CYTESPACE AFRICA LABORATORIES

MAKING A DIFFERENCE ONE SAMPLE AT A TIME

An independent and privately owned research pathology laboratory based in Pretoria, Gauteng, South Africa.

CONTACT US

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WHO WE ARE

Cytespace Africa Laboratories is a privately owned central and reference laboratory specializing in clinical trials in the international CRO industry.

- The only fully CAP accredited facility in South Africa.
- Based out of Pretoria, South Africa
- Established in 1999 as a central laboratory for Quintiles Transnational, largest Contract Research Organisation on the globe at the time.

Supporting a wide spectrum of clients including biopharmaceutical, medical device and diagnostics customers.

OUR SERVICES

The facility and processes are designed to ensure the safety of staff, participant samples, and the environment to help improve your probability of success in TB trials. Taking into account that the needs of your studies vary by protocol, we provide study-specific assay set up and development. By performing all TB assays, both phenotypic and genotypic, in the same location, we are able to reduce the amount of sample transport required.

A WIDE RANGE OF SCIENTIFIC METHODOLOGIES

- Automated Chemistry/ Urinalysis
- Haematology/Coagulation
- Flow Cytometry
- Immunology
- Microbiology
- Molecular testing including COVID-19 PCR
- Extensive Tuberculosis Capabilities

Cytespace Africa Laboratories where QUALITY is critical to success

TB KEY SERVICES

We work with clients to specifically setup assays aligned to their specific clinical trial requirements and expected outcomes.

- Smear Microscopy– conventional ZN and Fluorescent staining techniques
- TB Culture, MTBC Identification, and Susceptibility (1st and 2nd line)
- BD MGIT™ 960 system as well as on LJ medium
- HAIN LPA assays – Genotypic identification drug resistance (GenoType® MTBDRplus)
- GenoType® MTBDRsl) and Speciation (GenoType® Mycobacterium CM/AS test) - non-MTC Speciation
- GeneXpert® system
- QuantiFERON® – TB Gold plus testing
- Advanced immunological assays, e.g., ELISPOT
- Drug MIC determination and New drug susceptibility

ISO 15189
CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

Our Africa-Specific knowledge helps ensure your SAMPLES get to where they need to be ON TIME, and WITHIN TESTING PARAMETERS, which means you get the data you need WHEN YOU NEED IT.

FACILITY CAPABILITIES

This full-service laboratory includes capabilities spanning across the following services:

- **Biosafety Level 3 Laboratory (BSL3)**
- Pre-analytical (Sample accessioning)
- Analytical (Safety and Esoteric)
- Specimen Management and Storage (Ambient and Frozen)
- Clinic supplies (Kit building)
- Regulatory (Export / Import license) Expertise
- Logistics Support

What differenciates us

- Cytespace Africa Laboratory is one of the few clinical trial laboratories with a physical footprint in Africa.
- From a Quality Management perspective we are College of American Pathologist (CAP) and ISO 15189:2012 accredited as well as participating in the NGSP and CDC lipid certification programs certification.
- During years of experience supporting various studies, we understand the unique challenges involved in successful study execution, and have built logistics, processes and testing capabilities to support these.

Cytespace Africa understands the South African regulatory landscape. Working with us reduces the risk of import/export applications delays, through operating locally.

- The delivery models are custom fit to meet your specific study needs.
- In addition to clinical trials, we also provide a robust service to the Wellness market. The Occupational Health and Safety Act of South Africa requires employers to assess their responsibility for the health and well-being of their workforce. Special requirements included in the legislation have placed the accountability on employers to provide appropriate occupational health services to their employees.
- Contributes in providing customized services to support these goals.
- Numerous experts who can work with our clients before the initiation of a project to understand key requirements and strategies for effectively screening employees in accordance with National Health guidelines.
- From years of conducting clinical trials across Africa we have developed deep expertise to support trials across various indications.
- Full range of screening assays and robust experience in providing sample logistics throughout South Africa, as well as detailed reporting of the final screening results., adds value to organizations.
- Comprehensive screening and testing capabilities that provide a turnkey solution for companies.
- Advanced reporting capabilities brings additional value to Corporate Wellness screening programs.

Our History in Sub-Saharan Africa

1999	Quintiles Niehaus and Botha (Reference lab formed) 1st CAP Accreditation formed
2004	QLAB formed
2011	Opening of new QLAB Facility
2013	First TB study
2014	1st ISO 15189 Accreditation
2015	Q^2 Solutions Formed
2017	First Employee Health Screening study
2019	Cytespace Africa Acquisition
2021	Approved as a SARS-CoV-2 testing facility by the NDOH

Leadership Introduction

Prof. Oppel BW Greeff

Chairman & Lab Medical Director

Being involved in clinical research in the Pharma Industry for 13 years and was professor of Clinical Pharmacy at the University. He co-founded Clindepharm International in 1990, which he sold to Quintiles Transnational Corporation in August 1997. In 2002 he was appointed CEO of Early Development & Laboratory Services worldwide for Quintiles and located to the USA and in the same year as President: Global Product Development Services (PDS) and became a member of the Executive Committee of Quintiles. In August 2008 Prof Greeff was appointed professor and head of the department of Pharmacology, School of Medicine, Faculty of Health Sciences at the University of Pretoria and relocated back to South Africa. In November 2012 he joined Cytespace Africa as Chairman. Cytespace Africa is a clinical trials investigational site solutions organization. In 2016 Prof Greeff retired as Head of Department and currently still lectures at the University.

In 2016 Oppel founded Medwell SA, the first national home health care company in SA and is currently the CEO. Prof Greeff serves on the board of 18 companies in the health care industry in SA, the USA and India.

He serves on Scientific Advisory Boards and is invested in various biotech start-ups and companies globally in health care, focusing on drug and device development.

