

OSOM[®] Trichomonas Positive Control Kit

INTENDED USE

The OSOM[®] Trichomonas Positive Control Kit is intended for *in vitro* diagnostic use in quality control testing with the OSOM[®] Trichomonas Rapid Test.

SUMMARY

The OSOM[®] Trichomonas Positive Control Kit provides swabs coated with a dried mixture containing Trichomonas antigens. The level of Trichomonas antigen applied to the swab is sufficient to provide a positive result when used with the OSOM[®] Trichomonas Rapid Test. Sterile rayon swabs supplied in the Trichomonas Rapid Test kit are free of Trichomonas antigens and can be used as negative controls. When used for quality control in the OSOM[®] Trichomonas Rapid Test, these controls are useful as an aid in verifying test and operator performance.

MATERIALS PROVIDED

OSOM[®] Trichomonas Positive Control Swabs (approximately 1 x 10⁵ cell equivalents)- 10 polyester swabs coated with an antigen mixture derived from *Trichomonas vaginalis* organisms

MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM[®] Trichomonas Rapid Test
- Clock or Timer

WARNINGS AND PRECAUTIONS

1. DO NOT use the Controls beyond the expiration date.
2. Potential biohazard. Handle as if potentially infectious. Handle this product according to established good laboratory practices using appropriate precautions.
3. Not for patient use.

STORAGE

- The OSOM[®] Trichomonas Positive Control Kit must be stored at room temperature (15°-30°C; 59°- 86°F).
- Tightly close the canister after use to prevent deterioration of the positive control swabs.

Stability

Swabs stored in the closed canister at 15°-30°C (59°- 86°F) are stable until the expiration date printed on the canister and box label.

INSTRUCTIONS FOR USE

Use the OSOM[®] Trichomonas Positive Control Swabs as you would a patient sample in accordance with the procedure for the OSOM[®] Trichomonas Rapid Test. Read the procedural instructions from the assay product insert prior to testing.

EXPECTED RESULTS

The Negative Control should yield a negative result as described in the Interpretation of Test Results section of the assay product insert. The Positive Control should yield a positive result as described in the Interpretation of Test 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

Refer to the OSOM[®] Trichomonas Rapid Test directional insert for additional information on this assay.

ASSISTANCE

For assistance, contact Sekisui Diagnostics Technical Assistance at (800)332-1042.

RE-ORDER

No. 181-OSOM[®] Trichomonas Rapid Test (25 tests)
No. 182- OSOM[®] Trichomonas Positive Control Kit

OSOM[®] is a registered U.S. trademark of Sekisui Diagnostics, LLC.

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