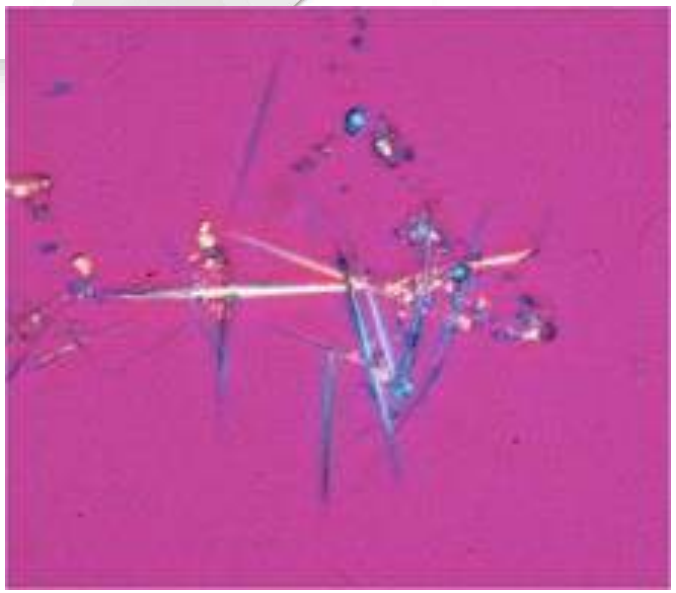
Considerations for Rheumatologists & ACR: Rheumatologists Performing Synovial Fluid Crystal Analysis



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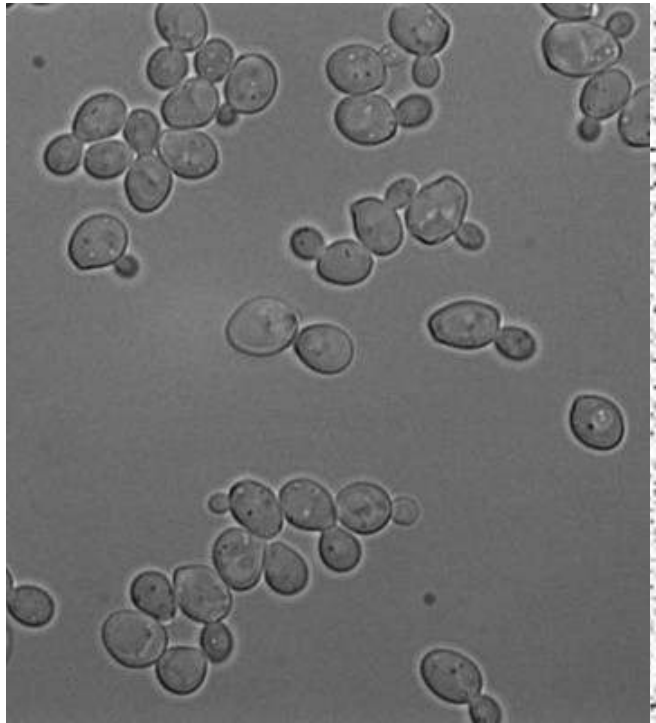
PPMP Provider Performed Microscopic Procedures

Adapted from May Ulibarri, Point of Care Testing Coordinator
University of Washington Medical Center 2/27/2025



Provider Performed Microscopy Procedures (PPMP) Current Rules

Provider Will Personally:

- ❑ Perform exam obtaining specimen
- ❑ Determine specimen integrity
- ❑ Perform PPMP test
- ❑ Enter results in medical record

Testing Limited to:

- ❑ MD
- ❑ DO
- ❑ DPM
- ❑ ARNP
- ❑ PA
- ❑ Dentist

(midwife and naturop recently removed)

PPMP Tests* Limited to:

- ❑ Wet Mount for presence/absence bacteria, fungi, parasites, cellular elements
- ❑ KOH
- ❑ Pinworm
- ❑ Fern Tests
- ❑ Post-Coital Direct Qualitative of Vaginal or Cervical Mucous
- ❑ Urine Sediments (UA Sed)
- ❑ Nasal Smears for Granulocytes
- ❑ Fecal Leukocyte
- ❑ Semen Qualitative limited to presence/absence and motility detection

