



REFERENCE No. AUC/ACDC/NC/001

EXPRESSION OF INTEREST

**TO SERVE AS CENTERS OF EXCELLENCE FOR AFRICA CDC TO ADVANCE
AVAILABILITY AND ACCESSIBILITY OF LABORATORY DIAGNOSTICS**

I. BACKGROUND

Africa's move towards greater integration requires a strong health strategy. In 2015, the African Union Commission (AUC) developed the Africa Health Strategy 2016-2030. This strategy offers a cohesive and consolidative platform encompassing all commitments in the health sector and provides strategic direction to Member States in their efforts in creating better performing health sectors, recognizes existing continental and global commitments and addresses key challenges to reduce Africa's burden of diseases.

Some of the continental and global instruments include the Agenda 2063: "The Africa We Want" and 2030 Agenda for Sustainable Development Goals; the Sexual and Reproductive Health and Rights Continental Policy Framework; the Pharmaceutical Manufacturing Plan for Africa (PMPA); the various African Union commitments aimed at combatting AIDS, tuberculosis and malaria in Africa, and the catalytic framework to End AIDS, TB and Eliminate Malaria in Africa by 2030.

The Africa Health Strategy 2016-2030 include strengthening health systems to achieve Universal Health Coverage (UHC) and Health Security by ensuring strong leadership and good governance; forging multi-sectoral partnerships to address the socio-economic and environmental determinants of health; refocusing service delivery and empowering communities; prioritizing human resources for health; ensuring commodity security; building the regulatory and support environment for provision of quality medicines and technologies; and establishing effective systems for disease surveillance and disaster management.

Access to diagnostics will be critical in achieving the Africa Health Strategy 2016-2030, the UHC, and Health Security of the continent, especially as it moves towards greater integration. Quality-assured In Vitro Diagnostics will improve decision-making, allowing health professionals faster and more accurate solutions for disease prevention and control. However, various gaps exist to accessing quality diagnostics: they do not exist, are inaccessible, or are costly. Moreover, slow introduction of innovative diagnostics hamper disease control programmes and response to

outbreaks. The UHC and Health Security Agenda in Africa cannot be achieved without creating sustainable access to diagnostics. The World Health Organization (WHO) prequalification of products is a very important process to maintain quality of laboratory diagnostics and their performance in the field, provides guidance to countries in selecting laboratory diagnostics to be implemented at programme level. However, a regional context and reality must be factored in and for many diseases prioritized for Health Security Agenda in Africa, laboratory diagnostics are either absent or are not WHO prequalified. The Publication of the first edition of the Model List of Essential In Vitro Diagnostics (EDL) by WHO in May 2018 is an important step to address IVDs availability and accessibility challenges. EDL recognizes that IVDs are an essential component to advance universal health coverage, address health emergencies, and promote healthier populations.

Cognizant of these, AUC through the Africa Centres for Disease Control and Prevention (Africa CDC), in collaboration with partners, launched the **Africa Collaborative to Advance Diagnostics (AFCAD)**, in 2018 during the Africa Society for Laboratory Medicine (ASLM) conference in Abuja, Nigeria. The initiative aims to promote and advocate for increase access and manufacturing of diagnostics in Africa, through better-coordinated and synergized efforts that align with the goals of the Africa Health Strategy 2016-2030. One of its objectives is to support systematic evaluation and impact assessment of IVDs working with multiple Centers of Excellence in Africa. This will help generate enough evidence in short period of time and hence facilitate subsequent decisions on IVDs including WHO pre-qualification. This is therefore a call for institutions to express interest to work with Africa CDC to advance the availability and accessibility of IVDs

II. OBJECTIVE OF THE CALL FOR EXPRESSION OF INTEREST

The purpose of this call for expression of interest is to allow Africa CDC to select 5 centres of excellence in line with the arrangement of its Regional Collaborating Centres for evaluation and validation of laboratory diagnostics to increase availability and accessibility of in vitro diagnostics for Africa CDC priority diseases.

III. Expectation from the Centres of Excellence

- Centres of Excellence are expected to work with Africa CDC to conduct evaluation and/or validation of in vitro diagnostics
- Centres of excellence are expected to share the laboratory diagnostics evaluation or validation report to Africa CDC on time
- Centres of excellence are expected to evaluate themselves to identify key capacity gaps and communicate and work with Africa CDC to build their capacity for evaluation and/or validation of in vitro diagnostics
- Centres of excellence are expected to serve as training centres for Africa CDC to advance laboratory diagnostics availability and accessibility.

