## APPENDIX A:

**Testing at Home Terms Guide**

A glossary of *critical terms* to help improve understanding and reduce confusion around the myriad of ways that tests can be performed at home, especially as telehealth supervised testing expands.

To further the understanding around the many tests that can be performed at home as telehealth expands, the ATA Home Testing SIG has begun building a dictionary of key terms. This appendix is focused on consumer conducted tests and suggests standard definitions of those terms that are *critical to having crisp and clear communications between patients, their clinicians and across industry constituents on these new phenomena.*

The glossary addresses terms in four broad categories spanning the home testing experience. Namely, the …

TYPE OF TEST / SAMPLE TYPES
What biological artifact is being tested and what kind of sample is needed

SOURCING THE TEST
How does one procure a test a test is sourced

THE TEST PROCESS
Steps include Collection, Processing, Resulting, Reporting, Follow up

TEST DEVICE TYPE
Different types of devices and physical processes performed at the lab, or inside the test device

If you, like many, are new to these terms, at the end of the glossary we have also included a simplistic primer on how testing fits in an infectious disease scenario.

| TEST SAMPLE TYPE<br>What biological artifact is being tested and what kind of sample is needed | |
|---|---|
| Antibody Test | Testing kits that determine the presence and/or quantity of specific antibodies in the patient, typically using a blood sample. May indicate that the person had previously been exposed to the target pathogen. May also be used in monitoring vaccine longevity. |
| Antigen Test | Testing kits and products that detect an unamplified feature of a pathogen (often a protein). Samples may be taken from swab, spit or blood. |
| Molecular Test<br><br>*aka* Nucleic Acid Amplification Test (NAAT) | Molecular tests look for a virus's genetic material in a test sample, which can be taken from a swab, spit, or blood. Genetic materials (specifically, nucleic acids) are isolated from a test sample and then copied many times, so that even small amounts of the genetic material can be detected. PCR and LAMP are two well-known types of NAAT. |

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| TEST DEVICE TYPE<br>Different types of devices and physical processes performed at the lab, or inside the test device | |
|---|---|
| Lateral Flow | A testing device that employs a wettable membrane to carry (or 'flow') the sample material to come into contact with one or more test wells shaped as lines (chemistries and controls). Test lines change color to indicate results of the interactions. The intensity and color of the lines can also provide information that can be used to interpret the result. |
| PCR (Polymerase Chain Reaction) | The most sensitive test for infectiousness is a molecular PCR test. This type of test takes a few hours to process, but can detect extraordinarily low levels of RNA, which can indicate that you might be or become contagious at times when other tests do not. |
| LAMP (Loop Mediated Isothermal Amplification) | Designed to detect a target nucleic acid without requiring sophisticated equipment, LAMP tests provide relatively high sensitivity but with rapid results and lower cost as compared to PCR tests. Reactions can be performed in as little as 5–10 minutes and with limited resources, using a water bath for incubation and detection of results by eye, or with real-time measurement and high-throughput instruments. |

| TEST PROCESS<br>Steps include Collection, Processing, Resulting, Reporting, Follow up | |
|---|---|
| Sample Collection Kit | These kits provide the supplies and instructions for the consumer to collect a sample themselves and how to send the sample to a lab. Sample Collection Kits by definition come together with a service from a lab that, at a minimum, processes the sample to generate results. Other services may be offered related to Reporting, Education, and Follow up. |
| Self-Test Kit | A product that enables a consumer, wherever they are, to test themselves without medical training. At a minimum, to collect a sample, insert the sample into a device that does the processing and generates results displayed back to the consumer. Self-Test Kit products may also include post-result services such as reporting to medical records or public health authorities, medical referrals and/or contact tracing. |
| Medical Lab Record vs. Undocumented Self Test | Tests that produce a report that gives the consumer a Medical Lab Record of the test result that can be included in their medical record and be used to fulfill formal screening requirements of employers, transportation systems and venues. Undocumented tests provide the consumer with a test result for informational purposes, but do not provide a Medical Lab Record and can not be used in place of a medical test. |

