

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) depending on country-specific regulatory registration approval.

The Synovasure Alpha Defensin Control Kit is used with the Synovasure Alpha Defensin Lateral Flow Test Kit as quality control samples to monitor performance and reliability of the Synovasure Alpha Defensin Lateral Flow Test Kit. The Synovasure Alpha Defensin Lateral Flow Test Kit and the Synovasure Alpha Defensin Control Kit are non-automated.

For more information on Synovasure Alpha Defensin Lateral Flow Test, including specimen collection and handling, patient population, test principle, assay procedure, performance characteristics, and country-specific requirements for both test kit and control kit, refer to Synovasure® Alpha Defensin Lateral Flow Test Kit IFU (M40004)



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.
- This product is non-sterile and should NOT be placed into sterile fields.

REAGENTS AND MATERIALS SUPPLIED

REF 00-8888-125-02 REF	Synovasure Alpha Defensin Control Kit	Quantity QTY
REF P50026 REF	Positive Control 0.25 mL of 16 µg/mL Alpha defensin in synthetic synovial fluid, lyophilized, glass vial with stopper	1
REF P50027 REF	Negative Control 0.25 mL of synthetic synovial fluid, lyophilized, glass vial with stopper	1
REF P50028 REF	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. Allow to warm to room temperature and tap to mix prior to each use.

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.

Note: Any complaints should be reported to Zimmer Biomet using the Product Experience Report Form (Form number GBLF04001) to product.experience@zimmerbiomet.com. Serious adverse events shall be reported to the Competent Authority of the respective EU Member State in which the event occurred. Healthcare professionals, users and patients should report any suspected serious incident related to the device by informing the Manufacturer at www.zimmerbiomet.com, or the local Zimmer Biomet distributor, and the competent authority, ministry of health, or delegated agency in the country where the suspected serious incident occurred. For patients in Australia please visit the Therapeutic Goods Administration (TGA) website: <https://www.tga.gov.au>

















Please contact Zimmer Biomet at the following number if you have additional questions: +1-800-348-2759 or +1-800-253-6190.

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Revision History

Version	Effective Date	Changes made from previous version
7	Jan 2024	<ul style="list-style-type: none"> Updated Intended Use statement, symbols, symbol key as per EU IVDR 2017/746 requirements. Updated CE mark with CE number. Added a Note to users with Zimmer Biomet contact information to report complaints/issues Added Revision History Section to meet EU IVDR 2017/746 requirements Updated 'Warning and Precaution' section to include 'This product is non-sterile and should NOT be placed into sterile fields.' Clarified use instructions after refrigerated storage (warm to room temperature and tap to mix)

Symbol Key

 IFUs, Patents & Symbol Glossary http://labeling.zimmerbiomet.com	Instructions for Use		Lot Number
	Item Number		Manufacturer
	Storage Temperature		Authorized representative in the European Community/European Union
	Use-By Date		IVD
	Non-sterile device		Precautions/Warnings
	Negative control		Quantity
	Positive control		Non-sterile
	Near patient Testing (EU only)		Contains sufficient for <n> tests

