

Synovasure® Alpha Defensin Control Kit

For *in vitro* diagnostic use

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NAME AND INTENDED USE

Synovasure® Alpha Defensin Control Kit provides a positive and a negative control for use with the Synovasure® Alpha Defensin Lateral Flow Test Kit (Ref 00-8888-125) or other kits requiring alpha defensin controls.

Synovasure® Alpha Defensin Control kit is intended for laboratory use only.

WARNINGS & PRECAUTIONS

- Failure to follow the instructions may lead to inaccurate results.
- When using with Synovasure® Alpha Defensin Lateral Flow Test Kit, follow safety precautions contained in the Instructions for Use.
- Do not ingest or inhale any of the kit components.
- Open glass vials carefully. Vials are under vacuum.

REAGENTS AND MATERIALS SUPPLIED

REF 00-8888-125-02	Synovasure® Alpha Defensin Control Kit	Quantity
• REF P50026	Positive Control 0.25 mL of 16 µg/mL Alpha defensin in synthetic synovial fluid, lyophilized, glass vial with stopper	1
• REF P50027	Negative Control 0.25 mL of synthetic synovial fluid, lyophilized, glass vial with stopper	1
• REF P50028	Control Reconstitution Bottle 2 mL of control dilution buffer-yellow dyed	1

Note: Store kit reagents between 2° to 30°C. Rehydrated controls can be recapped and stored up to 2 weeks at 2° to 8°C.

SYNOVASURE® ALPHA DEFENSIN CONTROL KIT PROCEDURE

1. Read the package insert thoroughly before using the product.
2. Always check the expiration date prior to testing. Do not use kits beyond the expiration date printed on the box. Always be sure to inspect the kit components for damage. If any of the components have been damaged, discard the kit and select a new kit for testing.
3. Select tube containing the positive control and remove cap. Remove cap from reconstitution bottle and add five (5) full drops of reconstitution fluid to vial containing the positive control. Replace cap on the positive control, wait 10 minutes. Mix by gently tapping tube with finger repeatedly until solution is thoroughly dissolved. Avoid inverting.
4. Repeat the steps above for the negative control.
5. Once controls have been prepared and their solutions thoroughly mixed, run samples according to the Instructions for Use contained in the Synovasure® Alpha Defensin Lateral Flow Test Kit or as validated in other applications requiring alpha defensin controls.

Synovasure® is a licensed trademark of Zimmer Biomet Holdings Inc., the successor of Zimmer Holdings Inc.

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