

March 23, 2018

World Health Organization
Strategic Advisory Group of Experts on
In Vitro Diagnostics (SAGE IVD)

Subject: Background Document

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to provide input to the World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE) on In Vitro Diagnostics (IVD) regarding its background document for the April 16-20, 2018 meeting to discuss the creation of a Model List of Essential In Vitro Diagnostics (EDL). AACC supports the creation of this document and offers its assistance in drafting and disseminating the EDL. The association is committed to ensuring that all persons, wherever they reside, have access to the laboratory services they and their doctors require to achieve better patient outcomes.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. The association has members in 110 countries residing in all regions of the world. AACC has worked diligently to assist its members working in resource-limited nations. Since 2011, the association's Global Lab Quality Initiative (GLQI) has conducted educational programs to help laboratory professionals improve their skills in 16 countries in the Latin American, Caribbean, and Asia-Pacific regions. Also through the GLQI, AACC works to improve newborn screening across the globe through educational activities and policy discussions. The association plans to continue expanding this effort in coming years.

AACC's flagship journal, *Clinical Chemistry*, is the world's leading peer-reviewed journal of clinical laboratory medicine, and *The Journal of Applied Laboratory Medicine* provides more practical guidance to laboratory professionals.

AACC's Annual Scientific Meeting & Clinical Lab Expo draws 20,000 attendees each year. The 2018 meeting will feature a plenary talk on the concept of an EDL by Drs. Tim Amukele and Lee Schroeder. Through its publications and educational vehicles, AACC can help disseminate throughout the global laboratory medicine community.

AACC agrees with the WHO's decision to include tuberculosis, malaria, HIV, and Hepatitis B and C on the first EDL. Given that much of the work has already been done in identifying the

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appropriate tests for these conditions, AACC encourages the SAGE IVD panel to consider expanding the first list to include other critical health conditions/tests. AACC recommends that SAGE IVD consider the following when creating and refining the EDL:

- AACC encourages WHO to develop a tiered approach for assigning and stratifying tests on the EDL. The model should consider the cost of the test, its effectiveness, already-established common practices in a region or country, and the ease of introducing the test to the community.
- The association suggests that the committee consider the following test-specific criteria when selecting the EDL assays:
 - test platform/reagent storage requirements;
 - sample collection, handling, and storage requirements;
 - level of technical expertise required to run and interpret tests;
 - knowledge and skill required to troubleshoot problems;
 - the specificity and sensitivity (false negative and false positive rates) of the assay; and
 - any follow-up confirmatory testing requirements.

AACC strongly supports this initiative and offers expertise in the development of the EDL. AACC hopes that knowledgeable clinical laboratory professionals are included on the SAGE-IVD panel; if not, the association can suggest several candidates. In addition, AACC can be a partner in the dissemination of the list and accompanying information and looks forward to working with WHO and the panel on this important issue.

If you have any questions, please email Vince Stine, PhD, AACC's Director of Government Affairs, at vstine@aac.org.

Sincerely,



Dennis J. Dietzen, PhD, DABCC, FAACC
President, AACC