

OSOM[®] hCG Serum Control Set

REF 138

R_XONLY

INTENDED USE

The OSOM[®] hCG Serum Control Set is intended for *in vitro* diagnostic use in quality control testing with the OSOM hCG Combo Test and the OSOM Ultra hCG Combo Test.

SUMMARY

The OSOM hCG Serum Control Set provides a Negative Control and a Positive Control in horse serum. The Positive Control contains purified hCG; the Negative Control is free of detectable hCG. When used for quality control in the 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 Serum Control - Negative, 5 mL/vial, contains horse serum with 0.2 % sodium azide
- OSOM hCG Serum Control - Positive, 5 mL/vial, contains approximately 50 mIU/mL hCG (3rd IS) in horse serum with 0.2 % sodium azide

Warning: Contains Azide

MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM hCG Combo Test (Catalog #124)
- OSOM Ultra hCG Combo Test (Catalog #1004)
- Clock or Timer

WARNINGS AND PRECAUTIONS

1. For *In Vitro* Diagnostic Use
2. DO NOT use the Controls beyond the expiration date.
3. 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.
4. 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 Serum 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 Serum Controls as you would a patient sample in accordance with the serum procedure of the OSOM hCG Combo Test or the OSOM Ultra hCG Combo Test. Read the procedural instructions from the assay product insert prior to testing.

LIMITATIONS

1. Obtaining accurate results from quality control material requires good laboratory practices.
2. Erroneous results can occur from improper storage, inadequate mixing, or sample handling errors associated with assay procedures.

3. 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.


Symbols


 Batch code

 Catalog number

 Caution: Federal law restricts this device to sale by or on the order of a physician

 *In vitro* diagnostic medical device

 Manufacturer

 Temperature limit

 Use by date

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