

ZymoSnap™ ALP (Alkaline Phosphatase)

Part No: HG-ZS-ALP-100 (for use with Hygiena EnSURE Luminometer)

ZymoSnap ALP is sold in packages of 100 devices.

Description and Intended Use:

ZymoSnap ALP (Alkaline Phosphatase) measures ALP enzyme levels in milk and other milk-based products. It is a rapid bioluminogenic method for determination of acceptable levels of ALP enzyme via conversion of RLU (Relative Light Units) to milliUnits per liter (mU/L) of enzyme, after pasteurization of milk. The 10 minutes test verifies sample meets required safe levels of ALP.

Principle:

The assay uses a single self-contained device in one simple procedure. Milk sample is added to ZymoSnap ALP device tube, activated to release detection reagent and incubated for 10 minutes. ALP enzymatic activity is measured in the EnSURE Luminometer. 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 monthly basis, or 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 Luminometer (Part No. ENSURE)
3. Dry block Incubator or water bath set at 55±1°C or 37±1°C

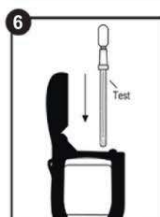
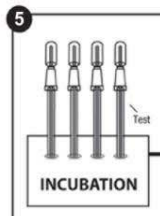
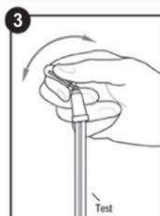
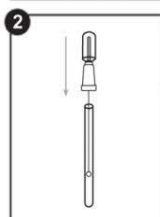
Test Procedure:

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.
3. Activate device by bending bulb forward and backward to break Snap-Valve. Squeeze bulb twice to release reagent into tube.
4. Shake and flick device in downward strokes to ensure all liquid and sample reaches bottom of tube.
5. Incubate for 10 minutes ± 10 seconds at 55°C or 37°C. During incubation time, turn on luminometer. If luminometer has been programmed, select appropriate program number.
6. Immediately place entire device into EnSURE Luminometer 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 relationship between ALP mU/L and RLU results on EnSURE luminometer.
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



Testing Other Milk Products:

Other products have been tested including flavored milks, cream, yogurts and milk shakes.

Table 1. Relationship between ALP Activity (mU/L) and EnSURE RLU output at 55°C and 37°C for 10 minutes for Cow's milk of different fat content

ALP (mU/L)	UK & Europe							
	Whole MILK (~4%) (RLU)		Semi Skim MILK (~2%) (RLU)		Semi Skim MILK (~1%) (RLU)		Skimmed MILK (~0.1%) (RLU)	
	55°C	37°C	55°C	37°C	55°C	37°C	55°C	37°C
<100	70	50	80	60	90	70	100	80
350	120	100	150	120	175	140	200	160
700	200	170	230	210	250	230	280	260

Data in Table 1 is **indicative ONLY** for EnSURE luminometer; given natural variation in ALP levels, RLU Pass/Fail level at critical limit of 350mU/L should be derived from user's specific milk. Follow instructions in ZymoSnap ALP Positive Control Kit (Part No. ZS-ALP-PC).

Storage & Shelf Life:

- Store bags of devices at 2° - 8°C
- Devices have a shelf life of 12 months. 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 a 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.