# Appendix

## TEST PROCESS (cont.)

**Steps include Collection, Processing, Resulting, Reporting, Follow up**

| | |
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| Supervised vs. Unsupervised Self Test | Supervised tests employ telehealth sessions or mobile app interaction to coach, proctor and/or validate the proper sample collection, testing steps and result interpretation. Usually, supervised tests generate a Lab Record of the test. Unsupervised tests are ones where the consumer takes the sample and conducts the steps of the test without observation or assistance. Some Unsupervised Tests provide a Lab Record while others do not. |
| Consumer Reporting / Federated Reporting | Test kits that generate a Lab Record provide a consumer facing method to download and store the Lab Record from the test. This allows the report to be forwarded at the consumer's discretion and/or shown on the consumer's phone as needed. Some solutions support opt-in services to report results automatically to connected systems. Such systems include Public Health surveillance, consumer medical credential services, provider medical record systems, pharmacy record systems. It is important to note that some tests generate no reports. There are also some tests that do not give the subject an ability to opt-out of reporting. |
| Rapid Test | A generic term to describe a Self-test kit or a clinician performed test that produces results right away or very quickly. A Rapid Test could be built around any number of sample types and devices. The term 'Rapid Test' has been used broadly to refer to many types of tests. Therefore, more specificity is required when referring to a "Rapid Test' to understand 'what' test can be done rapidly. |

## TEST SOURCING STRATEGY

**How one procures a test**

| | |
|---|---|
| Direct to Consumer (DTC) | DTC tests are marketed and sold directly to the consumer with purchase by the consumer at a physical or internet store. DTC tests may or may not require a prescription. Generally, DTC tests are Sample Collection Kits or Self-Collection Kits. |
| Over the Counter (OTC) | The FDA describes OTC as "Tests that can be purchased and used by anyone at home. These do not require a doctor's prescription. If manufacturers intend to sell their test kits over the counter, they must demonstrate that untrained lay persons can perform the tests and get good results." |
| Prescribed | Kits for tests that are prescribed by a medical professional can be sourced in various ways depending on the Type of Test and Process. Pharmacies and Labs offer services to perform prescribed tests and can provide kits for self-collection or self-test. In some cases, through internet-based outlets, the sourcing and prescribing is bundled into a single consumer purchase process and is rather seamless. |

## A Primer on the Pathology of Infection

To better understand where testing 'fits' in the diagnosis and monitoring of an infectious disease, it can be helpful to understand what happens when a pathogen enters the body.

After gaining entry to the body, a pathogen's genetic code drives it to begin to replicate itself, and multiply its ability to attack the body. If the body has never seen this pathogen before or any pathogens similar to this one, the pathogen can attack the cells of the body unchecked. Fortunately, this is rare, but can be fatal when it occurs.

Most of the time, a new pathogen has some features that resemble others that the body has seen before. These features, known as antigens, can be recognized by the body's immune system. The body creates and maintains an army of antibodies that specialize in detecting specific antigens of the invading pathogens it has encountered before. Our antibodies attach to the antigens that they are built to look for, and that process identifies the pathogen and alerts the entire immune system. If this detection happens early enough, and strongly enough, it will often give the immune system enough of an advantage to effectively attack and eliminate the pathogen.

When a new (novel) pathogen infects the body, such as when COVID-19 first emerged, the novel coronavirus does not exactly resemble the pathogens our bodies have seen before, and our initial resulting antibody response is weak. Once the novel pathogen starts to make the body sick, the antibody creation mechanisms go into overdrive trying to catch up. Anyone who survives an infection (through prior vaccination or luck) will at that point have new sets of antibodies that will recognize that novel pathogen very quickly if it shows up again.

Where does testing come to play in the case of infectious disease? That depends. What you learn from a test depends on what you are testing for.

> DID YOU HAVE IT?: A test looking for telltale antibodies will tell you if you ever had that pathogen in your body. But, it won't tell you if you are fighting an active infection now, or not. Antibody tests can be very useful for monitoring the lasting effects of vaccines.
>
> DO YOU HAVE IT NOW?: A test that can detect the specific antigen features of the pathogen can tell you if you have infectious / high levels of concentration of the pathogen in your body NOW. But, low concentrations of a pathogen, lower than can be reliably detected by an antigen test, are of real concern where the pathogen is very infectious, lethal or both.
>
> CAN YOU INFECT OTHERS?: For people without symptoms, the only reliable test for infectiousness is a high quality molecular PCR test. These tests take more time to process, but they look deeper into the omic codes in your body to see if the pathogen's (RNA) have appeared. Extraordinarily low levels of RNA can be detected, which can tell you that you might be or become contagious.

## APPENDIX B:

**Industry Resources**

**FDA:** The United States Food and Drug Administration (FDA or USFDA) is a federal agency of the Department of Health and Human Services. The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. (https://www.fda.gov/)

**CDC:** The Centers for Disease Control and Prevention (CDC) form one of the major operating components of the Department of Health and Human Services. The CDC is the nation's health protection agency, conducting critical science and providing health information to protect the nation against health threats in the form of disease, and responding when these arise. (https://www.cdc.gov/)

**CMS:** The Centers for Medicare & Medicaid Services (CMS) are part of the U.S. Department of Health and Human Services. CMS oversees many federal healthcare programs, including those that involve health information technology such as the meaningful use incentive program for electronic health records (EHR). CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA) regulations. (https://www.cms.gov/).

