SADCAS ACCREDITS FIRST MEDICAL LABORATORY FOR COVID-19 DIAGNOSTIC TESTING

SADCAS is proud to announce the accreditation of its very first medical laboratory for conducting Coronavirus disease 2019 (COVID-19) diagnostic testing. Diagnofirm Medical Laboratories Gaborone situated at Plot Number 12583, Nyerere Drive, Middlestar, Gaborone, Botswana has been accredited to ISO 15189:2012 for SARS- CoV-2/COVID-19 testing using the PCR/Bioer Extraction and Amplification System. The accreditation is a scope extension in the "Molecular Biology" scope. Diagnofirm was first accredited by SADCAS on 25 June 2015 to ISO 15189: 2012 and granted the accreditation number **MED 012** for the following scopes: Chemistry; Endocrinology; Haematology; Microbiology; Molecular Biology; and Serology. Diagnofirm Medical Laboratories Gaborone was re-assessed and renewal of accreditation was granted on 31 July 2020.

For COVID-19 Testing, Diagnofirm Medical Laboratories Gaborone underwent a scope extension assessment on 8 December 2020 by a team of two including Technical Assessor competent in the scope molecular biology. The assessment which was conducted virtually involved a vertical assessment and witnessing the scientist undertaking the test. No findings were raised during the assessment after which a decision to accredit in the test method "SARS-CoV-2/COVID-19" using the PCR Bioer Extraction and Amplification System was made by the SADCAS Accreditation Approvals Committee on 11 December 2020 based on the assessment team's recommendation.

The COVID-19 pandemic caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), is now a major public health problem globally. Medical laboratories play a critical role in the healthcare delivery system by providing information for patient management, public health, disease control and surveillance. Reliable results of medical laboratories conducting tests to detect the SARS-CoV-2 virus are essential in the management of the pandemic. Accurate and early detection of SARS-CoV-2 in infected people are key in limiting transmission of COVID-19 and informing interventional measures.

Accreditation to ISO 15189:2012 is a vital tool for laboratories to improve quality performance, efficiency and reliability. The SADCAS Medical Laboratory Accreditation Scheme (MLAS) was established in June 2010 and is a multi – disciplinary accreditation scheme operated in accordance with ISO/IEC 17011. The fields of accreditation under the MLAS include: Clinical Chemistry; Biochemistry; Cytology; Haematology; Histopathology; Immunology; Microbiology; Pathology; Virology; Serology; Molecular Biology; Endocrinology; Blood Transfusion/Blood Bank; Immunophenotyping; and Andrology. The MLAS is internationally recognized having achieved signatory status in the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) in 2017.

SADCAS congratulates Diagnofirm Medical Laboratories Gaborone for the achievement at a such a crucial time in the fight against the COVID-19 pandemic.