

Brand Name of Product	ETO Biological Test Pack with Instant Readout Integrator
Generic Name of Product	ETO Biological Test Pack
Product Code Number(s)	61301606710
Purpose of Product	The Steri-Pak Disposable ETO Biological Test Pack with Instant Readout Integrator is designed specifically for biological testing of EO gas sterilizers. The pack consists of a self-contained biological indicator containing <i>Bacillus atrophaeus</i> spores inside a small package of porous and nonporous material simulating the biological test pack as defined in AAMI ST41.
Range of Applications for Product	N/A
Key specifications of product	<ul style="list-style-type: none"> • Color changes from blue to black (for complete change and no air leaks). <ul style="list-style-type: none"> • Indicator Sheet • Process indicator spot is on the outside of box – blue to black. • Indicator stability: <ul style="list-style-type: none"> • Excellent before exposure. • Good when stored away from a light source after exposure.

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	<ul style="list-style-type: none"> • Do not store biological indicators near sterilants or other chemicals. • Do not use biological indicators after expiration date printed on packs. • Store at normal room temperature 10- to 38 °C (50- to 100 °F) and at 20–70% rh.
Packaging Conditions	Twenty-five (25) controls with a box of 100 test packs
Shelf Life	Please refer to the expiration date printed on the product packaging.

Instructions for Using Product	
Description of Use(s)	N/A
Preparation for Use	N/A
Diagrams (drawings, pictures):	N/A
Steps for Use of Product	<ol style="list-style-type: none"> 1) Load the sterilizer as normal. 2) Place the Biological Test Pack in the most challenging area of the sterilizer (e.g., in the center of a full load) or in accordance with the sterilizer manufacturer. 3) Process the load and run cycle. 4) Post-sterilization, perform either of the following: <ol style="list-style-type: none"> a) Remove the test pack from the sterilization load and transfer the load to the aerator. b) If hospital policy requires, leave the test pack with the load but examine the integrator card through the pouch while transferring to the aerator. 5) Open the pouch: <ol style="list-style-type: none"> a. Remove the plastic cylinder. b. Remove the end cap from the cylinder. c. Slide the self-contained biological indicator from the cylinder. 6) Activate the biological indicator and incubate (as described in the “Biological Indicator Testing Procedure” below): <ol style="list-style-type: none"> a. Activation of the biological indicator: Hold the biological indicator in a vertical orientation and carefully crush the inner glass media ampule by compressing the sides of the plastic body. Place the activated indicator in a microbiological incubator rack and incubate immediately. b. Incubation period: Recommended incubation for 48 hours at 35- to 39 °C (95- to 102.2 °F).

Interpretation of Results	<p>Instant Read-Out Integrator: An integrator card (printed with a chemical integrator) is contained within the test pack to demonstrate the test pack has been exposed to proper sterilization conditions.</p> <ul style="list-style-type: none"> • If the chemical indicator color is: <ul style="list-style-type: none"> ○ <i>Yellow</i>: not exposed to a sufficient ethylene oxide sterilization process. ○ <i>Brown</i>: exposed to proper ethylene oxide sterilization conditions; therefore, biological kill should be achieved. • Record data on the Integrator card. <p>Biological Indicator: Examine the biological indicator at regular intervals (i.e., 18-, 24-, 36-, 48 hours) for signs of color change. If indicator growth media changes to yellow, the biological spores have survived, and the load is NOT sterile.</p> <p>Use of Controls: Five (5) EZTest® Biological Indicators are supplied with each case of test packs for use as controls.</p> <ul style="list-style-type: none"> • Activate and incubate an unexposed control indicator with every sixth test pack run. • Examine the control indicator in accordance with your institution's policy for handling microbial waste. • Discard a biological indicator as soon as signs of biological growth are indicated. • Autoclave any positive indicators at 121 °C (250 °F) for at least 30 minutes.
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	<ul style="list-style-type: none"> • ⚠ CAUTION: Wear safety goggles when crushing vial. • Autoclave any positive indicators at 121 °C (250 °F) for at least 30 minutes.
Disposal	Dispose of indicators in accordance with your institution's policy for handling microbial waste.

Reprocessing Instructions	
Point of use	N/A
Preparation for decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, inspection, and testing	N/A
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	N/A
Storage	N/A
Additional Information	N/A

Related Healthmark Products	Steam Sterilization Integrators, Steam Sterilization Monitors
Other Product Support Documents	Steriking™ Sterilization Products Brochure, Steriking™ Sterilization Products Price List
Reference Documents	SteriTec Product Technical Data Sheet, ANZI/AAMI ST41:2008
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com