



# 2021 Annual Physician Notice

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Dear Healthcare Provider,

Acutis Diagnostics Inc. maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state and local laws. The Office of Inspector General for the U.S. Department of Health and Human Services ("OIG") has requested that clinical laboratories annually send an educational notice to physicians and practitioners authorized by law to order laboratory tests and are reimbursed by Medicare, Medicaid or another federally funded healthcare program (hereafter, "Federal Programs"). Accordingly, and as part of our corporate compliance program, Acutis is sending this to all physicians and practitioners who order tests from us. Please carefully review the information contained in this notice. If you have any questions, please contact Acutis at (844) 522-8847 and ask to speak with either our Compliance Officer or Medical Director.

### **Authorized Ordering Providers/Excluded Providers**

A clinical laboratory may examine a specimen only when the test has been ordered by a licensed physician, a qualified practitioner or designee. It is your responsibility to stop ordering tests and to immediately notify us if: (a) your license has been revoked or suspended; (b) you have been excluded from the Federal Programs; or (c) if your enrollment in Federal Programs has been revoked or suspended.

All orders shall consist of either (a) handwritten signature of name or initials, or (b) electronic or computer-generated signature of name or unique identifier acceptable to for Medicare and Medicaid Services (CMS).

### **Medical Necessity and Diagnosis Codes**

Federal Programs will only pay for tests if the test is covered, reasonable, and medically necessary for the beneficiary, given his or her clinical condition. A medically necessary test is defined as one that is reasonable and necessary for the diagnosis or treatment of an illness or injury. Physicians/practitioners should only order those tests that they believe are medically necessary for the diagnosis and treatment of their patient. Federal Programs will deny payment for a test that is not necessary, such as most screening tests (providers may only order tests as panels when each and every test is deemed medically necessary). In addition, your medical records must document the medical necessity for the tests ordered and, upon receipt of test results, updated to demonstrate how you used the information in the care and treatment of your patient.

CMS has developed National Coverage Determinations (NCDs) that define medical necessity for certain tests. Local Coverage Determinations (LCDs) are also published by contractors, such as NGS. You should review the NCDs and LCDs – particularly the medical necessity requirements – for the tests that you order. NCDs and LCDs can be viewed at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list%20type=ncd>.

In addition, physicians who order laboratory tests are required to provide diagnostic information at the time that the test is ordered. Acutis' requisition forms have designated space for you to include these codes as required. The ICD-10 codes selected by you must be accurate and as specific as possible, based on the patient's actual condition and information that is otherwise documented in the medical record. If you are ordering a test and cannot yet determine a diagnosis, you must provide the appropriate ICD-10 code that describes the patient's signs and symptoms.

Providing complete and accurate diagnosis information at the time the test is ordered not only meets government requirements, but also minimizes the need for Acutis to contact you afterwards to request additional diagnostic information. The OIG requires that, when the diagnosis is unclear or has not been provided, the laboratory "contact the ordering physician" to obtain the necessary information. Laboratories are prohibited from using diagnostic information provided by the physician from earlier dates of service (except for certain standing orders, as described below), and from inserting diagnosis codes based on their own evaluation of the patient's probable or most likely diagnosis, or from speaking with a patient. If the information your office has provided to Acutis is inadequate or incomplete, we will contact your office in accordance with OIG guidance.

Providing complete and accurate information is very important. The OIG takes the position that physician/practitioners who knowingly cause a false claim to be submitted to any federally funded program (for example, by ordering medically unnecessary tests) may be subject to sanctions or remedies available under civil, criminal and administrative law, such as the False Claims Act. Potential penalties also include exclusion from Federal Programs.

### **Practices Ordering Drug Tests**

Providers are responsible for knowing each payor's policy (whether it be Medicare, Medicaid or commercial insurance) prior to ordering a test for a patient (this includes knowing the testing frequency permitted by a payor). As it relates to drug tests, Medical records must support the need for each drug or drug class being tested.

Definitive (confirmation) testing should ONLY be ordered when medically necessary and in compliance with applicable federal and state laws, regulations and/or payor rules and policies. In general, samples should first have presumptive (screen) testing performed, and definitive/confirmatory testing may be ordered ONLY if:

- Screen results are positive, or
- Screen results are inconsistent with the patient condition

Definitive testing may be ordered directly when medically necessary if there is no presumptive testing available for the particular compound(s) needed to be tested.

