Laboratory Developed Tests & Their Role in the Multicancer Early Detection Market

Many medical tests are offered to providers for patients through the Laboratory Developed Tests (LDTs) pathway. This pathway **allows a single laboratory to perform a test if the laboratory has a Clinical Laboratory Improvement Amendment (CLIA) license**. To obtain and maintain the license, the lab must abide by CLIA rules and conduct analytical validation studies that verify the accuracy of the test. It's important to note that **these tests are not evaluated or approved by the Food and Drug Administration (FDA)** before being released and used with patients.

MCED Tests

Multicancer Early Detection Tests (MCED) currently on the market are available as an LDT, indicating they have not been assessed by an external agency for clinical validity or utility. **It's crucial for healthcare providers and patients to assess these tests before using them in a clinical setting**. The MCED Consortium has published white papers to aid in this evaluation, covering Clinical Utility to inform decision-makers about benefits and risks and Care Delivery to guide providers on potential use and considerations when discussing with patients. Visit **www.mced.info/wg-resources** to learn more.

The Clinical Laboratory Improvement Amendment (CLIA)

CLIA is regulated by the Centers for Medicare and Medicaid Services (CMS) and oversees all human laboratory testing in the U.S. (excluding research). **The CLIA program aims to ensure high-quality laboratory testing with a focus on the analytical validity or accuracy of tests**. CMS works with the Centers for Disease Control and Prevention (CDC) and provides scientific oversight with the Division of Laboratory Systems and the Clinical Laboratory Improvement Advisory Committee (CLIAC) as well as the FDA, which categorizes tests based on complexity for CLIA laboratories. For more information about these agencies collaborative efforts, visit:

www.cdc.gov/clia/index.html
www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments

FDA

Through the years, the FDA has typically approved tests designed for clinical use by multiple laboratories (test kits). Most genetic tests, including MCEDs, are considered "complex tests" and are not sold as kits. **On 10/03/2023, the FDA published a proposal** (FR Document 2023-21662 on www.archives.gov/federal-register) **amending regulations to clarify that in vitro diagnostic products (IVDs), even when manufactured by a laboratory, are considered devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act)**.

Other Oversight

Washington and New York have state accreditation programs exempt from CLIA requirements, with additional accreditation criteria. The NY State Clinical Laboratory Evaluation Program (CLEP) at the Wadsworth Center reviews non-FDA cleared or approved laboratory-developed tests (LDTs) before clinical use in New York. This involves accrediting the laboratory and evaluating each test it intends to offer in the state. For details, visit **www.wadsworth.org/regulatory/clep**.

Please use caution

Certain tests promoted on the internet assert the ability to detect multiple cancers, yet they do not leverage advanced genomic technologies. These tests are directly marketed to consumers without the involvement of healthcare providers. Despite being touted as a new technology harnessing Artificial Intelligence, it's crucial to understand that **the intelligence behind these tests relies on outdated standards with limited evidence in predicting cancers effectively**. It's noteworthy that **the efficacy of these tests in detecting most cancers has not been substantiated**.