

INTENDED USE

The OSOM ImmunoDip Control Kit is intended for *in vitro* diagnostic use in quality control testing with the OSOM ImmunoDip Urinary Albumin Test.

SUMMARY

The OSOM ImmunoDip Control Kit provides one positive and one negative control in human urine. Preservatives have been added to inhibit microbial growth. When used for quality control in the OSOM ImmunoDip Urinary Albumin Test, the Controls are useful as an aid in verifying test and operator performance.

MATERIALS PROVIDED

- OSOM ImmunoDip Negative Control - 6 mL
- OSOM ImmunoDip Positive Control - 6 mL

MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM ImmunoDip Urinary Albumin Test
- Clock or Timer

WARNINGS AND PRECAUTIONS

1. For *In Vitro* Diagnostic Use
2. The Controls are stable for 6 months after opening the vial, ten uses, or the expiration date, whichever comes first.
3. DO NOT use the Controls beyond the expiration date.
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 ImmunoDip Control Kit 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 vials stored at 2°- 8°C (36°- 46°F) are stable until the expiration date printed on the vial and box labels.
- Once opened, vials must be stored at 2°- 8°C (36°- 46°F) and are stable for six months from the date opened or the expiration date printed on the vial and box labels, whichever is sooner.

INSTRUCTIONS FOR USE

1. Bring Controls to room temperature prior to use.
2. Invert Controls several times prior to use, but avoid foaming.
3. Use the OSOM ImmunoDip Controls as you would a patient sample in accordance with the OSOM ImmunoDip Urinary Albumin Test procedure. Read the procedural instructions from the OSOM ImmunoDip product insert prior to testing.
4. Insert OSOM ImmunoDip device directly into control vial; do not transfer control liquid to any other container.
5. Ensure control level is up to or above the  on the OSOM ImmunoDip test device. If not, new controls should be obtained.
6. Immediately recap the controls and return to 2°- 8°C (36°- 46°F) when not in use.

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 OSOM ImmunoDip package insert.

EXPECTED RESULTS

The Positive Control should yield a positive result and the Negative Control should yield a negative result as described in the Expected Results section of the OSOM ImmunoDip 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 Assistance at 800-332-1042 (The Americas). International customers, please contact your local distributor.

RE-ORDER













No. 790-25 - OSOM[®] ImmunoDip Urinary Albumin Test
 No. 791 - OSOM[®] ImmunoDip Control Set
 OSOM[®] and ImmunoDip[®] are registered U.S. trademarks of Sekisui Diagnostics, LLC.

 Sekisui Diagnostics, LLC
 6659 Top Gun Street San Diego, CA 92121 USA

 Sekisui Diagnostics (UK) Limited
 50 Gibson Drive
 Kings Hill, West Malling
 Kent, ME19 4AF, UK



Key to Component Labeling

 Use by YYYY-MM	 Manufacturer/Manufactured by
 Batch code	 Consult instructions for use
 Catalog number	 Authorized representative in the European Community
 Contents sufficient for <n> tests	 Caution, consult accompanying documents.
 In vitro diagnostic medical device	 Positive Control
 Temperature limitation	 Negative Control