To help guide physicians who order urine drug testing (UDT), Medicare has issued the Limited Coverage Determination (LCD) which applies to all urine drug testing sent to Acutis. The document is available at the following link:

<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=56818&ver=10&keyword=UDT&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact>

Providers are also directed to the Medicare Learning Network publication entitled *"Provider Compliance Tips for Lab Tests – Other – Urine Drug Screening"* (available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceTipsforLabTests-Other-ICN909412.pdf>).

New York State Medicaid provides coverage and reimbursement policies for both Medicaid Managed Care (MMC) and Medicaid Fee-For-Service (FFS) for drug testing at the following link: [https://www.health.ny.gov/health\\_care/medicaid/program/update/2017/2017-04.htm#drugtest](https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-04.htm#drugtest)

In addition, there are a variety of educational resources available to ordering providers. The American Society of Addiction Medicine ("ASAM") and the National Institute on Drug Abuse are examples of organizations that provide online resources for providers ordering drug tests and treating patients with drug addiction.

## Practices Ordering Acutis Reveal™ infectious disease testing

Please note the performance of the tests has not been established for patients without signs and symptoms of respiratory infection. Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the practitioner who is evaluating and/or treating the patient. Viral and bacterial nucleic acids may persist in vivo independent of organism viability.

## Acutis reveal™ COVID-19

Acutis providers are encouraged to review and assess Federal, State and payer guidelines for appropriate ordering of COVID-19 tests for asymptomatic patients and healthcare workers.

Continued guidance on testing can be found on the Centers for Disease Control and Prevention (CDC) website here:

<https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>  
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html>



Please note CDC guidelines does not constitute payer coverage which may vary by state and health plan.

Our clinical consultants are available to speak with you to provide the information you need. Please feel free to reach out via secure email at [service@acutis.com](mailto:service@acutis.com) or via secure phone line at (844) 522-8847.

## Test Ordering

All tests are available to be ordered by paper requisition forms and through a secure electronic portal. The Acutis requisition form (whether ordering through the secure portal or on the paper requisition form) is designed to emphasize the importance of ordering only what is medically necessary as noted in the Medical Necessity section above. All required fields must be completed to ensure proper sample processing without any delays. For instances where the required fields are incomplete, Acutis will make the best effort to contact the ordering practitioner and organization for resolution. We appreciate your cooperation in submitting valid orders.

## Custom Profiles

With the recent guidance and direction received from Medicare Administrative Contractors, other government regulatory authorities and commercial insurers, Acutis Diagnostics will prohibit the use of custom test profiles. The decision to move away from custom test profiles was made in an effort to ensure that laboratory services ordered by clinicians for each patient are medically necessary.

## Standing Orders and Reflex Tests

In situations in which a patient is receiving an extended course of treatment, it may be necessary to create a standing order with the laboratory to have the same test conducted on a periodic basis. While such orders are not prohibited as a matter of law, the OIG notes that such orders have "too often in the past" led to "fraudulent and abusive practices." Like any other order for tests that will be reimbursed by Federal Programs, each test must be medically necessary, and the OIG takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law.

As a result, once it is no longer necessary to conduct a test specified in a standing order, the order must be terminated. The OIG asks laboratories to verify the patient's continuing need for a specified test. Accordingly, we will periodically contact you to conduct such verification.

Reflex confirmatory testing may be performed depending on the testing ordered by the physicians/providers. Reflex testing occurs when the initial test results are positive and/or inconsistent with expected results based on the patient's prescribed therapy and indicate that a second related test is medically appropriate. It is the physicians/providers' responsibility to ensure documentation is present in the patient's medical record to support reflex testing.



## American Medical Association (AMA) Defined Organ/Disease Panels

These panels may only be ordered when all components are medically necessary. Physicians/practitioners should order individual tests or a less inclusive profile if all tests in a panel are not medically necessary for an individual patient. A list of the 2019 AMA defined Organ/Disease Panels and their detailed test components is provided with this letter.

## Laboratory Services Provided to Hospitals and Skilled Nursing Facilities

When a hospital obtains laboratory tests for outpatients under arrangements with clinical laboratories, only the hospital can bill for the arranged services. The Medicare Outpatient Prospective Payment System (OPPS) states that payment for laboratory services provided to hospital outpatients is generally packaged into the payment for the outpatient procedure performed. Diagnosis related group (DRG) payments made to hospitals are packaged with the payment for clinical diagnostic laboratory tests provided to hospital inpatients under the Medicare Inpatient Prospective Payment System (IPPS).