Gillian Corken

Chief Executive Officer

A former CEO for Africa of the US based company Quintiles Transnational. There after she further wanted to pursue her passion for Africa and its people and to be in a position to contribute as a healthcare professional to this Sub Saharan region and other emerging markets. In 1990 co-founded Clindepharm International Pty Ltd, the first clinical contract research organization (CRO) in South Africa after gaining experience in the international pharmaceutical industry. She also co-founded two natural therapy companies Phytotherapy Pty Ltd and Phytoderm cc. She has initiated various community-based programmes in Brazil and South Africa which have enabled young disadvantaged youth to enter the workplace. In November 2012 Gillian joined Cytespace Africa, a clinical trials investigational site solutions organization. Offering efficiencies and productivity solutions to recruit patients into clinical trials in Asia and Africa as well as capacity building and skills transfers at clinical sites. In 2013 Aquipharma acquired Triclinium Product Development Pty Ltd and Gillian was the Chairman of the Board of Directors until the company was sold to a South African Enterprise in 2017. She is an International Council member for Accordia.com promoting clinical research in Africa.

Sorika van Niekerk

Chief Operating Officer

Joined the Clinical Research Industry in 1999 and her expertise covers all therapeutic areas with a specific focus on anti-infective diseases. Whilst being Executive Director Clinical operations she was the main driver behind developing and implementing a strategy to expand Clinical Operations to the rest of Africa. The outcome of this strategy was the opening of offices in both East and West Africa.

She has a passion for development of people and as such she took responsibility for development of an apprenticeship within the South African context with the aim to increase the availability of well –trained individuals within the clinical trial industry in Sub-Saharan Africa. Sorika participates as a member on various Industry led initiatives & committees such as the South African Clinical Research Association, Industry Clinical Trial Focus Group comprising of CRO, Pharma and Site representatives, Department of Health Import /export permit committee etc. She also acts as a mentor and promoter of post graduate students specific to the field of research at various Academic institutions.

Sorika continues to focus on the development and expansion of clinical trial & laboratory infrastructures in Sub Saharan Africa.

Team Overview

Our employees have undertaken upwards of 1100 clinical trials since 1999, across all trial phases I – IV. We have experience across a variety of Therapeutic Areas serviced, including:

- Infectious Disease /Vaccine
- Oncology
- CNS
- Cardiovascular
- Musculoskeletal
- Endocrinology

We have an experienced team with strong technical abilities, clinical knowledge and clinical methodology experience:

- All laboratory staff are HPCSA registered biomedical professionals
- Employee Retention 98%
- GCP & GCLP Trained / Certified
- Average management experience 12 years
- Specimen Receipt Team IATA Certified
- Average duration in role 6.3 years
- Experience working across Pharma, Biotech, NGO, Public & Private partnership structures
- Combined experience of 155 years

Why Choose us?

- **DELIVERY OVERNIGHT:** Delivery into Pretoria from all destinations within South Africa. We are currently serving 17 Sub-Saharan Africa countries from our base in Pretoria, South Africa.
- **SHIPPING:** We have validated shippers to ensure cold chain and we have a thorough understanding of import/export license requirements. We also understand the vast changing Regulatory environment in SSA and the need to stay up to date with the most recent information.
- **KIT BUILDING:** We have Kit Building within the region to ensure the sites have all the supplies they need to conduct the trial.
- **TURN AROUND TIME (TAT)**: Our laboratory has a 99% on-time performance for samples requiring a 48-hour turnaround.
- **PROFICIENCY TESTING (PT):** The laboratory has a 99.5% Pass Rate target with PT review, full investigation and unacceptable result trending.
- **EXPERIENCE:** We have provided laboratory solutions for more than 1,100 clinical studies involving more than 950,000 patients
- **VACCINE AND INFECTIOUS DISEASE EXPERTISE:** We are well experienced in the vaccine and infectious disease clinical trial space and understand the need to collaborate with many partners in order to successfully deliver on these. We offer regional expertise and can manage logistics, trial set-up, and receipt into our laboratory.
- **TB TESTING CAPABILITIES:** Tuberculosis (TB), human immunodeficiency virus (HIV) and malaria are the most prominent diseases in Africa, with a great deal of research being performed regarding disease prevention, vaccines, and anti-infectives. We offer testing capabilities addressing each disease.
- **SERVICE OFFERING:** Also includes COVID-19 PCR testing
- **EMPLOYEE HEALTH SCREENING:** Providing Employee Health Screening Solutions to clients with a complete, consistent view across locations that meets national guidelines and supports reporting against South Africa's National Strategic Plan.
- **A FULL SERVICE LABORATORY:** This lab is a full-service lab offering all testing disciplines in chemistry, haematology etc. In total, we have two Biosafety Level 3 TB labs with a full redundancy State of the art Building Management system (BMS). The lab is College of America (CAP) -accredited, and has the following capabilities: Pre-analytical (Sample accessioning) Analytical (Safety and Esoteric) Specimen Management and Storage (Ambient & Frozen) Clinical supplies (Kit building) Logistics Support. These end-to-end, services are tailored to meet the complexities of providing clinical trial sites support in Sub-Saharan Africa and are set up to help ensure timely turn-around of testing and result reporting, safe handling and transport of samples, and best-in-class project support.
- **REGULATORY LANDSCAPE:** We understand the SA Regulatory landscape. Working with us reduce the risk of import/export application delays through operating locally.

WE ARE PRIZED FOR

- Robust Quality Management System
- Vast experience in customer audits
- Customer Service
- Flexibility to accommodate Project Requirements
- Highly skilled experience team
- Strong knowledge within the Clinical Trial Industry
- Project Specific Pricing

Collaborate with us

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