Presentation to the PPC on Minerals and Energy

Covid-19 Response Progress

21 August 2020

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Outline

- Mintek's response to Covid-19
- Sanitizer production
- Development of Covid-19 rapid test kits
- Development of antigens and antibodies
- Summary

Mintek response to COVID-19 Pandemic

- Since COVID-19 was declared a global pandemic, **Mintek has repurposed its programs and facilities to contribute to the national COVID-19 response.** We have:
  - **Developed capacity** to produce 4 000 litres of **hand** and **surface sanitiser** per week, which we currently distribute to our employees and the DMRE.
    - We are busy with **massification of production** to commercially supply the market.
  - **Redirected** the point of care diagnostics research programme to develop **rapid test kits** for COVID-19.
  - Currently working to **develop capacity** to **produce antigens** and **antibodies** that are an essential ingredient of test kits.
    - **There is a need to build capacity to produce these in the country.**
  - All of these initiatives will not only benefit the country in the short term, but will also contribute to **stimulating the economy** and **creating jobs** in the biomedical/health field in particular.

Sanitizer Production

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Business case

- The **Covid-19 pandemic** has highlighted the **need for sanitizing products.**
- South African Public Health sector uses in excess of **100 000 liters per day**.
- Significant issues have been identified with the **quality of sanitizers** produced in South Africa.
- In many cases the alcohol content is well **below the 70%** required.

- Mintek identified the **need** / **opportunity** to produce **good quality sanitizing products**

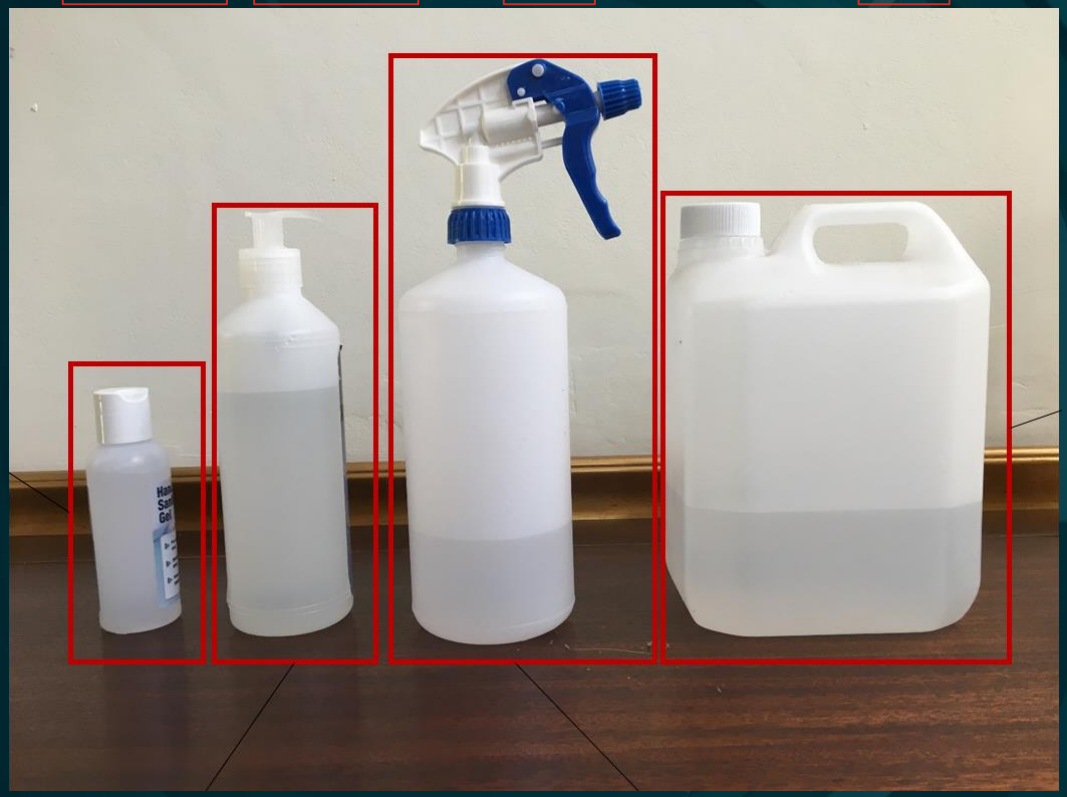
- In order to manage the costs and fully control the opportunity, a **semi-automated bottling facility** has been procured. This is the most versatile option for the future.

