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

Urine hCG Pregnancy Test

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 detect hCG in urine for pregnancy screening.

2. Scope

[Testing sites] performing the Urine hCG Pregnancy Test 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

Invalid result: No control line appears.

5. Materials, equipment and records

- hCG test kit **[Kit name and lot]**

Kit name and lot

- External positive and negative controls

6. Procedure

1. Use first morning urine when possible.

2. Bring kit and specimen to room temperature.

3. Add specimen per instructions **[Drops or dip time per manufacturer]**.

Drops or dip time per manufacturer

4. Read at the time stated in the insert **[Read time per manufacturer]**; do not read after the stated time.

Read time per manufacturer	

5. Report positive, negative or invalid; repeat invalid tests with a new device.

6. Run external controls per manufacturer and with each new lot/shipment.

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

• Dilute urine may give false negatives early in pregnancy.

• 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

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