

# AMERICAN COLLEGE OF RHEUMATOLOGY

## Position Statement

<b>SUBJECT:</b>	Synovial Fluid Crystal Analysis Credentialing
<b>PRESENTED BY:</b>	Committee on Rheumatologic Care
<b>FOR DISTRIBUTION TO:</b>	Members of the American College of Rheumatology Medical Societies Members of Congress Health Care Organizations/Third Party Carriers Managed Care Entities

## POSITION

1. The American College of Rheumatology supports the performance and interpretation of the synovial fluid crystal analysis as an integral part of the practice of rheumatology. Rheumatologists have extensive training in synovial fluid crystal analysis and this rapid and cost-effective clinical tool should be available to all practicing rheumatologists.
2. The American College of Rheumatology firmly recommends the designation of synovial fluid crystal analysis as a special waived test under CLIA regulations, when performed by a rheumatologist with documented training and credentialing.
3. The ACR supports insurance reimbursement by Medicare and other insurers for the performance and interpretation of the synovial fluid crystal analysis by rheumatologists.

## BACKGROUND

Rheumatologists diagnose and treat more than one hundred types of arthritis and autoimmune diseases. The evaluation of arthritis encompasses many factors and one of the most important factors often includes aspiration (the removal of fluid) from a swollen joint and subsequent synovial fluid analysis, the formal evaluation of synovial fluid. Synovial fluid analysis encompasses the automated evaluation of cells (Red Blood Cells and White Blood Cells), automated chemical analysis (glucose, protein) and crystalline evaluation performed by a trained professional. While the automated cellular and chemical analysis can take hours to complete, the bedside microscopic crystalline analysis can be determined immediately. This point of care evaluation allows critical decisions about treatment to be made by a trained provider with a basic microscope within minutes of the joint aspiration.

Examination for crystals can be tedious and is best done on 'fresh' joint fluid by the physician who is most involved with the process. Appropriately trained medical technologists and/or pathologists are not available at all times when clinical decisions need to be made, and transportation of the specimen to the lab as well as communication back to the provider takes hours under the best circumstances. Moreover, aspiration of small joints often yields only a drop

of synovial fluid that is best examined at the ‘point of care’ and it is generally not be feasible to transport to a central laboratory.

The technique of synovial fluid analysis was developed by rheumatologists and has historically been an integral part of clinical training in rheumatology. Through fellowship training and continuing medical education, rheumatologists become experts in arthrocentesis and in the interpretation of synovial fluid crystal analysis. The directors of rheumatology fellowship programs in the United States have developed a core curriculum in this area to ensure program quality and consistency. Correct identification of crystals in synovial fluid is required for initial rheumatology board certification and for maintenance of certification.

The Centers for Medicare Services (CMS) regulates all laboratory testing (except research) through the Clinical Laboratory Improvement Amendments (CLIA). CLIA assigns all testing done on human specimens in three complexity groups: low, medium and high. Low complexity tests are considered with low risk for an incorrect result and are considered a “waived” test (i.e. urine pregnancy test). To perform a waived test in a clinical setting, a CLIA certificate must be obtained but no inspection and minimal administrative burden is required. On the other hand, medium and high complexity tests are considered “non-waived” tests and require significantly more oversight and administrative burden. “Non-waived” tests require a CLIA certificate, have regular inspections by CLIA, and must meet the CLIA quality system standards (including proficiency testing, quality control and assessment) (1). Currently, synovial fluid analysis is currently considered a high complexity test, thus is a non-waived test and requires a significant administrative burden. The required paperwork and cost is insurmountable for many practicing rheumatologists. The inability for many to perform this procedure in the context of a clinic visit negatively impacts the quality of care provided.

We suggest that synovial fluid analysis belongs in a special category of waived tests that are exempt from the regulatory burden of CLIA certification given the training required to become a rheumatologist. If it is not possible to grant a specific exemption, we propose synovial fluid analysis be placed in the category of “Provider Performed Microscopy Procedures” (PPM) (2). PPM Procedures are moderately complex tests commonly performed by providers during patient office visits that require more training than simple “waived tests” (3). Examples of currently approved PPM tests include Urinary Sediment examinations, qualitative semen viability testing, direct wet mount preparations, and KOH preps of all types. Testing of this type already occurs successfully and safely in many clinics across the US and the addition of synovial fluid crystalline analysis to this group of tests will positively improve treatment of thousands of patients yearly.

## **REFERENCES**

1. <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/>
2. <https://www.rheumatology.org/Portals/0/Files/ACR-Comments-to-CMS-Clinical-Laboratory-Improvement-Amendments.pdf>

3. [https://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15\\_258020A\\_Stang\\_PPMP\\_Booklet\\_FINAL.pdf](https://wwwn.cdc.gov/clia/Resources/PPMP/pdf/15_258020A_Stang_PPMP_Booklet_FINAL.pdf)

Approved by Board of Directors: 08/2010  
02/2014  
02/2019