Microscope Limited to:

- ❑ Bright-field *or*
- ❑ Phase Contrast

PPMP are NOT Waived Tests

Definition: Waived Tests

- **Waived Tests:**
- *simple tests with a low risk for an incorrect result*. They include:
  - Tests cleared by the FDA for home use
  - Tests approved by the FDA for waived status
- 'Waived test' designation arises after FDA/CLIA-assessment of a commercial test.
  - Process: Application by reagent/kit company for 'waived' status for their test.
- Sites that perform only waived testing must have a CLIA certificate and follow the manufacturer's instructions;
- Other CLIA lab requirements do not apply to these sites.

Non-Waived Tests

- **Non-Waived Tests: 3 Classes**
  - High complexity
    - Requires skilled technologist (usually licensed, certified, bachelor degree medical laboratory scientist) and doctorate level supervision
  - Moderate complexity
    - Requires skilled technical staff and experienced supervisor
  - Provider-performed microscopy procedures (PPMP)
    - Performed by provider ‘near’ patient.
      - Classified as moderate complexity, but rules differ from other moderate complexity tests.

PPMP Justification & Rationale

Labile specimen so a delay in testing could compromise result accuracy

Test done during patient visit by provider

Limited specimen handling/processing

Control materials not available to monitor entire testing process

Different from waived tests, which are ‘never fail’ tests and linked to a reagent manufacturer

PPMP are considered moderate complexity, require more oversight than waived tests.

PPMP Rules: 'Moderate Complexity'

- **PPMP Lab Quality Required Actions**

Requirements for testing internal blind testing samples or external proficiency testing samples

- **Evaluate personnel (Provider)** at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.
- Record keeping requirements. Maintain at least 2 years, documentation requirements.
- Subject to inspection,
  - but not required (rarely done, unless complaints or problems)

Records Requirements

As part of a quality system, the laboratory or testing site must maintain in information or record system that includes:

- Positive identification of the specimen
- Date and time of specimen receipt into the laboratory
- Condition and disposition of specimens that do not meet the laboratory's criteria for acceptability
- Records and dates of all specimen testing as well as the personnel who performed the test(s)

Laboratories and testing sites must retain their records for at least two years or as required by their federal, state, or local agencies as

PPMP Policy – Competency Assessment

Testing personnel performance **must be evaluated and documented semi-annually during the first year of testing and annually thereafter**.

Competency assessment includes:

- **Direct observation** of routine patient test performance, including specimen handling/processing, and testing when applicable.
- Monitoring the recording and reporting of test results. Review of test results or worksheets.
- Assessment of test performance through testing internal blind specimen or external proficiency test.
- Assess problem-solving skills.

PPM Certificate.

Charge (2024) $297 Every 2 Years

Change Fee $150

For reference:

Typical billing for SF crystal exam: ~$25, $19 for provider

About 6-8 exams per year to recover certificate direct cost.

Other administrative cost (?)

General PPMP Experience in Hospitals (MW)

- In UWMC, over time, fewer PPMPs are being performed by fewer providers.
  - Time required for PPM procedure is a hurdle.
  - Compliance with annual (semi-annual) training is burdensome.
  - Direct observation of competency burdensome and stressful for providers and clinic directors and lab staff.
  - Record keeping hastle.
  - THREAT TO INSTITUTIONS if not compliant
    - Failure of one department or site threatens entire institution licensing/certification
      - Labs DO get inspected, and PPMP may get ‘caught’ in inspection process

SF xstal in Rheumatology Offices Without Physician Office Labs
(MW Impression)

- Being performed ‘below the radar’
  - Most rheumatologists not educated about PPMP rules > unaware
    - Regulatory rules for PPMP not taught in fellowships
  - Probably no bill, no reporting other than in clinical note, informal records.
  - Bill/ claim for arthrocentesis and steroid injection whether or not crystal exam.
  - Details re microscope, space, records up to office/provider
  - Do they want the ‘hastle factor’ of PPMP?

