FDA News Release

FDA unveils a streamlined path for the authorization of tumor profiling tests alongside its latest product action

Newly authorized test detects genetic cancer mutations in 468 unique genes

For Immediate Release

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Summary

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Release

The U.S. Food and Drug Administration today authorized Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets) tumor profiling test (assay), an in vitro diagnostic test that can identify a higher number of genetic mutations (biomarkers) that may be found in various cancers than any test previously reviewed by the agency. The IMPACT test uses next-generation sequencing (NGS) to rapidly identify the presence of mutations in 468 unique genes, as well as other molecular changes in the genomic makeup of a person's tumor. Cancer profile tests are gaining wider acceptance. By identifying what genetic mutations are present in a particular tumor, the test results can provide patients and health care professionals with useful insight that may help inform how best to treat the cancer.

Today's action advances a policy framework that paves the way for the efficient review and availability of other NGS-based cancer profiling tools. The FDA is also announcing the recent accreditation of the **New York State Department of Health (NYSDOH) as an FDA third-party reviewer (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/Accredit.CFM?party_key=9)** of in vitro diagnostics, including tests similar to the IMPACT test. Moving forward, laboratories whose NGS-based tumor profiling tests have been approved by NYSDOH do not need to submit a separate 510(k) application to the FDA. Instead, developers may choose to request that their NYSDOH application, as well as the state's review memorandum and recommendation be forwarded to the FDA for possible 510(k) clearance. Other accredited, third-party FDA reviewers also may become eligible to conduct such reviews and make clearance recommendations to the agency.

"The goal of allowing NGS-based tumor profiling tests to undergo review by accredited third-parties is to reduce the burden on test developers and streamline the regulatory assessment of these types of innovative products. As this field advances, we are modernizing the FDA's approach to the efficient authorization of laboratory tests from developers that voluntarily seek 510(k) clearance," said FDA Commissioner Scott Gottlieb, M.D. "This is another example of where the FDA is working to find creative and flexible approaches to regulation that spurs development and efficient delivery of innovative technology. We'll continue to look for opportunities to create regulatory efficiencies where possible to drive broader access to tools that improve American health, while maintaining the safety and efficacy standards that patients should expect from their FDA-reviewed products."

According to the National Cancer Institute at the National Institutes of Health, approximately 38.5 percent of American men and women will be diagnosed with a form of cancer at some point during their lifetime. Unlike many cancer diagnostics that are designed to detect one cancer biomarker for use with a single drug, the IMPACT test works by comparing tumor tissue to a "normal" sample of tissue or cells from the same patient to detect genetic alterations that might help guide treatment options. While the test is intended to provide information on cancer biomarkers, its results are not conclusive for choosing a corresponding treatment.

“NGS technologies can examine hundreds, if not millions, of DNA variants at a time; and we are only at the beginning of realizing the true potential for these devices to assist patients and their health care providers in learning about the genetic underpinnings of their disease,” said Jeffrey Shuren, M.D., director of the FDA’s Center for Devices and Radiological Health. “Recognizing the significant effect information about an individual’s biomarkers can have on their care planning and outcomes, the FDA worked closely with NYSDOH and MSK to help ensure that the IMPACT test is accurate, reliable and clinically meaningful. This collaboration is an excellent example of how the FDA can partner with the medical and development communities to review innovative tests as quickly as possible.”

The IMPACT test was reviewed by the FDA through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no legally marketed device (predicate device). Its ability to detect genetic mutations (analytical performance) was evaluated for precision, accuracy and limit of detection. Results indicated that the assay is highly accurate (greater than 99 percent) and capable of detecting a mutation at a frequency of approximately 5 percent (range of 2-5 percent). Additionally, detection of certain molecular changes (microsatellite instability) using the IMPACT test was concordant more than 92 percent of the time across multiple cancer types in 175 cases, when compared to traditional methods of detection.

Specific to the IMPACT test’s authorization, the NYSDOH previously conducted its own review and approved it for use on samples coming from patients in the state of New York. However, MSK had not previously submitted the test for the FDA’s review because it is a laboratory-developed test, for which the agency has generally not enforced premarket review and other applicable requirements. MSK submitted a de novo application for the IMPACT test to the FDA, including and extending the information submitted for NYSDOH’s prior review, to inform and expedite today’s FDA authorization.

Along with this authorization, the FDA is also establishing a Class II regulatory pathway for the review of other NGS-based tumor profiling tests for use in patients diagnosed with cancer. Class II designation allows these types of tests to be eligible to use the FDA’s 510(k) clearance process, either by submitting the application to the FDA directly or through an accredited third-party reviewer, like NYSDOH.

The FDA granted marketing authorization for the IMPACT tumor profiling assay to Memorial Sloan Kettering Cancer Center.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA: MSK-IMPACT Decision Summary (https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170058.pdf)**
- **FDA: CDRH’s Approach to Tumor Profiling Next Generation Sequencing Tests (PDF - 175KB) (/downloads/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/UCM584603.pdf)**
- **FDA: Medical Devices (http://www.fda.gov/MedicalDevices/default.htm)**
- **FDA: De Novo Pathway (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm462775.htm)**
- **FDA: Premarket Notification 510(k) (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotifica**

- **FDA: Third-Party Review (https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/thirdparyreview/def**
- **FDA: Laboratory-Developed Tests (https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/laboratorydevelopedtests/default.htm)**
- **FDA: CDRH Office of In Vitro Diagnostics and Radiological Health (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm115904.htm)**

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