STANDARD OPERATING PROCEDURE TEMPLATE · PRE-ANALYTIC: ORDERING, COLLECTION AND SPECIMEN HANDLING

Urine Specimen Collection (Random, Clean-Catch and 24-Hour)

Governing requirement: 42 CFR 493.1242(a)

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 collect urine specimens suitable for urinalysis, culture and chemistry testing.

2. Scope

Random, first morning, midstream clean-catch, catheter and 24-hour urine collections.

3. Responsibility

- Collectors (phlebotomists, nurses, medical assistants): follow this procedure and document collection.
- Specimen processing / accessioning staff: check acceptability and document problems.
- Supervisor: trains staff, monitors pre-analytic errors and reviews rejection logs.
- Laboratory director: approves the procedure and acceptance criteria.

4. Definitions

Clean-catch: Midstream urine collected after cleansing to reduce contamination.

24-hour urine: All urine passed over 24 hours, timed from an emptied bladder.

5. Materials, equipment and records

- Sterile cups, cleansing towelettes
- 24-hour containers with preservative per test **[Preservatives by test]**

Preservatives by test	

- Patient instruction sheet

6. Procedure

1. Give the patient written and verbal instructions.

2. Clean-catch: wash hands, cleanse the urethral area front to back, void the first portion into the toilet, collect midstream into the sterile cup, finish voiding in the toilet.

3. Cap tightly; label the container (not the lid) with two identifiers and collection time.

4. 24-hour: discard the first morning void and note the time; collect all urine for 24 hours including the final void at the same time next day; keep refrigerated or per preservative instructions.

5. Deliver to the lab within **[Maximum time at room temperature]** or refrigerate.

Maximum time at room temperature	

6. For culture, refrigerate if not processed within 2 hours or use a preservative tube.

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 collection type on the requisition.

9. Limitations and cautions

• Contaminated or improperly preserved specimens follow the rejection SOP.

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

10. References

• eCFR, 42 CFR Part 493 Laboratory Requirements (CLIA)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• 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

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

• eCFR, 42 CFR 493.1242 https://www.ecfr.gov/current/title-42/section-493.1242

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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