- Centres of excellence will work with Africa CDC to develop standard operation procedures or training materials on the in vitro laboratory diagnostics.
- Centres of excellence are expected to work with Africa CDC in pilot implementation and scale up of laboratory diagnostics

IV. KEY DELIVERABLES

- Centres of excellence will evaluate and/or validate laboratory diagnostics and submit the evaluation or validation report within three months after completion of the evaluation or validation study
- Centres of excellence will avail standard operating procedures and training materials on laboratory diagnostics in line with manufacturers' instructions
- Centres of excellence will provide report on the pilot implementation of the laboratory diagnostics and provide recommendations to Africa CDC.

V. QUALIFICATION AND EXPERIENCE

- Centers of excellence that have the infrastructure and human resources in favour of conducting standard evaluation or validation studies
- Centers of excellence that have reference laboratories with international accreditation (could be limited or full scope accreditation)
- Centers of excellence with previous experience of independent performance evaluation of IVDs or engaged in multi-country evaluation studies
- Centers of excellence with senior scientific staff with proven track record for the work on diagnostics evaluation and impact studies
- Centres of excellence that have bio repository or biobank

VI. BENEFITS FOR THE CENTERS OF EXCELLENCE

Africa CDC as continental public health agency is working to build capacity of institutions and individuals to build resilient health systems in the continent. Centres of excellence will be engaged in all Africa CDC led programs as needed in close collaboration with Regional collaborating centres. However, centres of excellence that will be selected to serve Africa CDC in evaluation and/or validation of laboratory diagnostics will receive additional support on the following areas:

- Training of staff of Centers of Excellence on good laboratory and clinical practice, protocol writing and data analysis and interpretation
- Support with development of generic protocol that can easily be customized
- Technical support during the conduct of evaluation studies and impact assessments
- Minor laboratory infrastructure supports to facilitate implementation of laboratory quality management systems
- Support on biosafety and biosecurity
- Support the strengthening of bio repository or bio bank
- Mobilization of resources for the evaluation studies

The African Union Commission now invites eligible Centres of Excellence to indicate their interest to work with Africa Centres for Diseases Control and Prevention for evaluation/and or validation of laboratory diagnostics. Interested candidates must provide information demonstrating that the centres of excellence have the required capacity and relevant experiences to serve as centres for evaluation and/or validation of in vitro diagnostics to advance Africa CDC's agenda on availability and accessibility of laboratory diagnostics.

VIII. EVALUATION CRITERIA

For evaluation of the expressions of interest the following criteria will be applied:

- a) Availability of laboratory infrastructure, scientific staff and accreditation of the reference laboratory (35 points);
- b) Experience in independent performance of evaluation of laboratory diagnostics or engagement in multi-country diagnostics evaluation studies (30 points);
- c) Availability of bio repository or bio bank (20 points)
- d) Commitment to serve as centre for evaluation of laboratory diagnostics, conduct evaluation studies under terms and condition to be set for evaluation of in vitro diagnostics and share evaluation report to Africa CDC and other relevant institutions timely as expressed in written letter from the head of the institution (15 points)

Interested centres of excellence are requested to submit the following documents for AUC's consideration:

- a) Capacity Statement
 - Indicating the laboratory infrastructure, human resource with focus on the scientific staff, partnerships with other organizations and how these capacity advances standard and independent evaluation of in vitro diagnostics (include CVs of key scientific staff)
 - Accreditation status of reference laboratory, presence of bio repository or bio bank and enrolment of the laboratory in external quality assessment program (submit recent certificate for accreditation)
 - Role of the organization in advancing research and adoption of technologies
- b) Experience in evaluation of in vitro diagnostics
 - Past experience in independent performance of evaluation of in vitro diagnostics
 - Past collaboration with other institutions in evaluation of in vitro diagnostics
 - Publications on the evaluation of in vitro diagnostics
- c) Expression of commitment

Letter of commitment signed by head of institutions to work with Africa CDC and despatch responsibilities described here.

- d) Please include the institutional contact person Name, Email Address and Telephone Number.

Further information can be obtained at the address below during office hours 8:00-13:00hrs and 14:00-17:00 hours Local Time.

RESPONSE TO THE CALL

Proposal must be delivered in a written form to the address below not later than 1500 hours' local time, 30 March 16, 2020.

African Union Commission,

Head of Procurement Travel and Store Division

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