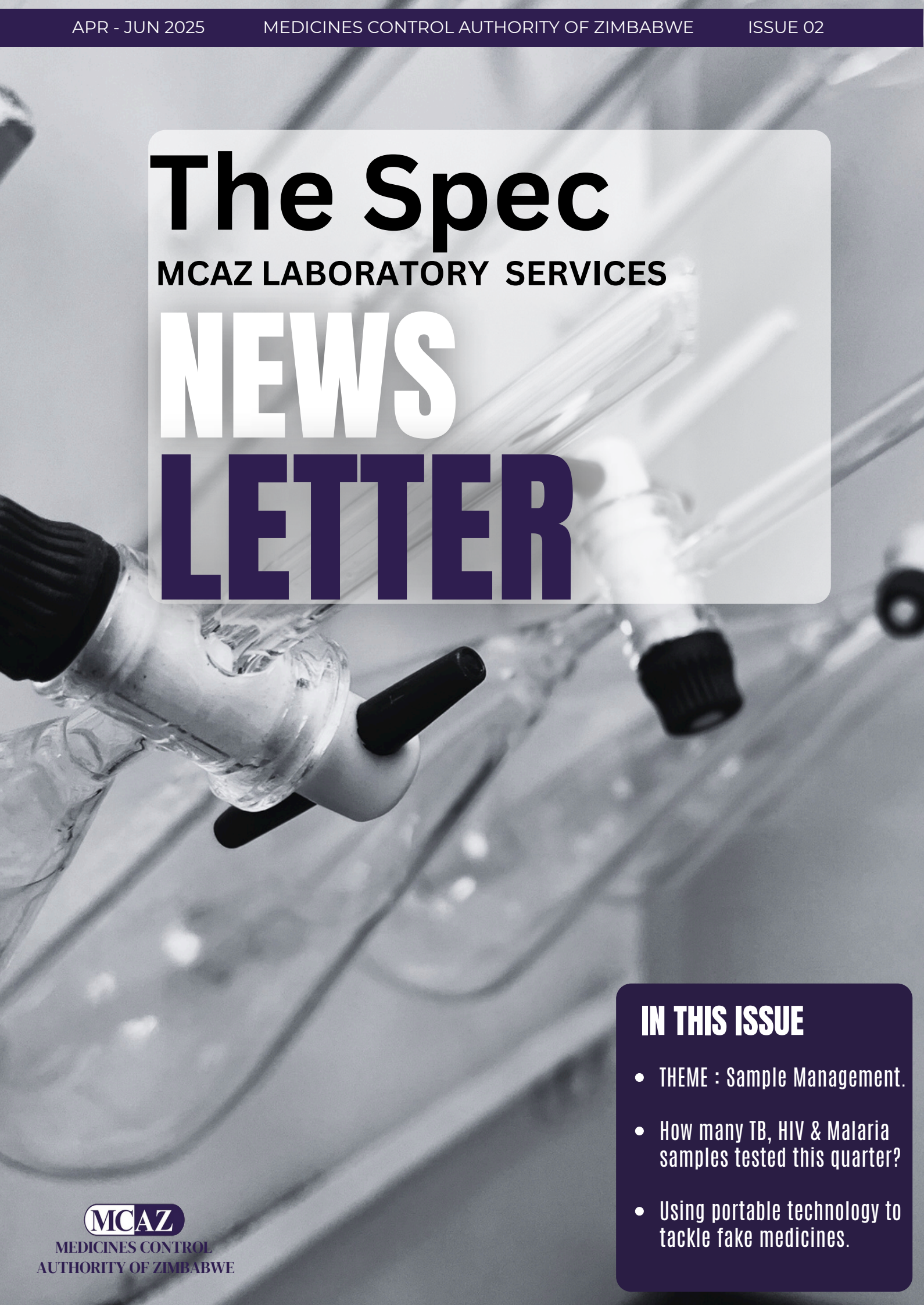
APR - JUN 2025 MEDICINES CONTROL AUTHORITY OF ZIMBABWE ISSUE 02

The Spec

MCAZ LABORATORY SERVICES

NEWS LETTER



IN THIS ISSUE

- THEME : Sample Management.
- How many TB, HIV & Malaria samples tested this quarter?
- Using portable technology to tackle fake medicines.

MCAZ
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

THEME FOR THE QUARTER : SAMPLE MANAGEMENT

Charity Kanjere -
Samples Repository Officer

SAMPLE MANAGEMENT & INTEGRITY - WHY IT MATTERS

At the Medicines Control Authority of Zimbabwe (MCAZ), sample management is managed by the Samples Repository Office. For samples submitted to MCAZ, the process begins with the receipt and verification of samples, ensuring container integrity, proper preservation, accurate labeling, and sufficient sample size. Samples that fail to meet these criteria are rejected, documented, and the customer is informed. Accepted samples are registered with unique identification numbers for traceability and stored under controlled environmental conditions. Proper handling, transportation, and a documented chain of custody ensure sample integrity and minimize contamination or degradation. All sample records are maintained from receipt to disposal, with automation of the system underway. Effective sample management supports regulatory compliance, data integrity, and operational efficiency, forming a critical part of the Quality Management System (QMS).

"Every sample tells a story - manage it well, or risk writing the wrong chapter" - anonymous

MAINTAINING SAMPLE INTEGRITY : FROM THE MARKET TO THE LABORATORY

SAMPLING

During sampling, the storage conditions are documented and any anomalies which may affect test results are noted. Sampling is conducted in such a way that the samples are not damaged.

