)

8

- The target audience for **ToT training** are senior staff, laboratory Managers, Lab Supervisor, Quality Manager, Coordinators, and Senior Medical Technologists and Department of Health Primary Health Care workers.
- NGO'S and mining companies included.

7

The Area Managers and Business Manager nominate the delegates for ToT training.

6

Training courses include:

- **Two practical activities** for sample collection
- **Four practical activities** to demonstrate COVID-19 Ag RDT testing
- **Theory and practical assessments.**
- The **certification successful** with 100% attendance for all modules, 100% pass on practical assessment and greater than 80% for the **theory assessment**

Meet the team

NATIONAL PRIORITY PROGRAMMES, NHLS MASTER TRAINERS

NHLS OUT & ABOUT

NATIONAL HEALTH
LABORATORY SERVICE

ISSUE: JANUARY - MARCH 2021

LABRAP Newsletter



Abel Makuraj
Lead Trainer

NATIONAL HEALTH
LABORATORY SERVICE

ASLM COVID-19 Antigen RDT training programme conducted by NHLS



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Lynsey Stewart-Isherwood



Olwethu Mahachi



Mbuti Radebe



Somayya Sarang



Puleng Marokane



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Antigen Testing Training Stats from NPP Master trainers

February to September 2021

23

“Master Trainers”

527

“Train-of-Trainer” attendance

279

“Train-of-Trainer” certified



366

“End-User” attendance

335

“End-User” certified



1,500

Healthcare Workers

- **December 2021:** To address the 4th wave, a further 1,500 HCWs were trained online (hosted by NDOH Knowledge Hub). NDOH/NHLS/ASLM (co-branded materials).
- **February 2022:** NHLS/CHAI currently training HCWs at Tertiary Education sites.
- NHLS continue to train, leveraging on the 279 certified ToTs.

Expansion of Antigen Testing

MOBILE LABORATORIES EXPAND AG-TESTING INTO COMMUNITIES AND BORDERS



NHLS Mobile Laboratory

All mobile laboratories have **full connectivity**

Mobile staffing: Driver-clerk and two nurses per van. Mobiles with PCR testing also have a technologist.



Sample collection station 1



Generator

Mobile Laboratories	Volume
MOBILE LABS EASTERN CAPE	50717
MOBILE LABS FREE STATE	43249
MOBILE LABS GAUTENG	424433
MOBILE LABS KWA-ZULU NATAL	107641
MOBILE LABS LIMPOPO	31711
MOBILE LABS MPUMALANGA	46248
MOBILE LABS NORTH WEST	8851
MOBILE LABS NORTHERN CAPE	41981
MOBILE LABS WESTERN CAPE	119735
Grand Total	874566



Sample collection station 2



LIS Registration Station



Antigen Testing – SD Biosensor and Panbio

Testing locations:

- Fixed facilities (labs and clinics)
- Mobile (communities and borders)

Data capture tools:

- TrakCare (NHLS testers)
- CSA (e.g. Mobile Labs, DoH & Tertiary Education testers)

NHLS (Fixed):
1,839,247

CSA:
290,208

Mobile Labs:
874,566

TOTAL: 3,004,021

22 October 2020 to 7 March 2022

<https://csa.nhls.ac.za>

Data provided by: CDW and CSA, NHLS

Data analysis: Silence Ndlovu, Graeme Dor, Floyd Olsen (NPP & DMMH)

Tertiary Institutions (CHAI Project)

Increased access to training and testing to support tertiary education facilities in South Africa

Duration of project: 1 February to 31 March 2022. Progress to date:

