

ZymoSnap™ ALP (Alkaline Phosphatase)

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

Required Materials (Not Provided):

1. Positive and negative control to be made per instructions in ZymoSnap ALP Positive Control Kit (Part No. ZS-ALP-PC)
2. EnSURE Monitoring System (Part No. ENSURE)
3. Dry block Incubator or water bath set at $37 \pm 1^\circ\text{C}$
4. Pipette and tips for 75 μL

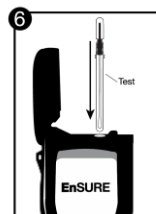
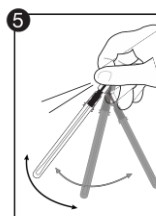
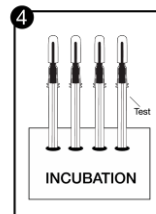
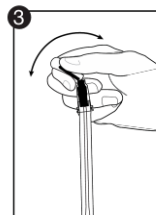
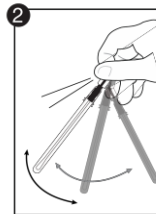
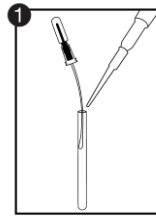
Test Procedure:

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

1. Allow ZymoSnap ALP device to equilibrate to room temperature (20 – 25 °C) for 10 minutes. Lift Snap-Valve bulb out of tube. Pipette 75 μL sample into tube.
2. Replace bulb in device tube. Shake and flick device in downward strokes to ensure all sample reaches bottom of tube.
3. Activate device by bending bulb forward and backward to break Snap-Valve. Squeeze bulb twice to release reagent into tube.
4. Incubate for 5 minutes \pm 10 seconds at $37 \pm 1^\circ\text{C}$. During incubation time, turn on luminometer. If luminometer has been programmed, select appropriate program number.
5. Shake device for 5 second to mix sample and reagent.
6. Immediately place entire device into EnSURE and press "OK" to initiate measurement. Results will be displayed in 15 seconds. Measure test device only once.

Interpretation of Results:

1. Pass/Fail RLU for your specific milk type is 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.
3. RLU output is directly proportional to mU/L of ALP.
4. RLU output is affected by type/fat content of milk and temperature of incubation.
5. For information about expected results on other Hygiena™ luminometers contact Hygiena.



Testing Other Milk Products:

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

Table 1. Relationship between ALP activity (mU/L) and EnSURE RLU output for Cow's milk of varying fat content

ALP (mU/L)	EnSURE RLU		
	Whole Milk (4%) 1 RLU = 1mU/L	Semi-Skim Milk (2%) 1.5 RLU = 1mU/L	Skimmed Milk (0.1%) 3 RLU = 1mU/L
10	10	15	30
100	100	150	300
350	350	525	1050
1000	1000	1500	3000
2500	2500	3750	7500
5000	5000	7500	9999

Data in Table 1 is for illustrative purposes ONLY.

Given natural variation in ALP levels, RLU Pass/Fail levels at the critical limit of 350mU/L should be derived from the user's specific milk. Follow instructions in ZymoSnap ALP Positive Control Kit (Part No. ZS-ALP-PC)

Storage & Shelf Life:

- Store devices in a cool dark place (2 – 8 °C)
- Devices have a 12 month shelf life. Check expiration date on label.

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 and Safety Regulations.

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

Hygiena Liability:

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

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