SF xstal in Rheumatology Offices With Physician Office Labs
(MW Impression)

- **If lab and staff have moderate complexity certification**, lab staff perform the test and do the billing as moderately complex test
  - Provider can do the exam and may generate a provider bill if they satisfy criteria for moderate complexity testing (may vary by state, but most rheumatologists will not).
  - Provider may do exam as a technical or clinical consultant to lab, and lab generates bill and claim without provider bill or claim.
  - Fully compliant with regulations.
- **If lab and staff do NOT have moderate complexity certification**, provider may perform ‘under the radar’ without provider bill or claim.
  - Non-compliant, but low risk of discovery.
  - Litigation or Medicare Audit risk low.

PPMP in Rheumatology Practices in Hospitals and Medical Schools (MW Experience)

Lab staff perform the test and do the billing as moderately complex test. Lab generates bill and claim

- Provider may help with exam as a technical or clinical consultant to lab.
  - Generally lab staff welcome clinician.
  - Mostly informal consultant role, but could be formalized.

- Some providers / rheumatologists/fellows may perform ‘under the radar’ without provider bill or claim.
  - Mostly not known to hospital lab director
  - When known to lab director, sometimes forced to end provider testing, but teaching may continue.

‘Under the Radar’ Unauthorized Clinical Microscopy

- Examples
  - Synovial fluid crystal exam
  - Head lice exams
  - Scabies exams.
  - ? Gram stains
  - Urinalyses (outside of Certified Site)

- Not formally studied or surveyed.
- Inspectors usually unaware or informally ignore

Possible Trends in Synovial Fluid Crystal Exam

- No data, but perhaps less frequently performed.
- Arthrocentesis for diagnosis of crystal disease may not be viewed as critically important
  - Ultrasound replacing arthrocentesis for diagnosis.
  - Dual energy CT (DECT) used for diagnosis.
- Barriers to testing
  - Time to perform procedure not adequately compensated or necessary for diagnosis
  - Microscope investment and maintenance
  - ? Less training and experience among trainees, with ultrasound focus.

What Do ACR Members Want?

- Continue status quo
  - ‘Under radar’ option
  - No compensation, but no regulation or hastle
  - If not performing, providers do not care.
- Try for Waived Status – UNLIKELY, not recommended
  - Would be totally novel (providers asking, not vendors) and not ‘fool-proof’ test
- Try for PPMP status for synovial fluid
  - Would need to develop a strong argument and approach

Barrier to Approval: Polarized Light Microscopy

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Anticipate resistance from CMS/FDA to addition of polarized light microscopy and compensated polarized light microscopy.

Argument: interpretation by rheumatologists is reliable.

PPMP Justification & Rationale for SF Crystal

- ✓Labile specimen so a delay in testing could compromise result accuracy.
  - Specimen in needle or tip of needle might be discarded by lab
  - Tophi crystals: no standard in labs, many labs without experience
  - Specimen drying, crystallization in the test tube, on a slide
- ✓Test done during patient visit by provider
- ✓Limited specimen handling/processing;
- ✓Control materials (commercial) not available to monitor
- ✓Similar to existing PPMP tests – (in fact, a form of wet mount)
- ✓EASIER than some other tests, since birefringence often bright

Opportunity for ACR

- If membership supports PPMP, might be seen as victory for rheumatologists.
- Could become proficiency testing source for annual testing.
  - Alone or partner with pathology.

- If neutral or against PPMP, encourage/ support clinical or technical consultant role for rheumatologists working with clinical laboratories.
- Encourage/support fellowship programs to work with system labs.
- Partner with CAP or related lab organization.

News from the College of American Pathologists (CAP)

- For first time, polarizing microscope with compensator will be a checklist item (requirement for certification) for labs certified by CAP that perform crystal exam.
- Previously, was considered ‘standard of practice’ but not called out as a requirement that lab inspectors would ask labs to document.

Survey Needed: https://forms.office.com/r/MDZhdQRLq0

Synovial fluid crystal analysis is not on the list of CMS-approved provider-performed microscopy procedures (PPMP). Should ACR try to have crystal exam earn PPM approved status? Please answer a few questions that will help influence ACR members' priorities.

https://forms.office.com/r/MDZhdQRLq0

Thank You

Addition Compliance & Record Requirements

Monitoring the recording and reporting of test results;

(1) Documentation of patient identity (at least 2 identifiers)

(2) Document site, date and time of specimen retrieval and testing performance.