**HCWs trained:
106 (target 191)**

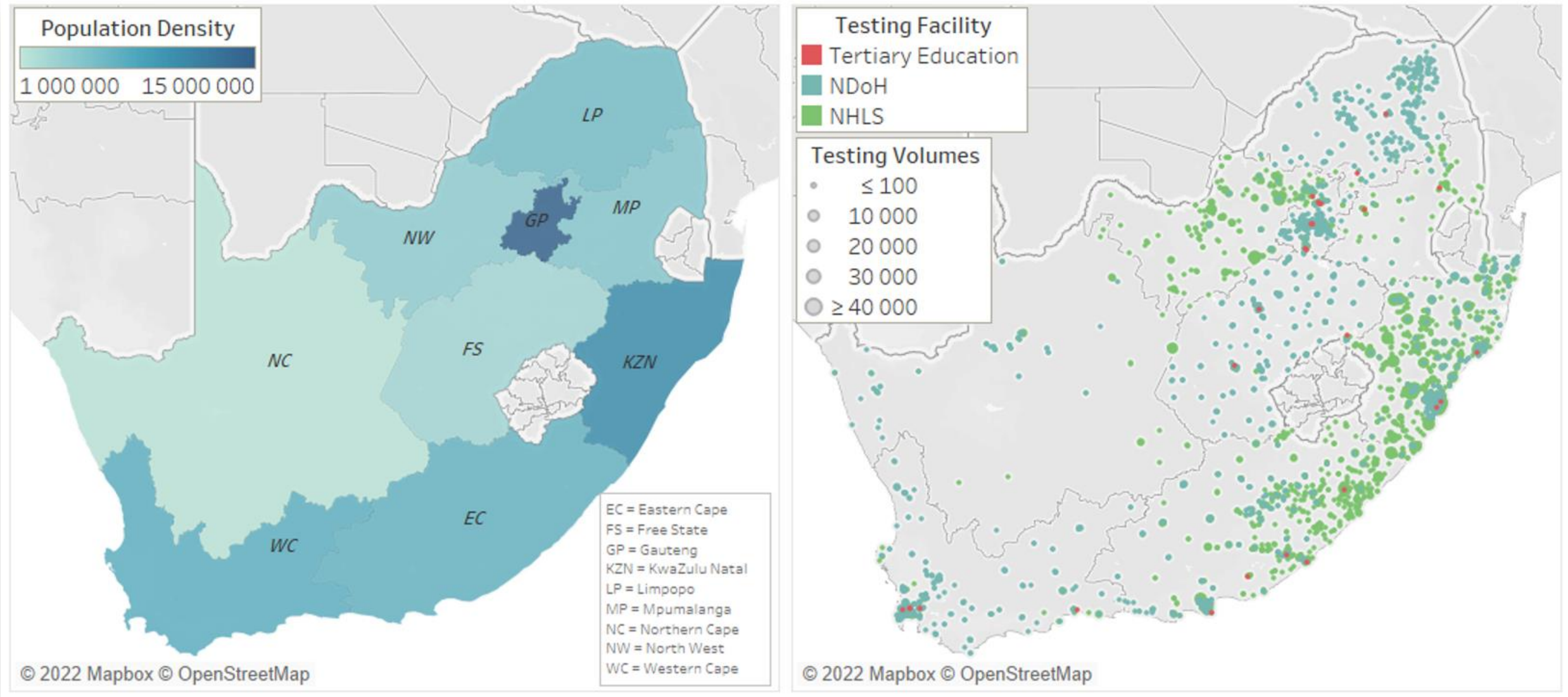
**# of sites:
19 (target 29)**

**# of tests:
195 (6 sites)**

- **CHAI South Africa** has been awarded a grant by **IRD to support the country in fighting the Covid-19 pandemic**, specifically for the introduction and strengthening of new testing technologies as well as scaling up of these testing innovations.
- The **focus of this grant** was to **expand the use of antigen testing**, with **the priority being non-health contexts**. During prior peaks, there were **multiple outbreaks at tertiary institutions**, and given the availability of campus health centers this was an ideal area to focus on. This also tied in well with the **mandatory vaccination policy** which requires weekly testing for all exempt students.
- In collaboration with the National Health Laboratory Service