- We are starting small but have already produced in **excess of 10 000 liters**.

Product line

- A **range of sanitizer products conforming to WHO formulations** have been developed, including:
  - Hand sanitizer
  - Surface sanitizer
  - Hand sanitizer gel
- These were initially produced **in Mintek's facilities.**
- **Massification commenced in partnership with Ascendis Health,** for commercial bottling.
- **A commercial bottling plant** has been ordered and is being installed at Mintek – due date early October 2020.

Product range



- Products are supplied in 100mL, 500 mL, 1L, 5L and 25L bottles

Total production at Mintek to date:

- Hand sanitiser - 9 000L
- Surface Sanitiser - 1 500L
- Gel hand sanitiser - 380L

Current manual production at Mintek: repurposed infrastructure

- Current production rate at Mintek is **700** x 500ml bottles per 8 hour shift
- Staff = **1** x Supervisor and **10** x operators

- Maximum production is therefore (3 x 8 hour shifts):
  - 2100 bottles per day or 1050L per day

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Challenges with the current manual operation

- Low production rate → high conversion costs
- Lack of consistent filling volume → low quality
- Poor labelling accuracy → low quality
- High unit cost → poor market competitiveness
- SAHPRA1 accreditation not possible → GMP2 non-compliant
- Restricted market

Manufactured products

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Bottling at a commercial facility






Ascendis HEALTH

Production of commercial scale quantities bottled at Ascendis Health at no cost to Mintek.

PetroSA supplied ethanol at a favourable price.

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Require a dedicated production facility

THE NEED: Require SAHPRA1 accreditation and GMP2 compliant facility

Require an **automated manufacturing** and **bottling facility** to be competitive in the market

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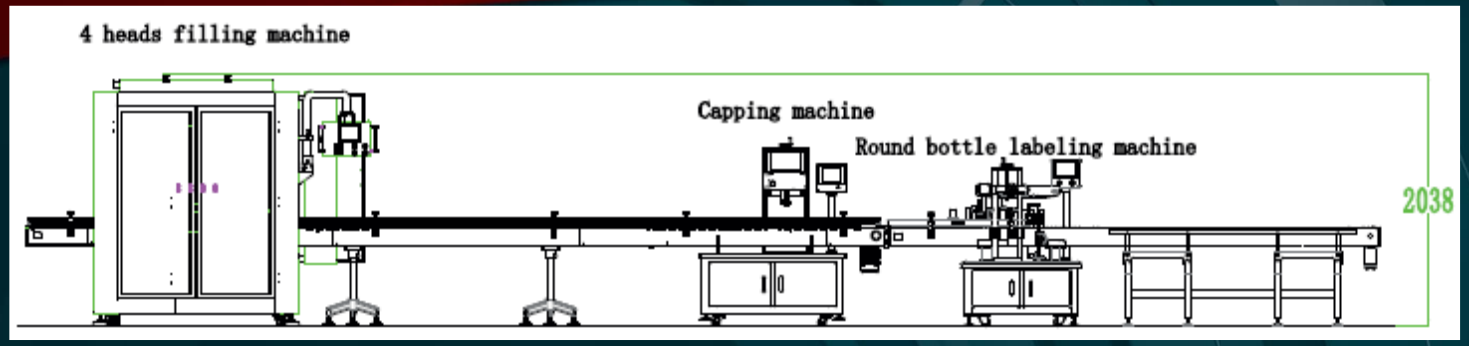
Planned production facility at Mintek



Facility prepared and ready to accommodate the new manufacturing and bottling plant

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Some of the new equipment to be installed at Mintek

