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

Urine Dipstick (Reagent Strip) Testing

Governing requirement: 42 CFR 493.15(e) (follow manufacturer's instructions) and 493.1773-1775

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 chemical urinalysis by reagent strip.

2. Scope

[Testing sites] performing the Urine Dipstick under the lab's CLIA certificate.

Testing sites

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

Reagent strip: Plastic strip with reagent pads for analytes such as glucose, protein, blood, leukocyte esterase and nitrite.

5. Materials, equipment and records

- Reagent strips **[Brand and lot]**

Brand and lot

- Reader (if used) **[Analyzer ID]**

Analyzer ID

- Positive and negative controls

6. Procedure

1. Test fresh urine within 2 hours or refrigerate and bring to room temperature.

2. Mix the specimen; dip the strip briefly, drain the edge.

3. Read each pad at the time stated by the manufacturer under good lighting, or use the analyzer.

4. Record results using the chart terms.

5. Run positive and negative controls **[QC frequency per manufacturer]** and with each new lot or bottle.

QC frequency per manufacturer	

6. Keep bottle capped; do not touch pads.

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

• Report results with units or grades as on the chart.

9. Limitations and cautions

• Ascorbic acid, highly colored urine and old specimens can interfere.

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

10. References

• CDC, Ready? Set? Test! Patient testing is important (waived testing booklet) https://www.cdc.gov/clia/php/waived-tests/index.html

• CDC, Clinical Laboratory Improvement Amendments (CLIA) https://www.cdc.gov/clia/php/about/index.html

• FDA, CLIA test categorization database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/search.cfm

• Manufacturer's package insert, operator manual and safety data sheets for each test system in use

• eCFR, 42 CFR 493.15 https://www.ecfr.gov/current/title-42/section-493.15

11. QC and patient testing log

Fill in electronically or print. Keep completed forms per the record retention policy.

Date	Kit lot / exp	Pos control	Neg control	Acceptable	Tech	Notes

12. Lab-specific notes

Notes and local requirements	

13. Revision history

Version	Date	Description of change	Author	Approved by

14. 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

Free template from Sound Lab Consultants, soundlabconsult.com. Download more free templates at soundlabconsult.com/laboratory-sop-library.