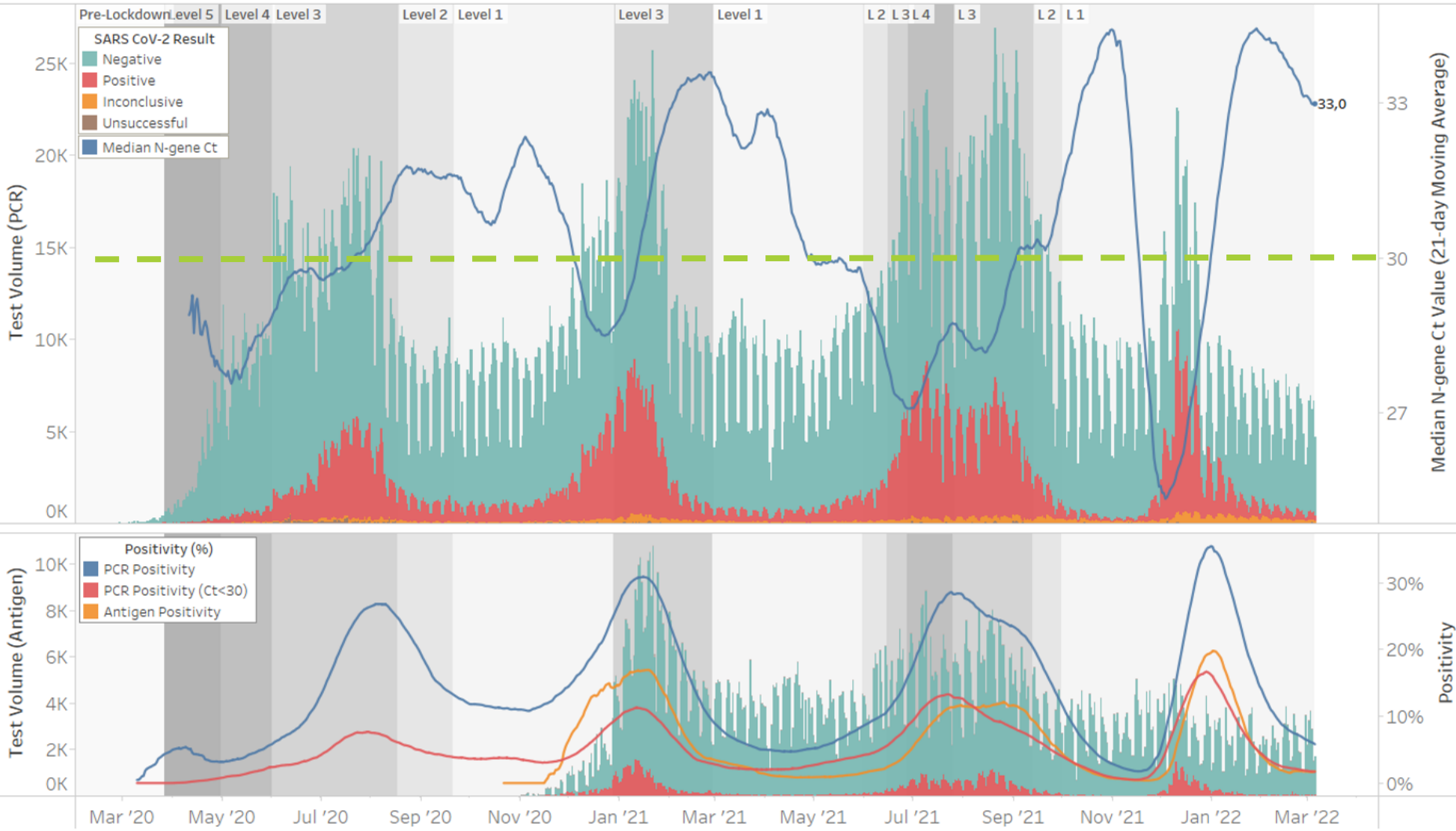
Distribution of C-19 Ag-RDT testing in South Africa

NDoH, NHLS and Tertiary Education sites supporting C-19 Ag-RDT testing sites: 22 October 2020 to 7 March 2022



Testing volumes, positivity rate and Ct values

Comparing the PCR and antigen testing volumes and positive rates, across the lockdown levels from March 2020 to March 2022



For the South African setting, antigen tests are most optimal at Ct<30 (i.e. performance acceptance criteria)

- Ct 30 = High VL
- Ct 30-35 = Medium to Low VL
- Antigen tests are valuable:
 - During waves to increase access to testing
 - Between waves, for disease surveillance
 - Beyond urban settings

Training implementation in collaboration with the NHLS Area and Business Managers

509 instruments



Training in South Africa commences: 15 March 2022

Watch this space!