Inpakt factory

Capper

Bottler

Labeller

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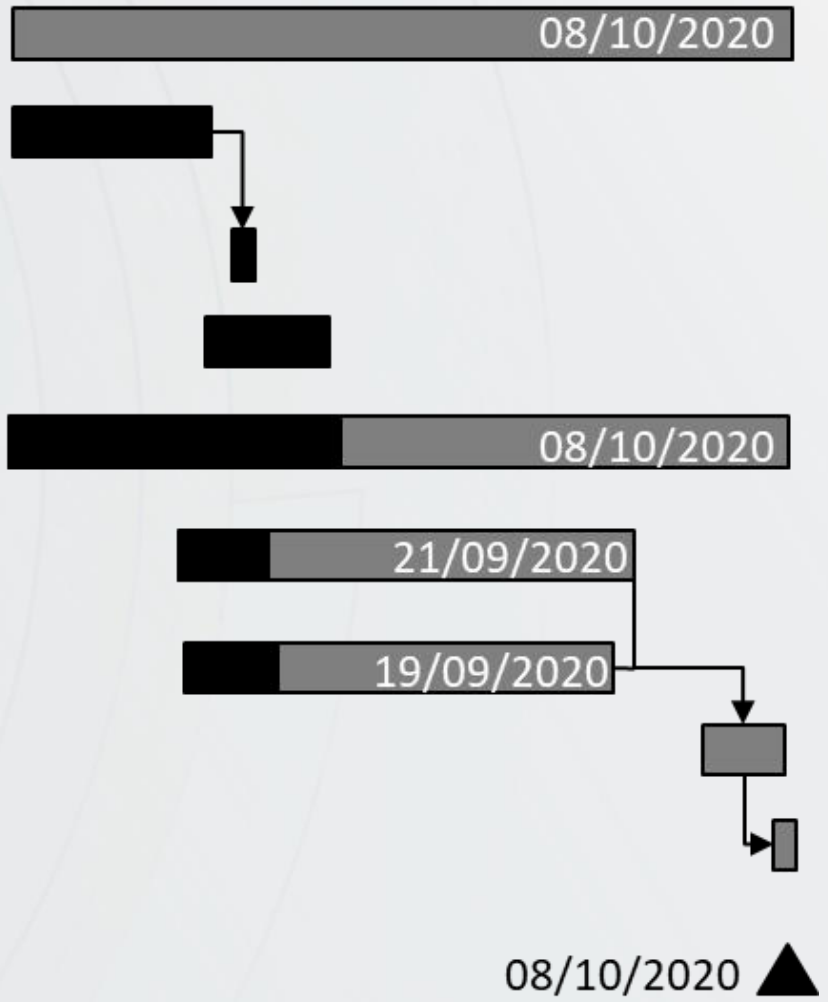
Progress on the upgrade of the production facility at Mintek

ID	Task Mode	Task Name	Duration
1		**Establishment of a hand sanitiser production facility at Mintek**	**115 days**
2		**Proposal preparation and acceptance**	**33 days**
11		**Project Charter**	**2 days**
13		**Place order for bottling plant**	**10 days**
16		**HMD: project management and execution**	**22 days**
21		**EMS: project execution**	**33 days**
44		**External contractors**	**32 days**
48		**Plant commissioning**	**5 days**
54		**Capacity demonstration**	**1 day**
55		Installed plant demonstrated	1 day



Production facility will be operational by **8 October 2020**

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Development of Rapid Test Kits

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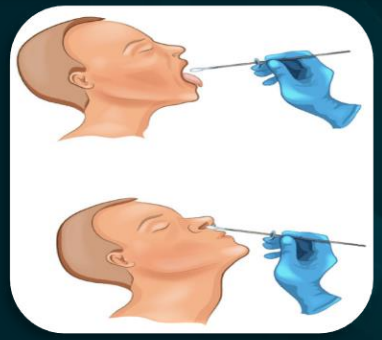
Two types of Covid-19 Rapid Tests developed

- **Antibody tests:** that detect SARS-Cov-2 Antibodies (**body's response to the virus**) from finger-prick blood – Shows people who have been infected:

RESULTS IN 15 MIN

- **Antigen tests**: that **detect part of the virus** (antigen) from a swab taken from nasal or oral swab Shows people who are infected:



RESULTS IN 15 MIN

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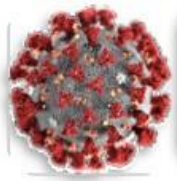
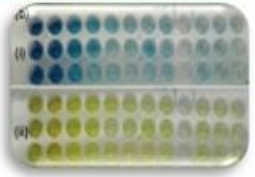
Covid-19 Rapid Test development roadmap