TRANSPORTATION

Good Transportation Practices (GTP) are followed during sample transportation. In transit, continuous monitoring of environmental conditions such as temperature and humidity is performed using data loggers where appropriate.

STORAGE

There is storage of products before and after testing. To maintain sample integrity, samples are stored in temperature controlled and monitored storage facilities.

MONITORING

The usage of environment monitoring devices (data loggers) is essential for real time recording of environmental conditions. These are located at all storage sections and in the laboratory.

DOCUMENTATION

At every stage of the sample life cycle for products destined for testing, the conditions of the samples are documented. This is important for regulatory compliance, audit and accountability, root cause analysis and quality assurance.

OFF TO KENYA - SAMPLE MANAGEMENT TRAINING : CHROMAFRICA.

As part of its commitment to continuous improvement, MCAZ sent a cross-functional team of four—including staff from the Samples Repository and Chemistry Laboratory—to ChromAfrica Instrumentation Services in Nairobi, Kenya, from 12–16 May 2025. The team received specialized training in sample management, chemical reference standards, laboratory information systems, and waste handling. This tailored program significantly enhanced the Laboratory's capacity to implement best practices—strengthening MCAZ's mission to uphold quality, safety, and scientific excellence. [Pictured from left to right, Charity Kanjere (MCAZ), Beatrice Mugwira (MCAZ), Caleb Oyugi (ChromAfrica), Faith Madumbu (MCAZ) and Linia Mukani (MCAZ).]

LIFE AT SUB ZERO : MANAGEMENT OF LOW TEMPERATURE PRODUCTS.

Some pharmaceutical microbiology, samples, reference cultures, and reagents require storage at ultra-low temperatures to maintain their stability and effectiveness. In the Microbiology Laboratory, consistent low-temperature storage—that can range from 2°C to below -70°C—is essential to prevent degradation, contamination, or loss of potency. Specialized low-temperature freezers provide precise temperature control, continuous monitoring, and strong insulation to protect these materials from fluctuations that could compromise test results or product quality. By using such equipment, MCAZ ensures compliance with regulatory standards, supports reliable testing, and contributes to the development of safe, effective medicines.

REVIEW OF THE SECOND QUARTER

SMALL DEVICE, BIG IMPACT : MCAZ EMBRACES PORTABLE TECH TO COMBAT FAKE MEDICINES.

Substandard and falsified (SF) medicines remain a critical public health concern, but MCAZ is leveraging cutting-edge portable technology to strengthen frontline defenses. Handheld Raman and Near-Infrared (NIR) spectrometers are now being used to rapidly verify the authenticity of medicines—without opening packaging or sending samples to a laboratory. Raman spectrometers use laser light to generate a unique chemical "fingerprint" of a drug, while NIR spectrometers analyze its internal structure using near-infrared light. These compact tools deliver fast, reliable results in minutes, are easy to operate in the field, and are already proving invaluable at pharmacies, clinics, and border checkpoints. By integrating these technologies into our quality surveillance efforts, MCAZ is striving to ensure that only safe, effective medicines reach the public—demonstrating that powerful change can come in small, portable forms.

BENCHMARKING IN LESOTHO : VISIT TO LUCAN LABS.

As part of MCAZ's strategic initiative to strengthen Zimbabwe's medical cannabis regulatory and analytical capabilities, two representatives—Douglas Mukena and Patience Mutsiba—participated in a knowledge exchange programme with LuCan Labs in Lesotho from 8 - 20 June 2025. The visit provided critical insights into advanced cannabis analysis techniques and compliance with European Union Good Manufacturing Practices (EU-GMP) standards, which are essential for aligning Zimbabwe's practices with international benchmarks. The team also explored frameworks for proficiency testing, collaborative analysis, and structured study visits, laying the groundwork for long-term scientific cooperation. These learnings are expected to directly support Zimbabwe's efforts to attract investment, improve regulatory oversight, and ensure product quality in the growing medical cannabis sector.

OUR WORK IN NUMBERS : APRIL - JUNE 2025

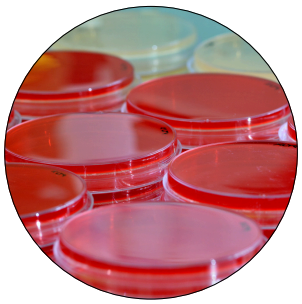
The Laboratory Services Division continued testing of various medical products between April and June 2025. Products submitted for testing may come from the Ministry of Health and Child Care through Natpharm or may be from private distributors. Provided as part of the statistics are samples tested for medicines used in the treatment of, Malaria, Tuberculosis and HIV/AIDS.

169 samples were received for Chemical testing.

124 samples tested in the quarter.

71 medical device batch samples were received for conformity testing

63 medical device batch samples were tested in the quarter.



16 samples were received for microbiological testing.

7 samples were tested in the quarter.

11 **Anti-malarial** medicines, eg, Artemether/ Lumefantrine Tablets were tested in Q2 of 2025 making a total of 23 for 2025.

3 **Anti -Tuberculosis** medicines e.g, Rifampicin/ Isoniazid Tablets, were tested in Q2 of 2025 making a total of 28 for 2025.

53 **ARV medicines** e.g, Dolutegravir tablets, were tested in Q2 of 2025 making a total of 107 for 2025.

OUR LAST WORD

"Sample stewardship is where regulatory compliance meets operational excellence."
— Anonymous

106 Baines Avenue
Harare

Tel : +263 242 736 981-7
708 255/ 792 165/
0772 145 191/2/2

Medicines Control Authority of Zimbabwe

www.mcaz.co.zw

mcaz@mcaz.co.zw