January 4, 2016

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

Dear Madam Secretary:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendation pertaining to non-invasive prenatal testing (NIPT), also referred to as cell-free fetal DNA testing.

BACKGROUND

CLIAC is the federal advisory committee charged with the responsibility of advising HHS on issues related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as general issues related to improvement in clinical laboratory quality and laboratory medicine practice. During the November 18-19, 2015 CLIAC meeting, the Committee deliberated on NIPT, and the potential need for providing information to physicians and patients regarding the appropriate use of NIPT and interpretation of test results. Background information was given to CLIAC, including the intended use of NIPT, its limitations, and concerns of stakeholders in the testing process. Following this, a presentation was given on current issues related to prenatal screening for Down syndrome using cell-free DNA and a genetic counselor presented a clinical perspective on NIPT. In response to the questions posed to the Committee, CLIAC voted to provide the following recommendations to HHS.

RECOMMENDATIONS

*HHS and CDC should support the development of NIPT-related enduring educational materials accessible to patients and health care providers. In order to support effective patient care decisions, these materials should include simple language and visual graphics to effectively convey information about risks, benefits, and limitations of different types of prenatal testing.

*HHS should require that ordering providers requesting non-invasive prenatal screening tests (of cell-free fetal DNA) should perform and

document a pre-test discussion to inform the patient of risks, benefits, and limitations.
*HHS should recommend laboratories performing NIPT to disclose information regarding test limitations and positive predictive values (likelihood that the fetus has a genetic condition) that is directly comparable to conventional techniques (e.g., by maternal age) while reporting results as well as risk interpretation and appropriate indications for confirmatory diagnostic testing.

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

If you have any questions regarding CLIAC's recommendations, please feel free to contact me via my personal email at burton.wilcke@med.uvm.edu or by telephone at 802-233-9753.

Sincerely,

Burton W. Wilcke, Jr., Ph.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:
Dr. Thomas Frieden
Director, CDC

Dr. William R. Mac Kenzie CLIAC Designated Federal Official
Deputy Director for Science, Division of Laboratory Programs, Standards, and Services

Dr. Barbara Zehnbauer, CLIAC Ex-Officio
Director (Acting), Division of Laboratory Systems, CDC

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

Dr. Alberto Gutierrez, CLIAC Ex-Officio
Director, Office of In Vitro Diagnostic and Radiological Health, FDA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington DC 20201

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Burton W. Wilcke Jr., PhD
Chairperson
Clinical Laboratory Improvement Advisory Committee
2877 Brandywine Road
Williams Building, Floor 2, Room 2716
Atlanta, Georgia 30341

Dear Dr. Wilcke:

Thank you for the Clinical Laboratory Improvement Advisory Committee's (CLIAC) recommendations regarding non-invasive prenatal testing (NIPT), also referred to as cell-free fetal DNA testing. Secretary Burwell asked that I respond to you on her 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. We are aware of NIPT's implications for medical decision making and for stakeholders in the testing process. I will discuss your recommendations among HHS agencies and will follow up accordingly.

We will carefully consider CLIAC's recommendations regarding NIPT and welcome any additional comments or suggestions that CLIAC may have.

Sincerely,

Mary Wakefield

Mary K. Wakefield
Acting Deputy Secretary