Research & Development Phase					Pre-clinical/ Clinical Phase	Regulatory Phase	Commercial Phase	
TRL 1 & 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 8	TRL 9
Biomarkers & Material Development Ethics Approval	Assay Development	Internal Evaluation	Internal Clinical Evaluation	Pilot Production	External Evaluations	Registration	Manufacturing	Sales & Distribution



- Research Ethics Approval
- Biomarkers



- Biomarker validations
- ELISA testing

- Testing on Lab samples

- Testing on Clinical samples

- Small scale production
- Lab testing

- Independent Clinical evaluations

- NHLS Verification
- SAHPRA Registration

- Large scale production

- Industry Partners

Covid-19 Antibody Test

Covid-19 Antigen Test

Work underway

External Evaluations

SAHPRA Registration

Manufacturing

Supply

September- October 2020

November 2020

December 2020

December 2020

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Highlights on Test Kits development

- Manufacturing facility received **ISO 13485 Certification** in June 2020
- **Mintek's Quality Management System** is deemed **safe** and **effective** for **manufacturing of medical devices**.

- Holder of **SAHPRA's Manufacturing License** for HIV and Malaria Tests
- Application for Covid-19 Manufacturing license from SAHPRA will follow suite.

- **Awarded** an MRC/ TIA/DSI **Funding** in May 2020 for development of local test kits and reagents for COVID-19.

- **In-house screening** via PCR test - currently being accredited.
- Number of **tests conducted - 1259** and **in-house screening** for Covid symptoms - **27 051**.

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Lloyd's Register

Current issue date: 5 July 2020
Expiry date: 4 July 2023
Certificate identity number: 10277480

Original approval(s):
ISO 13485 - 5 July 2020

Certificate of Approval

This is to certify that the Management System of:

Mintek Advanced Materials.

200 Malibongwe Drive Randburg, Johannesburg, Gauteng, South Africa

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00026042

The scope of this approval is applicable to:

Development and manufacturing of In-Vitro diagnostics kits

Luis Cunha

Area Operations Manager - SAMEA

Issued by: Lloyd's Register Quality Assurance (Shanghai) Co., Ltd.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS 001

CERTIFIED ISO 13485

CERTIFIED ISO 13485

UKAS MANAGEMENT SYSTEMS 001

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Collaborative partners

Product Development:

UNISA | university of south africa

Clinical samples Supply:

SANBS South African National Blood Service

External clinical validations:

NATIONAL HEALTH LABORATORY SERVICE

SAHPRA SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

University of Cape Town • iYunivesithi yaseKapa • Universiteit van Kaapstad

Covid-19 Funding for local manufacturing:

saMRC advancinglife

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science & innovation
Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA

technology innovation AGENCY

Steering Committee for Business Development:

the dtic
Department:
Trade, Industry and Competition
REPUBLIC OF SOUTH AFRICA

BSA BUSINESS FOR SA | COVID-19

IDC
Industrial Development Corporation
Your partner in development finance

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Development of Antigens and Antibodies

Product line

- **Antigens** and **antibodies** are the **active ingredients** in many diagnostic tests, vaccines and drugs.
  - **Antigens** are among the components for vaccines (therapeutic) and is also used in diagnostics.
  - **Antibodies** are used in diagnostics and as therapeutics/drugs
- **Antigens** and **antibodies** are currently applied to COVID-19, but applicable to most communicable diseases, e.g. flu.
- There is currently **very limited capacity** to produce outside the USA, Europe and China.
- **Access** to **antigens** and **antibodies** has significantly **hampered the developmen**t of **tests** and **vaccines for COVID-19**.
- **Mintek** is developing capacity to **produce locally.**

