



ZymoSnap ALP (Alkaline Phosphatase)

Product No: ZS-ALP-100 (100 tests)



Description and Intended Use

ZymoSnap ALP measures Alkaline Phosphatase (ALP) enzyme levels in milk and other milk-based products. The 5-minute test verifies pasteurization efficiency to meet regulatory standards and demonstrates the absence of raw milk. It is a rapid bioluminogenic method that determines the level of ALP enzyme via the conversion of Relative Light Units (RLUs) to milliunits per liter (mU/L) of ALP in pasteurized milk samples. ZymoSnap ALP is intended for use with pasteurized liquid milk and dairy products. It is not suitable for use with long life or ambient stable milk products.

Principle

The assay uses a single self-contained device in one simple procedure. A milk sample is added to the ZymoSnap ALP tube, the device is activated to release the detection reagent and the sample is incubated for 5 minutes. ALP enzymatic activity is measured in the EnSURE® Touch Monitoring System. ZymoSnap ALP is sensitive enough to measure below regulatory levels (350 mU/L of ALP). Before using ZymoSnap ALP test devices, a positive and negative control must be prepared with the ZymoSnap ALP Positive Control Kit (Part No. ZS-ALP-PC) to establish Pass/Fail RLUs. The Pass/Fail RLUs should be rechecked with controls on a regular basis (e.g., monthly), and whenever a change in process has occurred.

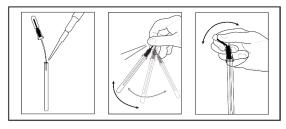
Required Materials (Not Provided)

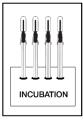
- 1. Positive and negative control, made per instructions in ZymoSnap ALP Positive Control Kit (Part No. ZS-ALP-PC)
- 2. EnSURE Touch Monitoring System (Part No. ETOUCH) or EnSURE Monitoring System (Part No. ENSURE)
- 3. Dry block Incubator or water bath set at 37 ± 1 °C
- 4. Pipette and tips to deliver 75 μL

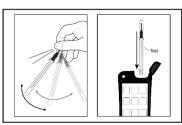
Test Procedure

Before using ZymoSnap ALP devices, ZymoSnap ALP Positive Control Kit (Part No. ZS-ALP-PC) should be run to establish Pass/Fail RLUs for each specific milk type.

- 1. Allow the ZymoSnap ALP device to equilibrate to room temperature (20 25 °C) for 10 minutes. Lift the Snap-Valve bulb out of the tube. Pipette 75 μ L of sample into the tube.
- 2. Replace the bulb in the device tube. Shake and flick the device in downward strokes to ensure all sample reaches the bottom of the tube.
- 3. Activate the device by bending the bulb forward and backward to break Snap-Valve. Squeeze the bulb twice to release the reagent into the tube.
- 4. Incubate for 5 minutes \pm 10 seconds at 37 \pm 1 °C. During the incubation time, turn on the luminometer. If the luminometer has been programmed, select the appropriate program number and control.
- 5. Shake the device for 5 seconds to mix the sample and reagent.
- 6. Immediately place the entire device into EnSURE Touch/EnSURE and press "OK" to initiate the measurement. Results will be displayed in 10 seconds. Measure each test device only once.







ZymoSnap ALP INS-ZS-ALP-100-REVA





Interpretation of Results

- 1. Pass/Fail RLUs for your specific milk type are determined by using ZymoSnap ALP Positive Control Kit (Part No. ZS-ALP- PC).
- 2. Refer to Table 1 for a typical relationship between ALP mU/L and RLU results on EnSURE Touch/EnSURE.
- 3. RLU output is directly proportional to mU/L of ALP.
- 4. RLU output is affected by the type/fat content of milk and incubation temperature.
- 5. For information about expected results on other Hygiena® luminometers, please contact Hygiena.

Table 1. Relationship between ALP activity (mU/L) and EnSURE Touch RLU Output for Cow's Milk of Varying Fat Content*

ALP (mU/L)	EnSURE Touch RLUs		
	Whole Milk (4%)	Semi-Skim Milk (2%)	Skimmed Milk (0.1%)
10	7	10	19
100	67	100	190
350	236	350	666
1,000	673	1,000	1,903
2,500	1,682	2,500	4,757
5,000	3,364	5,000	9,514

^{*}Data in Table 1 is **intended as only an example of different RLU values from different milk types**. Data shows the average RLU from the min/max range given in the positive control kit insert and uses that as the RLU value for 350 mU/L. All other mU/L values are then calculated using that ratio. Given the natural variation in ALP levels, RLU Pass/Fail levels at the critical limit of 350 mU/L should be derived from the user's specific milk product.

Testing Other Milk Products

Other products have been tested including flavored milks, cream, yogurts and milkshakes. Data and application notes are available for the above products and can be obtained by contacting Hygiena.

Storage & Shelf Life

- Store devices in a cool dark place (2 8 °C)
- Check the expiration date on the label do not use devices after the expiration date.

Caution & User Responsibility

Components of ZymoSnap ALP devices do not pose any health risk when used correctly. Used devices should be disposed of in compliance with Good Laboratory Practice and local Health & Safety Regulations.

- 1. Devices are designed for single use. Do not reuse.
- 2. Do not use devices after the expiration date.
- 3. Sampling should be done aseptically to avoid cross-contamination.
- 4. When activating devices, ensure that all liquid in the bulb is transferred to the tube.
- 5. Ensure proper incubation temperature and time.
- 6. Devices are light-sensitive. Do not leave devices out of the bag for long periods of time.

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Product Instructions



Hygiena Liability

Hygiena will not be liable to the user or others for any loss or damage, whether direct or indirect, incidental or consequential, from the use of this device. If this product is proven to be defective, Hygiena's sole obligation will be to replace the product, or at its discretion, refund the purchase price. Promptly notify Hygiena within 5 days of discovery of any suspected defect and return the product to Hygiena.

Contact Information

If more information is required, please visit our <u>help page</u>, email us at <u>techsupport@hygiena.com</u> or contact us by phone at 805.388.8007.

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