OSOM® hCG Urine Control Set

Catalog #134

INTENDED USE
The OSOM hCG Urine Control Set is intended for *in vitro* diagnostic use in quality control testing with OSOM hCG-Urine, OSOM Card Pregnancy, OSOM hCG Combo Test and the OSOM Ultra hCG Combo Test.

SUMMARY
The OSOM hCG Urine Control Set provides 1 Negative Control and 1 Positive Control in saline. The Positive Control contains purified hCG; the Negative Control is free of detectable hCG. When used for quality control in OSOM hCG-Urine, OSOM Card Pregnancy, OSOM hCG Combo Test and the OSOM Ultra hCG Combo Test, the Controls are useful as an aid in verifying test and operator performance.

MATERIALS PROVIDED
- OSOM hCG Urine Control - Negative, 10 mL/vial, contains saline with 0.2 % sodium azide
- OSOM hCG Urine Control – Positive, 10 mL/vial, contains 50-100 mIU/mL hCG (3rd IS) in saline with 0.2 % sodium azide

Warning: Contains Azide

MATERIALS REQUIRED BUT NOT PROVIDED
- OSOM hCG-Urine, OSOM Card Pregnancy, OSOM hCG Combo Test or OSOM Ultra hCG Combo Test
- Clock or Timer

WARNINGS AND PRECAUTIONS
- For *In Vitro* Diagnostic Use
- DO NOT use the Controls beyond the expiration date.
- The Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded Controls down a sink.
- Potential biohazard. Handle as if potentially infectious. Handle this product according to established good laboratory practices using appropriate precautions.[1-3]

STORAGE
The OSOM hCG Urine Control Set must be stored refrigerated (2°-8°C; 36°- 46°F).
- Do not freeze
- Tightly seal the vials after use to prevent evaporation.
- Store vials upright to prevent spills and leakage.

STABILITY
- Unopened and opened vials stored at 2°- 8°C (36°- 46°F) are stable until the expiration date printed on the vial and box label.

INSTRUCTIONS FOR USE

1. Bring Controls to room temperature prior to use.
2. Invert Controls several times prior to use.
3. Use the OSOM hCG Urine Controls as you would a patient sample in accordance with the procedure of OSOM hCG-Urine, OSOM Card Pregnancy, OSOM hCG Combo Test (urine procedure) or the OSOM Ultra hCG Combo Test (urine procedure).
4. Read the procedural instructions from the assay product insert prior to testing.

LIMITATIONS
- Obtaining accurate results from quality control material requires good laboratory practices.
- Erroneous results can occur from improper storage, inadequate mixing, or sample handling errors associated with assay procedures.
- Do not use the quality control material if there is visible evidence of microbial growth in the vial.

For more information about procedural limitations, refer to the assay product insert.

EXPECTED RESULTS
The Negative Control should yield a negative result as described in the Expected Results section of the assay product insert.

The Positive Control should yield a positive result as described in the Expected Results section of the assay product insert.

DISPOSING OF MATERIALS
Dispose of hazardous or biologically contaminated materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.

REFERENCES

1. Centers for Disease Control. 1988. Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B virus and Other Bloodborne Pathogens in Healthcare Settings. MMWR, 37: 377-382, 387, 388.
2. National Committee for Clinical Laboratory Standards. Protection of laboratory workers from instrument biohazards and infectious disease transmitted by blood, body fluids, and tissue; approved guideline. NCCLS Document M29-A. Wayne (PA): NCCLS; 1997 Dec. 90p.
3. Federal Occupational Safety and Health Administration, Bloodborne Pathogens Standard, 29 CFR 1910.1030.

ASSISTANCE
For assistance, call Sekisui Diagnostics Technical Service at 800-332-1042.

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SEKISUI DIAGNOSTICS

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