LumiraDx: Training approach

LMDX approach to training

- Create training materials that are easy to use and universally understandable in Africa (French, Portuguese, English)
- Develop video content with easy to follow instructions
- Certify users through quiz materials relevant to content
- Build on the Train the trainer (ToT) model
- Integrated the training into the Africa CDC training for COVID-19 diagnosis

Innovation lies in the use of the LumiraDx online learning management system

- Online platform accessible via web browser or downloadable App
- Content is available once a user is registered and enrolled into a course
- Blended or online learning environment where user can self-certify after working through their content: blended end-users training documents can be loaded on the system and be accessible for further follow up
- Users have “lifetime” access to course content and can recertify or have training modules added as more content becomes available
- Latest content is always available
- Ability to manage and trace all training with easy access to users/trainee progress report
- Comprehensive Reporting
- ToT's outside of LumiraDx can utilise the platform
- 2015 ToT's registered and trained in Africa using the platform

Our key lessons learned

SHARING OUR KEY LESSONS LEARNT IN SOUTH AFRICA

Overall:

- Elect a training **champion** for each district (i.e. are NHLS Area and Business Managers were involved)
- NHLS Laboratory Managers are our champions
- Cadre for an ideal training team:
 - **Phlebotomist/Healthcare worker** (collects the sample)
 - **Medical Technologist** (conducts the test)
- Strong collaboration between **clinical and laboratory** staff
- Strong collaboration between provincial **department of health and NHLS**
- Additional training input/support from **Specialists** (e.g. Pathologist to present on epidemiology)
- **Lack of centralised data** collection tools (training specific data)
- Training should transcend across **both public and private health**

(**Mr. Igsaan Noordien**, Regional Programme Coordinator (HIV/TB), NHLS, Western Cape):

- More **emphasis on QC** is needed
- **In-person training** is the most optimal
- During practical sessions, **trainees are often nervous**
- Although trainees are used to working with POC test, **organised and tidy workspaces still need to be elaborated** on
- PPE for swabbing is **common knowledge** now
- Western/Northern Cape (NHLS) developed **own training videos** and were valuable to trainees
- A **detailed worksheet** was developed
- The **CSA portal** also needs to be shown “live” using a fictitious patients, for trainees to truly understand. The instruction manual does help but trainees need to do it themselves.

(**Mr. Pakiso Letanta**, Business Manager: Universitas Academic Business Unit Bloemfontein, NHLS, Free State):

- “Nothing beats teamwork!”

Conclusion and Recommendations

- NHLS Area Managers, Business Managers and laboratory managers support the COVID-19 Ag RDT end-user training in their districts for laboratories and the Department of Health.
- A **centralised mechanism** to collect **training specific data** needs to be developed in collaboration with Ministry of Health and the National Health Laboratory Service.
- There is a need to ensure that **COVID-19 Ag RDT testing training is carried out in a standardised manner** in South Africa and globally.
- There is growing interest for the use of the COVID-19 Screening App (CSA) developed by the NHLS IT department where COVID-19 patients data and results are to be captured. The results are linked to the NHLS CDW so that managements reports can be generated per facility.
- A **detailed and standardised testing worksheet** (with all CSA requirements) is needed at all testing sites
- Trainees and tester often need to be reminded to check the **sample type** that is required (to refer to the package insert).
- Communication to key stakeholders for the **introduction of new kits into a region/country**, needs to be strengthened

Acknowledgements

- National Department of Health (*Dr Norbert Ndjeka, Victor Manyokho*)
- Provincial Departments of Health
- National Health Laboratory Service (*Dr Kamy Chetty, Violet Gabashane*)
- NHLS Area Managers
- NHLS Business Managers
- NHLS Laboratory Managers
- NHLS Pathologists
- Global Fund (*Nomvuyiseko Maduna*)
- ASLM Learning Academy
- National Priority Programmes (NPP), NHLS
- Anglo Coal Highveld Hospital (*Dr Alina Riba*)
- De Beers Group (*Channel Mulligan*)
- Anglo American (*Laura Sawyer*)
- DMMH, Faculty of Health Sciences, University of the Witwatersrand (*Wendy Stevens, Lesley Scott, Vidya Keshav, Anura David, Graeme Dor, Silence Ndlovu, Floyd Olsen and partners providing reference materials for evaluations*)
- Bill & Melinda Gates Foundation
- iLEAD (Innovations for Laboratory Engineered Accelerated Diagnostics)
- SAHPRA



Practical demonstrating on COVID-19 Ag RDT testing by Ms Dimpho Mashego

Venue: Brakpan Civic centre. **Collaborators:** NDoH, NHLS