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MCAZ LABORATORY SERVICES

NEWS LETTER

MCAZ
MEDICINES CONTROL AUTHORITY OF ZIMBABWE

IN THIS ISSUE

THEME FOR THE QUARTER : ENSURING VALIDITY OF TEST RESULTS

TRUSTWORTHY RESULTS : ENSURING SCIENTIFIC INTEGRITY FOR THE GREATER GOOD

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Every tablet, capsule, or injection that reaches patients' hands should be safe, effective, and of the highest quality. To guarantee this, the Medicines Control Authority of Zimbabwe's' (MCAZ) Laboratory is tasked with ensuring that the medicines and medical devices available on the market meet international standards for safety, quality, and efficacy. This is not just a technical process; it is a public health safeguard that protects patients, strengthens trust in healthcare systems, and ensures compliance with standards of recognised bodies such as the World Health Organization (WHO) and ISO/IEC 17025. The MCAZ Laboratory's work ensures protection of patients from harmful medical products, empower healthcare professionals to prescribe confidently, and keeps the pharmaceutical market aligned with global standards. In this quarter, the focus of this newsletter is to share how the MCAZ laboratory ensures that the results from tests it conducts are accurate.

WHAT MAKES TEST RESULTS RELIABLE? : Accreditation, and why it's important.

Accreditation is the process of providing recognition to an organization for its competence in performing specific tasks. For testing laboratories, IEC/ISO 17025 is the standard that sets requirements for, competence, impartiality, and consistent operation to ensure reliable and valid results by testing laboratories. Accreditation according to the standard involves the assessment of technical competence in providing conformity assessment services by an organisation. The MCAZ laboratories are ISO/IEC 17025 accredited and operate in line with WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL) and International Council for Harmonisation (ICH) guidelines. For accreditation, MCAZ employs some of the systems and practices described below;

QUALIFIED PERSONNEL

Highly trained and competent analysts who are continously assessed and constantly up to date with the latest scientific knowledge.

SECONDARY REVIEW

All results are checked by a qualified reviewer who is a technical signatory for accredited techniques.

VALIDATED METHODS

The laboratory uses internationally recognised, standards, pharmacopoeias and validated analytical methods for product testing.

STANDARD PROCEDURES

Every test is performed under approved, version-controlled Standard Operating Procedures (SOPs). These are reviewed when necessary.

CALIBRATED EQUIPMENT

Instruments undergo strict installation, qualification, and routine calibration, using traceable certified reference materials and accredited service providers.

QUALITY CONTROL

Use of suitable controls, reagents, blanks, chemical reference standards and system stable suitability tests to ensure accuracy before results are released.

DATA INTEGRITY

Results are safeguarded under the ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available).

INTER-LABORATORY PROFICIENCY TESTING How MCAZ laboratories compare against other laboratories.

The laboratories at MCAZ participate in inter-laboratory proficiency testing schemes. Inter-laboratory proficiency testing (PT), also known as round-robin testing or external quality assessment (EQA), involve multiple laboratories analyzing identical samples under specified conditions. The goal is to assess the accuracy, consistency, and reliability of their analytical results. Statistical analysis is conducted on the all results from participating laboratories to assess how each laboratory's results compare to those of others, whether their performance is within acceptable limits and if there are any outliers or inconsistencies. The reports are used for performance evaluation, quality assurance, method validation, training and improvement and in supporting accreditation. Below are some of the PT schemes that MCAZ laboratories participated in;

Microbiology Laboratory
LGC Pharmassure Proficiency Test
The laboratory obtained satisfactory results in microbiology sterility proficiency testing round conducted by LGC UK. The laboratory correctly identified the sterility of each of the samples provided.

Chemistry Laboratory
European Directorate for the Quality of Medicines & HealthCare (EDQM)
The laboratory participated in two (2) proficiency testing studies offered by EDQM and the results were excellent.

African Medicines Quality Forum (AMQF) 2025 Inter-laboratory comparison (ILC) testing scheme
The aim of the ILC was to assess the ability of African laboratories to detect the presence or absence of Diethylene glycol (DEG) and Ethylene glycol (EG) in pharmaceutical preparation by Gas Chromatography. The reports are expected before the close of the year.

Medical Devices Laboratory
Enersol Proficiency testing scheme
The laboratory participated in the 2025 round for assessment of various methods for testing male latex condoms. The reports are expected by the end of the year

REVIEW OF THE THIRD QUARTER

NATURAL AND LIFE SCIENCE RESEARCH CONFERENCE 2025

On August 8, 2025, the MCAZ Chemistry Unit participated in the Natural and Life Sciences Research Regional Conference organized by Zimbabwe Chemical Society (ZCS), LAB Insiders, and Natural Products Research Network for Eastern and Southern Africa (NAPRECA). The event, themed "Bridging Research Gaps and Building Scientific Synergy in Southern Africa," showcased research from Chinhoyi University of Technology (CUT), Midlands State University (MSU), University of Zimbabwe (UZ), National University of Science and Technology (NUST) and Great Zimbabwe University (GZU), among others. The conference highlighted opportunities for MCAZ to collaborate with researchers on public health projects.

ISO/ TC 157 MEETING 2025- BANGKOK, THAILAND

Two officers from the MCAZ Medical Devices Laboratory, Mr. Tinashe Gono (Chief Analyst) and Ms. Yvonne Zviuya (Analyst), participated in the annual ISO/TC 157 meeting held from 22nd to 25th September 2025. ISO/TC 157 is the international technical committee responsible for standardizing non-systemic contraceptives and STI barrier methods, including condoms, diaphragms, and intrauterine devices. The meeting focused on reviewing and updating standards related to packaging integrity, burst requirements, chemical residues, and clinical trials, while also aligning its work with global health priorities such as the Sustainable Development Goals (SDGs). As an observer member, Zimbabwe benefits from these developments, which directly impact condom testing protocols at the MCAZ Medical Devices Laboratory.

ACCREDITATION AND CERTIFICATION AUDITS 2025

It was a busy September as far as accreditations and audits were concerned for the Laboratory Division. The laboratory was audited by both the Southern African Development Community Accreditation Service (SADCAS) and Standard Association of Zimbabwe (SAZ).

SADCAS Accreditation Reassessment

From the 15th - 16th of September 2025, all three MCAZ laboratories and the Quality Unit underwent an accreditation reassessment audit for the ISO/IEC 17025 quality management system standard. This standard, sets requirements for, competence, impartiality, and consistent operation to ensure reliable and valid results by testing laboratories. The laboratories were recommended a new five year cycle of accreditation. All the analysts assessed to be Technical Signatories and the Nominated Representative were deemed competent.

Standards Association of Zimbabwe Surveillance Audit

The Standards Association of Zimbabwe, from the 18th - 19th of September 2025 conducted an ISO 9001 Surveillance audit for MCAZ as an organisation. ISO 9001 is the standard for quality management systems (QMS), providing a framework for organisations to consistently meet customer and regulatory requirements. The Laboratories were also audited together with the rest of the divisions /units at MCAZ and were recommended continued certification.

OUR WORK IN NUMBERS : JULY - SEPTEMBER 2025

CHEMISTRY LABORATORY

139 samples were received for Chemical testing.

121 samples tested in the quarter.

MICROBIOLOGY LABORATORY

45 samples were received for Microbiological testing.

19 samples tested in the quarter.

MEDICAL DEVICES LABORATORY

89 samples were received for conformity testing

65 samples tested in the quarter.

OUR LAST WORD

"An error in any part of the cycle can produce a poor laboratory result. A method of detecting errors at each phase of testing is needed if quality is to be assured."
— WHO Quality Management System Overview

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