**CLIA:** Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. Run by CMS and jointly supported by the CDC and FDA, the CLIA program works to ensure quality laboratory testing across the country. In total, CLIA covers approximately 260,000 laboratory entities. Once a year CMS publishes key performance information about relevant laboratories in their Laboratory Registry.

(https://www.cdc.gov/clia/about.html)

(https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA)

(https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Laboratory_Registry)

**Many Types of Labs:** Clinical laboratories are healthcare facilities providing a wide range of laboratory procedures which aid the physicians in carrying out the diagnosis, treatment, and management of patients. These laboratories are manned by medical technologists (clinical laboratory scientists) who are trained to perform various tests on samples of biological specimens collected from its patients. Most of the clinical laboratories are situated within or near hospital facilities to provide access to both physicians and their patients. Classifications of clinical laboratories indicated below reveal that these facilities can provide quality laboratory tests that are significant for addressing medical and public health needs: Types of labs: https://www.ncbi.nlm.nih.gov/books/NBK535358/

# References:


i Kathleen McLaughlin, "Growing use of home Covid-19 tests leaves health agencies in the dark about unreported cases," STAT, December 7, 2021, https://www.statnews.com/2021/12/07/growing-use-of-home-covid19-tests-leaves-health-agencies-in-the-dark/.

ii Jenny Cordina, Jennifer Fowkes, Rupal Malani, and Laura Medford-Davis, "Patients love telehealth—physicians are not so sure," McKinsey & Company, February 22, 2022, https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/patients-love-telehealth-physicians-are-not-so-sure.

iii Oleg Bestsennyy, Michelle Chmielewski, Anne Koffel, and Amit Shah, "From facility to home: How healthcare could shift by 2025," McKinsey & Company, February 1, 2022, https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/from-facility-to-home-how-healthcare-could-shift-by-2025.

iv Lok Wong Samson, Wafa Tarazi, Gina Turrini, Steven Sheingold, "Medicare Beneficiaries' Use of Telehealth Services in 2020 – Trends by Beneficiary Characteristics and Location (Issue Brief No. HP-202127)," Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, December 3, 2021, https://aspe.hhs.gov/reports/medicare-beneficiaries-use-telehealth-2020; "Medicare Telemedicine Data Snapshot," Centers for Medicare & Medicaid Services, Medicare Claims and Encounter Data for March 1, 2020 to February 28, 2021, Received by September 9, 2021, p5, https://www.cms.gov/files/document/medicare-telemedicine-snapshot.pdf

v Gary W. Procop, Kamran Kadkhoda, Daniel D. Rhoads, Steven G. Gordon, Anita J. Reddy, MD, "Home testing for COVID-19: Benefits and limitations," Cleveland Clinic Journal of Medicine, February 9, 2021, https://www.ccjm.org/content/early/2021/02/11/ccjm.88a.ccc071#sec-12. DOI: 10.3949/ccjm.88a.ccc071

vi Rita Rubin, "COVID-19 Testing Moves Out of the Clinic and Into the Home" September 22, 2021 JAMA. 2021;326(14):1362–1364. doi:10.1001/jama.2021.15679 https://jamanetwork.com/journals/jama/fullarticle/2784554

vii Michelle Andrews, "Young people at risk for STDs often don't get tested, study says," PBS, June 4, 2016. https://www.pbs.org/newshour/health/young-people-at-risk-for-stds-often-dont-get-tested-study-says; Jessica L. Morris, Hamid Rushwan, "Adolescent sexual and reproductive health: The global challenges," International Journal of Obstetrics and Gynecology 131 (2015), S40-S42, https://doi.org/10.1016/j.ijgo.2015.02.006

viii Gay Becker, Edwina Newsom, "Socioeconomic Status and Dissatisfaction With Health Care Among Chronically Ill African Americans", American Journal of Public Health 93, no. 5 (May 1, 2003): pp. 742-748. https://doi.org/10.2105/AJPH.93.5.742.

ix "Strengthening Clinical Laboratories," Centers for Disease Control and Prevention, last modified November 15, 2018, https://www.cdc.gov/csels/dls/strengthening-clinical-labs.html.

x Eli Saslow, "'Out here, it's just me': In the medical desert of rural America, one doctor for 11,000 square miles," The Washington Post, September 28, 2019, https://www.washingtonpost.com/national/out-here-its-just-me/2019/09/28/fa1df9b6-deef-11e9-be96-6adb81821e90_story.html.

