



External Controls – FOB Rapid Test

Instructions For Use

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

For *In Vitro* Diagnostic Use Only.
For Prescription Use Only.

REF	GEFOB-PNK2	• 1 x 1mL Positive Control Bottle - Blue Cap (contains 0.2% NaN₃ as a preservative) • 1 x 1 mL Negative Control Bottle- White Cap (contains 0.17% NaN₃ as a preservative) • 1 Instructions for Use
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INTENDED USE

The External Controls – FOB Rapid Test is a ready-to-use external control kit for use with the Healgen® FOB Rapid Test kit. This kit is designed to verify proper test procedure and performance of the Healgen® FOB Rapid Test.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Do not use after the expiration date.
- Use only with the Healgen® FOB Rapid Test. Incompatibilities between this product and other manufacturer's test kits may occur.
- CAUTION: The Positive Control is prepared from material derived from human blood. The source materials are tested for the presence of antibodies to human immunodeficiency virus (HIV) and Hepatitis B Surface antigens (HBsAg) and found to be negative. However, no test method can offer complete assurance that HIV, HBsAg, or other infectious agents are absent; these reagents should be handled as potentially infectious. Such materials should be handled at Biosafety Level 2, as defined by the U.S. Centers for Disease Control and Prevention.
- Follow Good Laboratory Practices. Wear protective clothing. Use

disposal gloves.

- Do not eat, drink, or smoke in the testing area.
- The control and test device should be discarded in a proper biohazard container after testing.
- WARNING: The Positive and Negative Controls contain sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up.

STORAGE AND STABILITY

- Store as packaged, either refrigerated or at room temperature (2-30°C/36-86°F).
- The control is stable through the expiration date printed on the label.
- Control bottles should always be stored upright.
- Do not freeze (below 0°C/32°F).

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Timer, clock, or watch
- Healgen® FOB Rapid Test kit

TEST PROCEDURE

Controls should be run once for:

- Each new kit lot, each new operator, each new shipment, every 30 days to check storage, or as required by site quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.

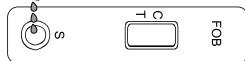
Allow the test cassette and controls to reach room temperature (15-30°C/59-86°F) prior to testing.

1. Remove the Healgen® FOB Rapid Test from the foil pouch and use it as soon as possible. Best results will be obtained if the cassette is used within one hour.
2. Place the Test Cassette on a clean, flat surface.
3. Hold the control bottle upright, then unscrew and remove the upper cap.
4. Squeeze 3 drops (~90 µL) of the control sample solution into the sample well of the Test Cassette and start the timer. Use either the Positive Control or Negative Control, not both, on the Test Cassette.

Unscrew and open
the upper cap

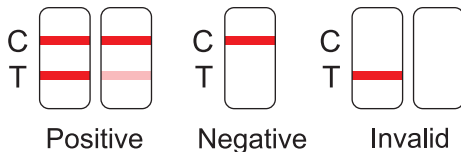


3 Drops of control sample solution



5. Wait for the colored line(s) to appear. Read results at 5 minutes.
Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS



POSITIVE:

The presence of two lines, at the control line (C) and test line (T) within the result window, indicates a positive result.

NEGATIVE:

The presence of only the control line (C) within the result window indicates a negative result.

INVALID:

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. **DO NOT CONTINUE** reading the results.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device.

SYMBOL INDEX

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 2-30°C (36-86°F)		Keep Dry
LOT	Batch Number	REF	Catalog#		Keep Away from Sunlight
UDI	Unique Device Identifier	IVD	For <i>in vitro</i> diagnostic use only		Manufacturer
	Prescription Use Only		Do not use if package is damaged		Positive control
	Negative control				

ASSISTANCE

For questions regarding the use of this product, call Technical Support at 1-866-982-3818 (8:30 a.m. to 5:00 p.m. CT)

Manufactured For:

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