

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

BACKGROUND:

1
2 Physician office laboratory testing offers numerous benefits to patients and physicians. The
3 prompt receipt of test results and the capability to evaluate specimens directly improves the
4 efficiency of the physician in many common ambulatory patient encounters. Treatment plans can
5 be established or modified in a timely manner in this situation.

6
7 **Office testing is an important component of a comprehensive patient care program**

- 8
- 9 • It is convenient for patients to have all tests performed at one facility.
 - 10
 - 11 • Individuals with acute symptoms, or the elderly or disabled, can be evaluated more
 - 12 effectively in the office.
 - 13
 - 14 • Patients with rheumatic diseases may have severe mobility limitations. This could present
 - 15 considerable hardship if they were required to travel to an outside laboratory.
 - 16
 - 17 • Appropriate office testing can be cost-effective. It may reduce the number of return visits as
 - 18 well as saving travel time and costs for patients and their families, including leave time for
 - 19 employed patients.
 - 20
 - 21 • The expertise of the rheumatologist may insure better laboratory support in areas such as
 - 22 synovial fluid analysis and specialized tests such as rheumatoid factor.

23 **POSITION:**

24
25 1. The American College of Rheumatology believes that all laboratories, including
26 physician office laboratories, should participate in appropriate quality assurance
27 activities. The following components must be included:

- 28
- 29 • Selection of test methods appropriate to the needs of those served by the
30 laboratory and within the technical capabilities of the facility;
- 31
- 32 • A quality control program which monitors precision of laboratory performance;
- 33
- 34 • A proficiency testing program;
- 35
- 36 • An instrument maintenance program;
- 37
- 38 • A continuing education program for the laboratory staff, as well as review and
39 maintenance of a laboratory procedures manual;
- 40
- 41 • Reasonable documentation of laboratory functions;
- 42
- 43 • Efficient record-keeping, reflecting both historical and current information to
44 allow for ready comparison of test results which can be applied to the therapeutic
45 situation at hand.
- 46

47 2. Physician office laboratories should be required to meet the following standards:

- 48
- 49 A. Physician office laboratories shall have sufficient space, equipment, facilities, and
50 supplies for the performance of their required volume of work with accuracy,
51 precision, efficiency, and safety and to provide prompt and reliable reporting of
52 results.
- 53
- 54 B. Physicians who direct the laboratory shall be responsible for ensuring that there is
55 sufficient personnel with adequate training to conduct the work of the laboratory.
56 A certified (ASCP, state or equivalent) medical technician should be permitted to
57 serve in the capacity of general supervisor when the laboratory physician director
58 is not on the laboratory premises.
- 59

60 3. Federal regulation of physician office laboratories should explicitly recognize private sector
61 regulation programs as appropriate whenever possible. New regulation should build upon
62 existing programs, such as that of the Commission of Laboratory Assessment (COLA). There
63 is precedent for this in other sectors of the health care system, e.g., the Joint Commission
64 (previously known as JCAHO).

65
66 Those laboratories which meet the standards of an approved private sector accreditation body,
67 should be **automatically** approved for federal certification provided that the accreditation

68 body has standards that are “equal to or more stringent” than those of the Department of
69 Health and Human Services (HHS). This should preclude the need for laboratories to apply
70 separately for federal certification or to provide additional, duplicative documentation and
71 fees to HHS once the laboratories have satisfied the requirements of a private accreditation
72 body.
73

74 4. Physician office laboratories provide an important and cost-effective service to patients that
75 must be recognized and preserved under any federal policies to promote quality assurance.
76

77 5. Rheumatologists, in directing their office laboratories, are the most qualified managers for
78 determining the utilization of specific tests and for analyzing their results and applying these
79 results to therapeutic situations.
80

81 6. When proficiency-testing results are requested by interested parties, the information
82 necessary for their interpretation must be included.
83

84 7. Because patients with arthritis and other rheumatic diseases have difficulty traveling, it is
85 appropriate to offer laboratory services conveniently available to their source of care. In-
86 office laboratory testing minimizes the risk of sample loss and provides more timely results
87 for patient care.
88

89 8. Laboratory services should be considered separate from evaluation and management
90 services. The ACR opposes any cost containment efforts that recommend the bundling of
91 laboratory services into physician office visit payments. Payment for new diagnostic lab test
92 must take into account appropriate reimbursement for in-office testing. Any reimbursement
93 proposal, based on averaging of laboratory test payments, is inherently inequitable because it
94 is practically impossible to measure individual physician case-mix and severity of illness
95 categories and adjust for them accordingly.
96

97
98 Approved by Board of Directors: 08/99
99 10/02
100 08/05
101 08/09