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Self-Collection Kits in the Crosshairs

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By: Nathan A. Brown, Caroline D. Kessler

The Food and Drug Administration (FDA) has begun 2026 with a clear signal to the direct-to-consumer testing industry: self-collection devices remain firmly within the agency's regulatory reach, notwithstanding the 2025 court ruling on laboratory developed tests (LDTs). Last week, the agency published warning letters previously issued to four companies—Genetrace, Genovate, Germaphobix and ProDx Health—selling human immunodeficiency virus (HIV) tests that rely on unauthorized self-collection kits.

According to the warning letters, these companies offer HIV testing services that include distribution of self-collection kits containing dried blood spot (DBS) cards, which allow patients to collect blood samples at home and mail them to laboratories for testing. FDA considers these DBS cards to be medical devices, and they lack agency authorization for use for self-collection.

This compliance activity comes after a significant setback for FDA last year, when the U.S. District Court for the Eastern District of Texas vacated the agency's final rule on LDTs. The rule would have formally established FDA's authority to regulate LDTs as medical devices, resolving a longstanding disagreement over the agency's role in overseeing these tests. This is not the first time FDA has taken advisory actions relating to HIV self-collection kits. FDA had issued a warning letter to another entity offering an HIV DBS card self-collection kit in October 2024, but that preceded the court's decision on the LDT Rule.

While FDA can no longer rely on the vacated LDT Rule, the agency has consistently asserted that it retains authority over collection devices used to collect samples that are then analyzed on LDTs. FDA signaled this in the preamble to the LDT Rule, in which the agency

clarified that its policy towards LDTs did not apply to collection devices, even if used with an LDT.

These warning letters confirm that FDA retains that position, and will initiate compliance actions accordingly, at least in some situations. However, it is noteworthy that these warning letters were issued by the Center for Biologics Evaluation and Research (CBER), which regulates HIV tests, rather than the Center for Devices and Radiological Health (CDRH), which regulates most types of tests.

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