Skilled nursing facilities (SNFs) may have an agreement with a reference laboratory for the reference laboratory to provide services. Referenced in the Medicare Claims Processing Manual, CH. 16, Sec. 40.4.1, Only SNFs can bill the Medicare Administrative Contractor (MAC) under Part A. Payment for clinical diagnostic laboratory tests under Part A are provided to SNFs similar to the DRG payments to hospitals. The reference laboratory may bill the MAC under Part B. CMS policy requires that the service be paid under the fee schedule, whether or not the beneficiary is in a Medicare certified bed.

If Acutis' laboratory services are ordered for a hospital patient or a skilled nursing facility resident, please notify your Acutis account manager to ensure that the services are billed appropriately.

## Advance Beneficiary Notice of Non-Coverage

If you deem it clinically appropriate to order a test that Medicare may find to be medically unnecessary and thus not reimbursable, we ask that you have the patient complete and sign a Medicare Advance Beneficiary Notice of Non-coverage form. This notice informs that patient that the test may not be covered by Medicare and that he or she thus may be liable for paying for the test. In cases in which medically unnecessary tests are performed for a Medicare patient, the patient generally may not be billed for the service without such a notice having been completed. You can find the Advance Beneficiary Notice of Non-coverage Form (CMS-R-131), instructions on using the form and more information from CMS on this topic here:

<https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN#:~:text=The%20Advance%20Beneficiary%20Notice%20of,payment%20is%20expected%20to%20be>

## Medicare Clinical Laboratory Fee Schedule

The current Medicare fee schedule for all clinical lab testing can be found at this link: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched>



Please note that Medicaid fees vary from state to state and are usually at or below the above schedule.

### Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), Acutis Diagnostics Inc. is a health care provider and a covered entity. It is our policy to fully comply with the HIPAA privacy and security standards. Our privacy policy is available at <https://www.acutis.com/hipaa-privacy>

### Prohibited Referrals and Inducements

It is Acutis' policy that all management, employees, independent contractors, vendors, agents, and others that are affiliated with Acutis comply with all federal and state anti-kickback and Stark laws and regulations.

Stark law's (also known as the physician self-referral law) self-referral ban prohibits a physician from making a referral for certain specified "designated health services" that are paid for by Medicare or Medicaid to an entity when the physician (or his or her immediate family member) has a "financial relationship" (that is, an ownership interest, an investment interest or a compensation relationship) with that entity and the relationship does not fit into one of the law's exceptions.

Federal law prohibits offering or paying any remuneration for the referral of tests that are covered by Medicare, Medicaid or other federal health care programs. Violation of the Federal anti-kickback law to secure the referral of federal health care program testing business is strictly prohibited.

Violation of prohibited referrals and inducements should be reported to the Acutis compliance hotline by calling (631) 606-4192.

### Provision of Supplies

Acutis provides supplies and materials to ordering physicians and practitioners only to the extent that such items are directly related to the collection, preservation, transport or storage of specimens for which tests are being ordered from Acutis. In addition, such supplies and materials are provided only to the extent that there are assurances that these items are, in fact, being used exclusively for these limited purposes. Acutis tracks the volume of supplies provided to physicians/practitioners and compares that volume with the number of tests ordered by the physician/practitioner, to ensure proper usage by the ordering physician/practitioners and to prevent improper or excessive ordering.

Acutis may provide computers and related equipment to physicians/practitioners. This equipment is provided only for the limited purpose of allowing the physician/practitioner to order tests from Acutis and to receive the test results once the tests are completed. This equipment, by its design, cannot be used for other purposes, and remains, at all time, the property of Acutis.



Acutis does not supply personnel to physicians/practitioners to operate physician/practitioner owned equipment, perform phlebotomy services in the physician's/practitioner's offices, except where permitted by regulation, or to provide any other service to the physician/practitioner in his or her office.

### Financial Assistance Program

Under its Financial Assistance Program, Acutis provides reductions in patient responsibilities only if there is some form of documentation to the patient's financial need. In the usual case, such documentation can be supplied by the ordering physician/practitioner, who must explain the patient's financial need, detail the extent of the discount required, and attest that he or she is providing a comparable discount to the patient.

Such financial assistance will be provided only in consideration of a patient's true need. Acutis will provide financial discount based upon a multiple of the Federal Poverty Guidelines. Documentation of such requests will be maintained as per New York State Guidelines.

It is illegal to offer remuneration to a patient or practitioner to induce the patient to order an item or service for which payment may be made under Federal Healthcare Programs.

### Contact

Should you have any questions on these materials, please contact the Acutis Compliance Office at (844) 522-8847. Acutis' anonymous Compliance Hotline can be reached at (631) 606-4192.