

Synovasure® Alpha Defensin Control Kit

 For *in vitro* diagnostic use

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 00-8888-125-01, -05, -10, -30) or other kits requiring alpha defensin controls.

Synovasure Alpha Defensin Control kit is intended for professional 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.
- The Control Reconstitution Bottle included in this kit contain a Dilution Buffer. The Dilution Buffer contains a preservative which may cause an allergic skin reaction. Avoid breathing mist or fumes. May cause skin, eye, and respiratory irritation. Refer to the SDS available at www.cddiagnostics.com.
- Open glass vials carefully. Vials are under vacuum.

REAGENTS AND MATERIALS SUPPLIED

REF	Synovasure Alpha Defensin Control Kit	Quantity
REF 00-8888-125-02	Synovasure Alpha Defensin Control Kit	
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	1

Note: Store kit reagents between 2° to 30°C. Rehydrated controls can be recapped and stored up to three (3) weeks at 2° to 8°C.



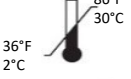






SYNOVASURE ALPHA DEFENSIN CONTROL KIT PROCEDURE

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 vial 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.

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For additional product information, visit www.cddiagnostics.com

Symbol Key

	<i>In vitro</i> diagnostic medical device		Authorized Representative in the European Union		Temperature Limitation
	Consult instructions for use		Use by		Manufacturer
	Non-sterile device		Positive Control		Negative Control



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