

Check List

Review check list prior to performing Synovasure Lateral Flow Test

- **This assay is for prescription use only in the United States and for laboratory use in Canada and Australia. For all countries outside of the United States, Canada, and Australia, this assay is for professional use only.**
- Check expiration date before using.
- Test must be performed on a flat, stable surface in an area with adequate lighting.
- Conduct the test at room temperature, between 12-25°C.
- Ensure timer is available and set to 10 minutes.
- Use of Synovasure Alpha Defensin Control Kit (00-8888-125-02), should be used in accordance with local requirements.

Step 1. Prepare Materials

- Remove 1 white pouch and 1 silver pouch from the Synovasure box and allow to come to room temperature.
- The pouches contain the following items:
 - White pouch**
 - 1 x Synovasure device
 - Silver pouch**
 - 1 x Sample cup
 - 2 x Microsafe[®] tubes
 - 1 x Dilution bottle



Step 2. Sample Collection

- Do **NOT** inject fluids (saline, lavage, dyes, etc.) into the joint prior to aspiration as diluted synovial fluid can lead to inaccurate results.
- Aspirate the synovial fluid from the total joint using standard technique.
- Dispense the synovial fluid from the syringe into the sample cup.
- Remove the purple cap from the dilution bottle and set aside.



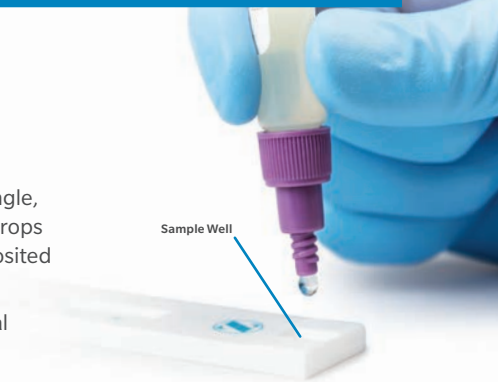
Step 3. Sample Preparation

- Do **NOT** squeeze the bulb of the tube.
- Place a Microsafe Tube horizontally into the cup.
- Capillary action will automatically draw the fluid to the black line.
- Allow the fluid to reach the **black line**.
- Viscous fluid may take longer to fill (up to 60 seconds).
- Second tube is supplied as a reserve if needed.
- To transfer the contents, immerse the tube into the pre-filled dilution bottle.
- Squeeze the bulb several times to ensure fluid removal.
- Recap the bottle and mix by gentle inversion.



Step 4. Performing the Test

- Place the device onto a flat surface.
- Remove clear cap from dilution bottle.
- Hold the dilution bottle vertically at a 90 degree angle, to ensure full, free falling drops of diluted fluid will be deposited on the device.
- Practice dispensing several free falling drops onto a disposable towel.
- Dispense 3 free falling drops of fluid into the sample well at the bottom of the device.

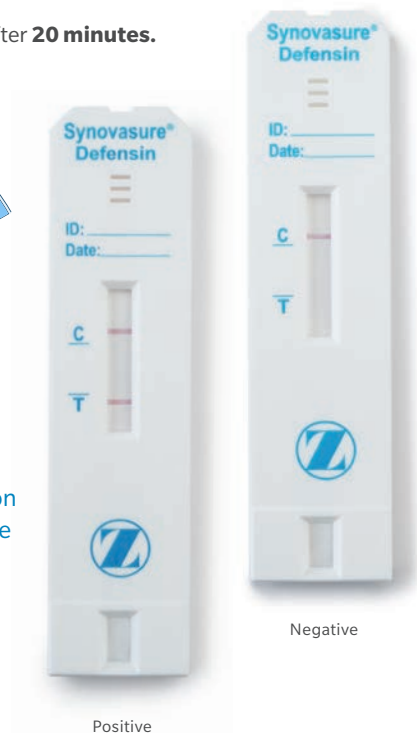


Step 5. Results

- Keep the device flat throughout the entire process.
- Read the results **10 minutes** after depositing the drops.
- The control line (C) should always be present when performing the Synovasure test. If the line does not appear, the test is invalid, re-run the test using a new device.
- **If a line appears next to the (T) test area, this is considered a positive result. No matter how faint the line in the (T) test area, the result is considered positive.**
- If no line appears in the (T) test area, the result is considered negative.
- Do **NOT** read the results after **20 minutes**.



Note: See interpretation of results on the reverse side of this card.



Positive

Negative

Synovasure® Alpha Defensin

Test Results Reference Guide

Reference Guide Only

Refer to the package inserts for important product information, including, but not limited to: full instructions for use, contraindications, warnings, precautions and adverse effects.

If 2 lines appear Synovasure test is **POSITIVE**, regardless of the line intensity.

If only the control line appears, Synovasure test is **NEGATIVE**



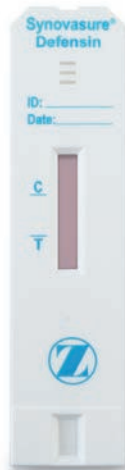
The test is **INVALID** and should be repeated with a new device if after 20 minutes the following occurs.



No control line appears*



Test line not fully developed



Background fails to clear

* May be due to inadequate addition of sample to the test well.

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Zimmer Biomet does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received. This test has been developed for use with synovial fluid only. The use of this test kit with any other specimen type may lead to inaccurate test results.

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