Workshop Glossary

Community Voices: Forging the Path Forward for HIV Self-testing and Personalized Viral Load Monitoring

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Term	Abbreviation	Description
Affordable, Sensitive, Specific, User-friendly, Rapid & robust, Equipment-free, Delivered to the end-user	**ASSURED**	WHO-designated, important criteria for point-of-care (POC) diagnostics *Related:* **REASSURED**: Real-time connectivity, Ease of specimen collection, Affordable, Sensitive, Specific, User-friendly, Rapid & robust, Equipment-free or simple, and Deliverable to end users
Antigen/Antibody test	**Ag/Ab test**	A test for the presence of specific antigen (e.g., viral protein) or antibody (i.e., evidence of a prior immune response) in a bodily fluid (e.g., blood, saliva, urine, etc.)
Anonymous testing		Personal identifiers are removed or coded so that only the user will know their results *Related:* **Confidential testing**: The user's test result will be a part of their medical record and is protected by confidentiality and privacy laws
Assay		A test to determine the presence, amount, and/or function of a target substance
Class I medical device		Class I medical devices are among the most common class of devices regulated by the U.S. Food and Drug Administration (FDA). Class I devices present minimal potential for harm to the user and low impact on their overall health (e.g., electric toothbrush, bandages, wheelchairs). The majority of Class I devices are exempt from FDA premarket notification (510(k) and premarket approval (PMA).
Class II medical device		Class II devices are more complicated than Class I devices and present more risk to the user. These include devices that come into contact with the user's internal organs and diagnostic tools (e.g., catheters, contact lenses, pregnancy test kits). Most Class II devices are approved via FDA's 510(k) application process.
Class III medical device		Class III devices are intended to sustain or support life and may include implanted devices (e.g., pacemakers, cochlear implants, implanted prosthetics). Class III devices are subject to the stringent PMA approval process. Currently, HIVST devices are Class III medical devices.
Clinical Laboratory Improvement Amendments (of 1988)	**CLIA**	Regulation for all U.S. facilities that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease *Related:*

		CLIA-waived: Tests cleared by the FDA for home use. Typically, CLIA-waived tests are simple and have a low risk for erroneous results.
Clinical validation		The process of testing a device's accuracy to meet clinical standards
Colorimetric detection		A test that forms a color (or changes in color) to indicate a result
Diagnostic		A test performed to aid the diagnosis or detection of disease
Emergency use authorization	**EUA**	The FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency (as designated by the Secretary of the U.S. Department of Health and Human Services) to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, and nuclear threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.
Fingerstick blood		A procedure in which a finger is pricked to obtain a small amount of blood for testing
U.S. Food and Drug Administration	**FDA**	As codified in the Federal Food, Drug, and Cosmetic Act, the FDA has legal authority to regulate medical devices
HIV self-testing	**HIVST**	A self-administered HIV antibody test that can be used at home or in a private location. *Related:* **Directly assisted HIVST**: When trained providers or peers give an in-person demonstration on how to perform the test and interpret the test result. **Unassisted HIVST**: When individuals self-test and only use an HIVST kit with manufacturer-provided instructions. **Mail-in HIV test**: An antigen/antibody test that involves collecting fingerstick blood and sending the sample to a lab for testing.
In vitro diagnostics	**IVD**	Tests done on samples, such as blood or tissue, that have been taken from the human body. IVD can detect diseases or other conditions. Some tests are used in the laboratory or health care settings, while others are available for consumers to use at home.
Index case testing	**ICT**	HIV testing of the contacts of an index client who is known to be have HIV.
Lateral-flow assay	**LFA**	A paper-based, simple device to detect the presence or absence of a target substance in a liquid sample without the need for specialized equipment or electricity.
Limit of detection	**LOD**	The smallest concentration that can be detected using a given test or procedure.
Loop-mediated isothermal amplification	**LAMP**	A low-cost, simple, isothermal nucleic acid amplification technique that is an alternative to polymerase chain reaction (PCR) technology.