xi Ernest Moy, Macarena C. Garcia, Brigham Bastian, et al, "Leading Causes of Death in Nonmetropolitan and Metropolitan Areas — United States, 1999–2014," MMWR Surveill Summ 2017;66(No. SS-1):1–8. DOI: http://dx.doi.org/10.15585/mmwr.ss6601a1; CDC 2022

xii Shraddhaa Narasimha, Kapil Chalil Madathil, Sruthy Agnisarman, Hunter Rogers, Brandon Welch, Aparna Ashok, Aswathi Nair, and James McElligott, "Designing Telemedicine Systems for Geriatric Patients: A Review of the Usability Studies," Telemedicine and e-Health, Jun 2017, 459-472, http://doi.org/10.1089/tmj.2016.0178; Jan Trøst Jørgensen, "Improvement of Patient Convenience in Treatment with Growth Hormone" Journal of Pediatric Endocrinology and Metabolism 7, no. 2 (1994): 175-180. https://doi.org/10.1515/JPEM.1994.7.2.175; Jing Jin, Grant Edward Sklar, Vernon Min Sen Oh, Shu Chuen Li, "Factors affecting therapeutic compliance: A review from the patient's perspective," Therapeutics and Clinical Risk Management. 2008; 4(1): 269-286, doi: 10.2147/tcrm.s1458 https://www.dovepress.com/factors-affecting-therapeutic-compliance-a-review-from-the-patientrsqu-peer-reviewed-fulltext-article-TCRM; Pierre Chue. "Compliance and Convenience: Do Physicians and Patients See Depot Medication Differently?" Acta Neuropsychiatrica 16, no. 6 (2004): 314–18. doi:10.1111/j.0924-2708.2004.00099.x. https://www.cambridge.org/core/journals/acta-neuropsychiatrica/article/abs/compliance-and-convenience-do-physicians-and-patients-see-depot-medication-differently/69F6D43366CB30BD1E8F31866D521DAD

xiii "Can Colorectal Polyps and Cancer Be Found Early?" American Cancer Society, last modified June 29, 2020. https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/detection.html

xiv "Chronic Diseases in America, "National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), last modified January 24, 2022, https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm; Stella Ogunwole, Megan Rabe, Andrew Roberts, Zoe Caplan, "U.S. Adult Population Grew Faster Than Nation's Total Population From 2010 to 2020," United States Census, August 12, 2021 https://www.census.gov/library/stories/2021/08/united-states-adult-population-grew-faster-than-nations-total-population-from-2010-to-2020.html#:~:text=In%202020%2C%20the%20U.S.%20Census,from%20234.6%20million%20in%202010.

xv "Diabetes Basics," Centers for Disease Control and Prevention, last reviewed December 16, 2021 https://www.cdc.gov/diabetes/basics/type2.html; "Chronic Kidney Disease Basics," Centers for Disease Control and Prevention, last reviewed February 28, 2022 https://www.cdc.gov/kidneydisease/basics.html "Heart Failure" Centers for Disease Control and Prevention, last reviewed September 8, 2020 https://www.cdc.gov/heartdisease/heart_failure.htm;

xvi Laura Plantinga, Kirsten Johansen, Dean Schillinger, Neil Powe. "Lower Socioeconomic Status and Disability Among US Adults With Chronic Kidney Disease, 1999-2008," [Erratum appears in Preventing Chronic Disease 2012;9. http://www.cdc.gov/pcd/issues/2012/12_0047.htm.] Preventing Chronic Disease 2012;9:110052. DOI: http://dx.doi.org/10.5888/pcd9.110052; Majid Davari; Mohammad Reza Maracy; Elahe Khorasani, "Socioeconomic status, cardiac risk factors, and cardiovascular disease: A novel approach to determination of this association," ARYA Atherosclerosis Journal, 15, 6, 2019, 260-266. doi: 10.22122/arya.v15i6.1595 https://arya.mui.ac.ir/article_10706.html; Kritkantorn Suwannaphant, Wongsa Laohasiriwong, Nattapong Puttanapong, Jiamjit Saengsuwan, and Teerasak Phajan, "Association between Socioeconomic Status and Diabetes Mellitus: The National Socioeconomics Survey, 2010 and 2012." Journal of clinical and diagnostic research : JCDR vol. 11,7 (2017): LC18-LC22. doi:10.7860/JCDR/2017/28221.10286 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5583803/

xvii Morten Schmidt, Kathryn E Mansfield, Krishnan Bhaskaran, Dorothea Nitsch, Henrik Toft Sørensen, Liam Smeeth, Laurie A Tomlinson, "Adherence to guidelines for creatinine and potassium monitoring and discontinuation following renin-angiotensin system blockade: a UK general practice-based cohort study," BMJ open vol. 7,1 e012818. 9 Jan. 2017, doi:10.1136/bmjopen-2016-012818 https://pubmed.ncbi.nlm.nih.gov/28069618/