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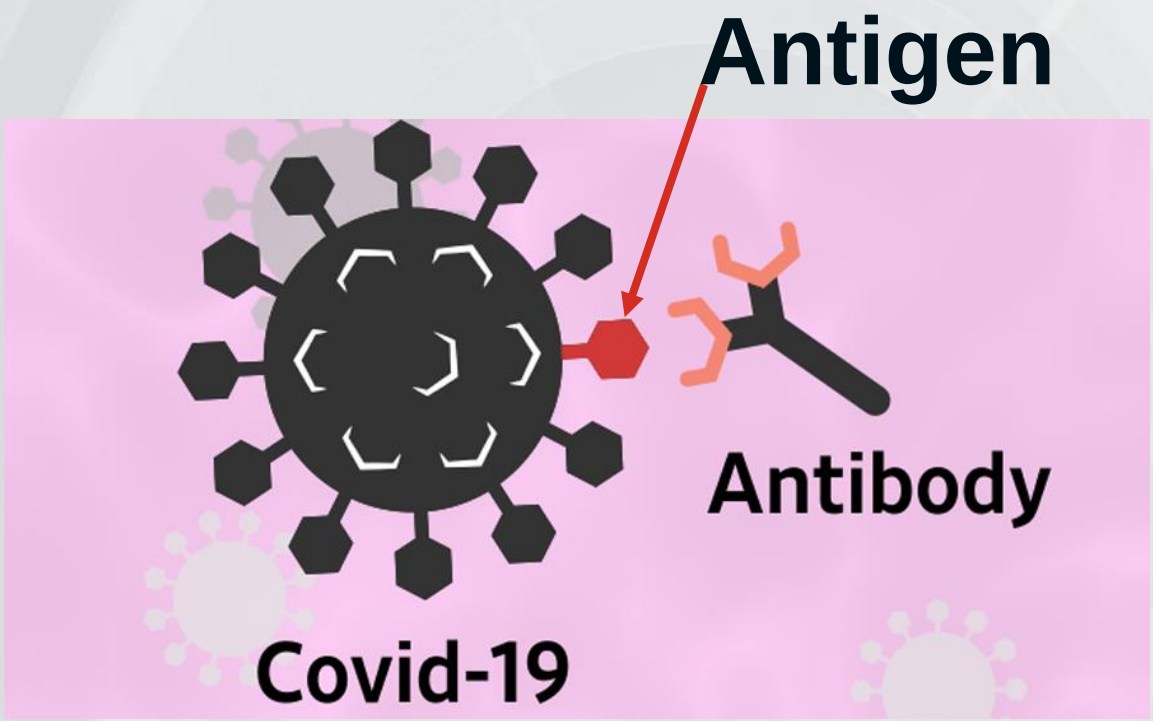
How it works



- **Antibodies** attach to the **virus**
- **Antigens** attach to an **antibody**

The **antigen** or **antibod**y is then **conjugated** to an active molecule for use as a

- **diagnostic test** or
- to **fool** the **body** into believing it is infected with Covid-19 so that the body produces natural antibodies ➡ vaccine

Progress

- Currently **three Covid-19 antibody sequences** have been **identified** and **isolated**.
- **Two** of these have been shown to be **active**.
- These have been cultured using first bacterial cells and then mammalian cells to **produce sufficient material** for further **testing** and **validation**.
- **Once validated**, **larger quantities** will be produced in a bioreactor.

Progress time-lines

Production of Antibodies from known SARS-CoV-2 sequences

- Finalizing current mammalian and bacterial expressions
- Validations of recombinant antibodies

September – October 2020

- Laboratory upscaling

November – December 2020

- Pilot bioreactor upscaling

January – May 2021

Antibody commercial product

Production of Antibodies from convalescent Covid-19 patients (novel)

- Ethics approval for Covid-19 patient blood sample collection

October 2020

- Collection of samples from consenting Mintek employees

November 2020

- B cell isolation, RNA purification and PCR

December – January 2021

- Contruction of Phage library and selection of best binders. Expression and purification of these constructs

February – May 2021

Novel Antibody ready for commercial development

Concluding Remarks

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Concluding remarks

- A **range of sanitizing products** has been developed consisting of **surface** and **hand sanitizer**, and **hand gels**. These are being produced in commercial quantities.
- A bottling facility is being **installed at Mintek** and will be **fully commissioned in early October 2020.**
- The development of **rapid test kits is progressing well**:
  - **Antibody tests** (to determine who was infected) are undergoing **external clinical evaluation**
  - **Antigen tests** (to determine who is infected) are currently entering **internal clinical evaluation**
- **Final approval** and **manufacturing** is expected in **December 2020**.
- **Antigen** and **antibody production** is **proceeding well**, currently **two suitable antibodies have been identified** and are **being produced** from bacterial and mammalian cells.
- The antibodies will then be **evaluated** in the **laboratory** before proceeding to **clinical evaluation**.

Thank You

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