Microfluidics		A system that analyzes very small amounts of fluid in small channels incorporated into microfluidic chips.
Mobile health	**mHealth**	Medical and public health practice supported by mobile devices.
Multiplex		Simultaneous testing for multiple pathogens in a single experiment.
National Institute of Biomedical Imaging and Bioengineering	**NIBIB**	NIBIB's mission is to transform through engineering the understanding of disease and its prevention, detection, diagnosis, and treatment. NIBIB supports new tools and technologies to improve human health within its internal laboratories and through grants, collaborations, and training.
NIH Rapid Acceleration of Diagnostics	**RADx®**	The RADx initiative served as a national call for scientists and organizations to submit their innovative ideas for novel COVID-19 testing approaches and strategies. Funded projects encompassed novel applications of existing technologies aimed at enhancing the ease of test utilization, increasing accessibility, and improving accuracy.
Nucleic acid amplification tests/Nucleic acid tests	**NAAT/NAT**	Molecular-based diagnostic tests used to amplify and detect nucleic acids (genetic material) from pathogens. NAAT, also known as nucleic acid tests (NAT), can detect HIV sooner than antigen/antibody tests and is a critical tool in the early detection and management of HIV.
OraQuick		This rapid self-administered, over-the-counter (OTC) HIV test is the only in-home HIV test approved by the FDA for use in the United States. The test uses oral fluid to check for HIV antibodies and produces a result in 20-40 minutes.
Over the counter	**OTC**	Medicine, medical devices, and health supplies that can be purchased without a prescription
Point of care/Point of care testing	**POC/POCT**	Simple medical tests that can be performed at the time and place of patient care. Handheld devices and/or portable equipment may be required. *Related:* **Near point of care**: On-site testing that can be performed outside conventional laboratories by non-laboratory personnel, with results delivered within 24 hours.
Point-of-Care Technologies Research Network	**POCTRN**	The NIBIB created the Point-of-Care Technologies Research Network (POCTRN) to develop technologies with clinical applications using a network model that enhances complementary strengths and builds multidisciplinary partnerships. Each POCTRN center performs or facilitates five core functions: • Conducts in-house clinical testing of prototype point-of-care devices • Collaborates with physical, biochemical and computational scientists, and engineers on exploratory technology development projects • Completes clinical needs assessments in areas anticipated to advance the field of point-of-care

		testing and disseminates this information to the technology development community • Provides training to technology developers on clinical issues related to the development of point-of-care devices • Provides an adequate administrative structure to ensure that the large complex center achieves its goals
Premarket approval	**PMA**	Class III medical devices are required to submit a PMA application that includes technical information, non-clinical laboratory studies, and clinical investigations to demonstrate the safety and effectiveness of the device. It is a stringent, costly, and lengthy process. The PMA application is reviewed by the FDA and may be referred to an outside advisory committee when the device is a first of its kind. The FDA will also inspect the manufacturing process of the device.
Premarket notification 510(k)	**510(k)**	A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is as safe and effective (substantially equivalent) as a legally marketed device.
Rapid diagnostic test/Rapid test	**RDT**	Diagnostic tests with short performance times that sometimes produce less sensitivity and/or specificity than standard laboratory assays
Regulatory requirements		Requirements that are established by law
Reverse transcriptase polymerase chain reaction	**RT-PCR**	A laboratory-based molecular technique used to amplify nucleic acid (genetic material) from specific targets. RT-PCR is used primarily to amplify and detect RNA (i.e., the genetic material of HIV), while PCR can be used to amplify and detect DNA.
Sensitivity		The ability of a test to designate a positive result correctly
Sexually transmitted infections	**STI**	Viral and bacterial infections that are spread predominantly through sexual contact. Some STIs also can be transmitted during pregnancy, childbirth, breast/chestfeeding, and through infected blood or blood products.
Specificity		The ability of a test to designate a negative result correctly
Status		Whether HIV is in a person's body
Testing algorithm		A diagnostic testing plan to confirm rapid screening test results
Use case		A specific situation in which a product or service could potentially be used
Window period		A timeframe when a person has HIV but antibodies to the virus cannot be detected. Most people (97%) will develop antibodies in the first three months following HIV acquisition, though it can take up to six months. It takes time for the immune system to produce enough antibodies for a test to detect them, so the window period can vary based on the test device and on the individual.

World Health Organization	**WHO**	WHO is a specialized agency of the United Nations that is responsible for international public health. Among many other roles, WHO supports regulatory authorities and manufacturers to ensure quality, safety, and performance of medical devices. The WHO Global Model Regulatory Framework for Medical Devices (GMRF), recommends guiding principles and harmonized definitions for medical devices, including in vitro diagnostic medical devices, and specifies the elements of regulations to be embodied within national laws.

Additional Reading:

Ma S, Manabe YC. Highlighting and addressing barriers to widespread adaptation of HIV self-testing in the United States. *Expert Rev Mol Diagn*. 2023 Mar;23(3):191-198. doi: 10.1080/14737159.2023.2187291. Epub 2023 Mar 8. PMID: 36891583; PMCID: PMC10119889

Rodriguez NM, Burleson G, Linnes JC, Sienko KH. Thinking Beyond the Device: An Overview of Human- and Equity-Centered Approaches for Health Technology Design. *Annu Rev Biomed Eng*. 2023 Jun 8;25:257-280. doi: 10.1146/annurev-bioeng-081922-024834. Epub 2023 Apr 17. PMID: 37068765