AMERICAN COLLEGE OF RHEUMATOLOGY POSITION STATEMENT

SUBJECT:	Office Laboratory Testing
PRESENTED BY:	Committee on Rheumatologic Care
FOR DISTRIBUTION TO:	Members of the American College of Rheumatology Members of Congress Centers for Medicare & Medicaid Services Medical Societies Arthritis Foundation and other Groups that advocate on behalf of people with rheumatic disease

POSITIONS:

- 1. The ACR strongly believes that all patients should have access to in-office laboratory testing as a component of their care when an in-office laboratory is available.
- 2. Insurance payment for diagnostic lab tests must provide appropriate reimbursement to cover the labor and processing costs of in-office testing.

BACKGROUND:

The availability of in-office physician laboratory testing remains an integral component of comprehensive patient care. Proximity to the rheumatologist ensures better communication between the rheumatologist and the laboratory staff about tests that require special handling, for example, synovial fluid analysis. Serologic tests such as antinuclear antibody (ANA) require advanced training to be appropriately performed and interpreted, and the rheumatologist can provide oversight and feedback to laboratory staff about these processes. The capability of the healthcare provider to evaluate specimens directly and receive results promptly inside their own medical record improves his or her ability to efficiently make informed decisions regarding a patient's treatment plan in a timely fashion. The close working relationship between the provider and the laboratory staff ensures better communication about tests and close feedback on concerning or unusual results.

The convenient access to an in-office lab draw decreases time away from work or school. Eliminating travel requirements also decreases hardship for individuals with transportation challenges due to limited income or geographic distance, and those who are acutely ill, elderly, or disabled. For pediatric patients, in-office phlebotomy ensures pediatric patients seeing pediatric rheumatologists have access to experienced pediatric phlebotomists. In-office testing is costeffective for the healthcare system, as lab processing costs in the hospital setting are often much higher than in the outpatient sector. Finally, it is important that the reimbursement for laboratory testing in the office setting be fair and appropriate for the testing and work performed. In-office laboratory is a longstanding ancillary service provided to patients as part of a comprehensive health-care experience. As with all accredited clinical laboratories, physician office laboratories must utilize test methods within the technical capabilities of the facility and appropriate for the patients it serves. A quality control program which monitors precision of laboratory performance is necessary. This program should include proficiency testing, instrument maintenance, and continuing education for staff. Staff should regularly review and maintain a procedure manual, including compliance procedures. As part of efficient record-keeping, there should be easily accessible historical and current information to allow for comparison of test results.

Physician office laboratories should be required to have sufficient space, equipment, facilities, and supplies for the performance of their required volume of work with accuracy, precision, efficiency, and safety. They should provide prompt and reliable results. Physicians who direct the laboratory shall be responsible for ensuring that there are personnel with adequate training to conduct the work of the laboratory. A certified (ASCP, state or equivalent) medical technician or medical laboratory scientist should be permitted to serve in the capacity of general supervisor when the laboratory physician director is not on the laboratory premises.

Federal regulation of physician office laboratories should explicitly recognize private sector accreditation programs as appropriate whenever possible. New regulations should be compatible with the workflow of existing organizations that credential office laboratories, such as COLA (previously known as the Commission on Office Laboratory Accreditation). Those laboratories that meet the standards of an approved private sector accreditation body should be automatically approved for federal certification, provided that the accreditation body has standards that are equal to or more stringent than those of the Department of Health and Human Services (HHS). This should preclude the need for laboratories to apply separately for federal certification or to provide additional or duplicative documentation and fees to HHS once the laboratories have satisfied the requirements of a private accreditation body.

CONCLUSION:

Physician office laboratories provide an important and cost-effective service that must be preserved under any federal or payer policy. The benefits for the patient and for the physician and health care professional are numerous. Rheumatologists who direct their office laboratories are the most qualified managers for determining the utilization of specific tests, analyzing results, and applying these results to therapeutic situations. The ACR strongly supports efforts to maintain access for patients to in-office laboratory testing for reasons of quality care, improved communication, and improved access for all patients.

Note: This position statement was formerly titled "Clinical Laboratory Testing" Approved by Board of Directors: 08/99 10/02 08/05 08/09 08/2013 11/2017 8/2021 11/2023