

## AMERICAN COLLEGE OF RHEUMATOLOGY POSITION STATEMENT

**SUBJECT:** Clinical 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 diseases

### **POSITION:**

The ACR strongly believes that all patients should have access to in-office laboratory testing as a component of their care. Physician office laboratory testing is a crucial component of a comprehensive patient care program. There are several benefits to patients who are able to get their ordered laboratory studies at the same location where they see their provider. These include, but are not limited to, the following:

1. The American College of Rheumatology believes that all laboratories, including physician office laboratories, should participate in appropriate quality assurance activities to ensure the integrity of results.
2. The capability of the healthcare provider to evaluate specimens directly and receive results promptly improves his or her ability to make informed decisions regarding a patient's treatment plan. Timely and accurate results are often critical to prevent clinical decline and morbidity. Some treatments require labs on the day of the visit, which would be highly difficult to perform without an in-office laboratory.
3. It is helpful for patients to see their healthcare provider and have laboratory tests performed at the same facility. The expediency of in office lab draw allows minimization of time away from work for employed adults or school for pediatric patients. Eliminating travel requirements also decreases hardship in individuals with transportation challenges due to limited income or geographic distance, and those who are acutely ill, elderly, or disabled. This is particularly relevant in the population of patients treated by rheumatologists.
4. In-office laboratory testing improves patient compliance with ordered laboratory studies. Patients who must travel to a separate location for ordered studies may delay or forget to

complete them. This will lead to missed laboratory abnormalities and loss of opportunity for prompt adjustment of the treatment plan.

5. In-office testing is cost-effective for the healthcare system, as lab processing costs in the hospital setting are much higher than in the outpatient sector.

6. The expertise of the rheumatologist ensures better accuracy in tests which require special handling, for example, synovial fluid analysis and serologic tests such as antinuclear antibody (ANA) require advanced training to be appropriately processed and interpreted.

7. In global pandemics, such as the SARS-2 coronavirus pandemic which began in 2019 and is ongoing, access to in-office laboratory services decreases the need for patients to seek care at multiple locations. Traveling and interacting with multiple providers increases infection risk. Many rheumatology patients are on immunosuppressant medications, so minimizing this risk is an important component of patient safety.

8. In-office lab testing ensures pediatric patients have access to experienced pediatric phlebotomists.

9. Insurance payment for diagnostic lab tests must provide appropriate reimbursement to cover the labor and processing costs of in-office testing.

#### **BACKGROUND:**

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 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 regulation programs as appropriate whenever possible. New regulations should build upon existing programs, such as that of the Commission of Laboratory Assessment (COLA). There is precedent for this in other sectors

of the healthcare system, e.g., the Joint Commission (previously known as JCAHO). Those laboratories which 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.

The ACR opposes any cost-containment proposals that recommend bundling of laboratory services and evaluation and management services. The ACR considers any reimbursement proposal which is based on calculations using an average of payments to be inherently inequitable, as this does not account and adjust for the wide variety of demographics and patient complexity which comprise individual physicians' practices.

**CONCLUSION:**

Physician office laboratories provide an important and cost-effective service that must be recognized and preserved under any federal policies to promote quality assurance. 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. When proficiency-testing results are requested by interested parties, the information necessary for their interpretation must be included.

Approved by Board of Directors: 08/99 10/02 08/05 08/09 08/2013 11/2017 8/2021