

February 6, 2018

The Honorable Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendations regarding the rapid supplanting of clinical microbiology culture-based tests with culture-independent diagnostic tests (CIDTs).

BACKGROUND

During the August 29-30, 2012 CLIAC meeting, the Committee was provided an overview on the increasing use of culture-independent microbiology diagnostics and the impact of this change on public health. The Committee acknowledged the potential impact of CIDTs on public health surveillance, and agreed that discussion and resolution of related issues should be part of the FDA clearance process. During the November 1-2, 2017 CLIAC meeting, the Committee was provided an update on the CIDT issues since 2012, including major changes and trends in clinical microbiology practices, and the increasing use of whole genome sequencing for identification of microorganisms. The Committee discussed the challenges of sustaining culture-based testing in light of current and emerging technology.

After deliberation on the issues, the Committee voted to provide the following recommendation to HHS.

CLIAC Culture-Independent Diagnostic Test Recommendation

In clinical microbiology, culture-independent diagnostic tests (CIDTs) are rapidly supplanting culture-based tests, but cultures are indispensable for surveillance and outbreak prevention, which are both cost-effective and vital to public health and national security.

CLIAC recommends that CDC urgently convene a cross-agency coordinating group to assess the impact of CIDTs on public health surveillance, and to

recommend impactful solutions that are brought to the attention of agency and government leaders.

CLIAC is committed to providing HHS thoughtful advice related to clinical laboratory quality improvement and laboratory medicine practice. Thank you for your consideration.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via email at rarnaout@bidmc.harvard.edu or by telephone at 617-538-5681.

Sincerely,



Ramy A. Arnaout, M.D, D.Phil
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:

Dr. Anne Schuchat
Acting Director, CDC

Dr. Reynolds M. Salerno, CLIAC Designated Federal Official
Director, Division of Laboratory Systems, CDC

Ms. Karen Dyer, CLIAC Ex-Officio
Director, Division of Laboratory Services, CMS

Dr. Peter Tobin, CLIAC Ex-Officio
Chemist, Office of In-Vitro Diagnostic and Radiological Health, FDA



THE DEPUTY SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

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Ramy A. Arnaout, MD, DPhil
Chairperson
Clinical Laboratory Improvement Advisory Committee
2877 Brandywine Road
Williams Building, Floor 2, Room 2716
Atlanta, Georgia 30341

Dear Dr. Arnaout:

Thank you for the Clinical Laboratory Improvement Advisory Committee's (CLIAC) recommendations regarding the rapid supplanting of clinical microbiology culture-based tests with culture-independent diagnostic tests (CIDTs). Secretary Azar asked that I respond to you on his behalf.

The Department of Health and Human Services (HHS) recognizes the important role that CLIAC plays in keeping HHS informed of potential issues that affect or could affect clinical laboratories, physicians, and patients. Cultures are an indispensable tool for public health surveillance and outbreak prevention. Therefore, the exclusive use of CIDTs should be evaluated.

We will carefully consider CLIAC's recommendation regarding a cross-agency coordinating group to assess the impact of CIDTs and welcome any additional comments or suggestions CLIAC may have to best address this public health issue.

Sincerely,

A handwritten signature in black ink, reading "Eric D. Hargan". The signature is written in a cursive style.

Eric D. Hargan