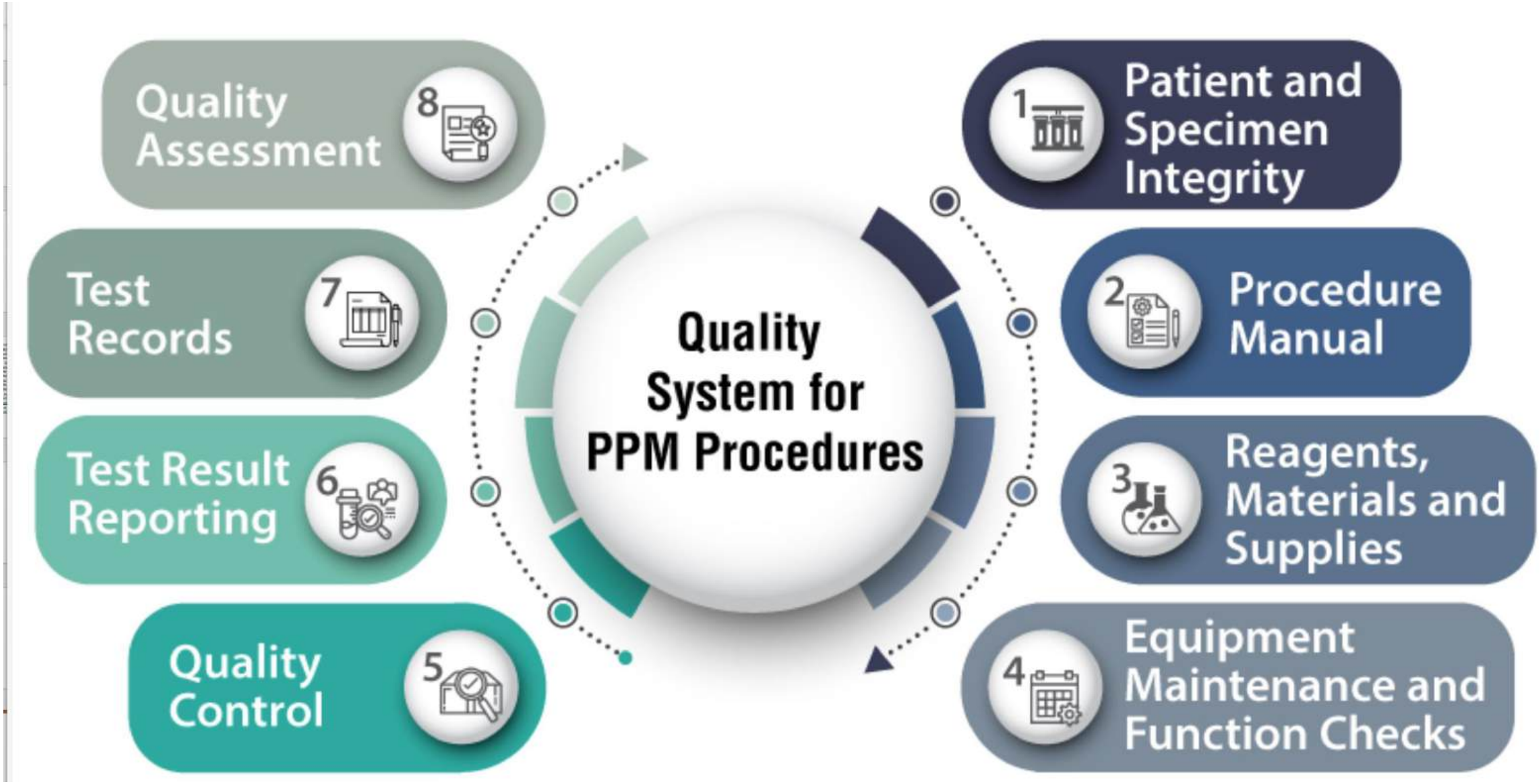
(3) Review of test results or worksheets;

(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and

(5) Assessment of problem solving skills; and

(d) Evaluate and document the performance of individuals responsible for PPM testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations and documentation must be performed at least annually.

Quality Systems for PPMPs



PPMP For Rheumatologists: 'Legalistic Approach'

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