STANDARD OPERATING PROCEDURE TEMPLATE · WAIVED TESTING AND POINT-OF-CARE TESTING

Provider-Performed Microscopy (PPM) Procedures

Governing requirement: 42 CFR 493.19

Applies to: ☐ Waived ☑ Moderate complexity ☐ High complexity

Laboratory name		**CLIA number**	
Document number		**Version**	
Effective date		**Next review due**	
Author		**Department / section**	
Approved by (laboratory director)		**Director signature**	
Approval date		**Supersedes document**	

Important: Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

1. Purpose

To perform PPM procedures correctly under a PPM certificate.

2. Scope

PPM procedures performed by physicians, midlevel practitioners or dentists during the patient visit.

3. Responsibility

- Testing personnel: follow the manufacturer's instructions exactly and document QC and results.
- Site supervisor / testing coordinator: trains staff, reviews logs and orders supplies.
- Laboratory director: approves the procedure and holds responsibility for the certificate.

4. Definitions

PPM procedure: One of the specific microscopy tests listed in 42 CFR 493.19(c).

Bright-field / phase contrast: Microscopy types allowed.

5. Materials, equipment and records

- Microscope **[Microscope ID]**

Microscope ID	

- Slides, coverslips, saline, 10% KOH

6. Procedure

1. Only qualified providers perform PPM tests during the patient's visit.

2. Wet mount: mix specimen with saline, coverslip, examine at 10x and 40x for organisms and cells.

3. KOH prep: add KOH, coverslip, warm if required, examine for fungal elements.

4. Urine sediment: centrifuge, decant, resuspend and examine.

5. Record findings in the patient record.

6. Maintain the microscope and document cleaning.

7. Assess competency semiannually the first year, then annually.

8. Enroll in PT or perform alternative assessment twice yearly.

7. Quality control

• Follow the laboratory's QC policy and the manufacturer's instructions; record QC before reporting patient results.

• Stop patient testing and take corrective action when QC or acceptance criteria are not met.

8. Interpretation, reporting and documentation

• Record the activity, date, result and initials on the form or log, and have the supervisor review records **[Review frequency]**.

Review frequency	

• Keep records per the record retention SOP (at least 2 years under 42 CFR 493.1105 unless a longer period applies).

9. Limitations and cautions

• PPM labs are subject to nonwaived quality standards for these procedures.

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

10. References

• CMS, State Operations Manual Appendix C: Survey procedures and interpretive guidelines for laboratories https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf

• CMS, Clinical Laboratory Improvement Amendments (CLIA) https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments

• eCFR, 42 CFR 493.19 https://www.ecfr.gov/current/title-42/section-493.19

• eCFR, 42 CFR 493.1236 https://www.ecfr.gov/current/title-42/section-493.1236

11. Lab-specific notes

Notes and local requirements	

12. Revision history

Version	Date	Description of change	Author	Approved by

13. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

Review date	Reviewed by	Signature	Changes needed (Y/N)	Comments

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