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ALP (Alkaline Phosphatase) Positive Control Kit

USER MANUAL

Cat No.: ALP0401E

1. Description and Intended Use

The Positive Control Kit for ALP Test Swab(Alkaline Phosphatase) consists of 10 vials of one concentration of ALP (350 mU/L). This is the globally recognized regulatory maximum for ALP levels in pasteurized milk products. A Negative Control is made by heat-inactivating a sample of the milk type the user is calibrating. This provides a background reading that can be used as a baseline. Each Positive Control vial is then reconstituted with the heat-inactivated milk.

The Positive Control confirms the functionality of ALP Test Swab and calibrate each type of dairy product sample.

Prior to using ALP test swabs, positive and negative controls should be run initially. Calibration using negative and positive controls should be performed regularly (e.g., once a week), although the instrument default setting is once a month. Recalibration is required whenever a new manufacturing lot of ALP Test Swabs is introduced or when testing a different type of milk.

2. Required Materials (Not Provided)

a. Luminometer

b. ALP Test Swab ALP0401

c. Dry block Incubator or water bath set at 37 ± 1 °C

d. Water bath set at 95°C (for preparation of Negative Control)

e. Vortex mixer

f. Timer

g. Pipettes 10 µL – 100 µL and 100 µL – 1000 µL

h. Centrifuge tube 50 mL

i. Ice bath for cooling

3. Product Composition

Composition	Quantity
Positive Control	10 bottles
User manual	1 copy
COA	1 copy

4. Test Procedure

4.1 Preparation of Negative Control

a. Heat 5 – 10 mL milk sample in a 50 mL centrifuge tube in a water bath set at 95 ± 1°C for 2 minutes. The water level in the water bath shall fully cover the milk sample. Do not heat the sample in a microwave oven. If protein precipitation occurs during preparation, heat the sample at 75°C for 15 min as an alternative.

b. Cool rapidly on ice, cover, and store at 2 – 8°C for up to 48 hours. Rapid cooling and cold storage are critical to avoid reactivating ALP.

Negative Control can be stored frozen at -15°C for up to 2 months.

c. Negative Control must be tested before preparation of Positive Control.

d. Use the Negative Control to reconstitute the Positive Control vial for the corresponding milk type.

4.2 Negative Quality Control Test

a. Lift the Snap-Valve bulb out of the tube.

b. Pipette 75 µL of the Negative Control into the tube.

c. 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.

d. 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. Shake the swab for 5 seconds to mix the sample and reagent.

e. Incubate for 5 minutes±10 seconds at 37±1°C. During the incubation time, turn on the Luminometer and enter the alkaline phosphatase test module. Select whole pasteurized milk or skim pasteurized milk according to the type of test sample.

f. After the timer expires, shake the swab for 5 seconds to mix the sample and reagent.

g. Immediately place the ALP Test Swab into Luminometer for testing.

h. If the negative control sample passes the test (0–20 mU/L), proceed to sample testing. If the test fails, repeat the analysis. If two retests still yield unacceptable results, prepare a new negative control sample.

4.3 Preparation of Positive Control

Negative Control must be tested before preparation of Positive Control. Use the Negative Control to reconstitute the Positive Control vial for the corresponding milk type.

a. To avoid confusion, label each positive control vial with the milk type to be tested.

b. Carefully remove the metal seal and cap.

c.Pipette x mL (refer to the label on the positive control vial for the reconstitution volume) of the prepared Negative Control into the ALP Positive Control vial.

d. Replace the cap and Vortex for 60 seconds to mix contents until completely dissolved.

e. After dissolution, keep refrigerated or in an ice bath for at least 10 minutes. Mix vigorously before each use. Store the vial at refrigerated temperatures (2–8°C) for 48 h. Refrigerated temperature shall be maintained during use.

4.4 Positive Control Test

a. Lift the Snap-Valve bulb out of the tube.

b. Pipette 75 µL of ALP Positive Control into ALP Test Swab tube.

c. 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.

d. 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. Shake the swab for 5 seconds to mix the sample and reagent.

e. Incubate for 5 minutes±10 seconds at 37±1°C. During the incubation time, turn on the Luminometer and enter the alkaline phosphatase test module. Select whole pasteurized milk or skim pasteurized milk according to the type of test sample.

f. After the timer expires, shake the swab for 5 seconds to mix the sample and reagent.

g. Immediately place the ALP Test Swab into Luminometer for testing.

h. Repeat for a total of 2 replicates. If the positive control sample passes the test (225–525 mU/L), proceed to sample testing. If the test fails, repeat the analysis. If two retests still yield unacceptable results, prepare a new positive control sample.

4.5 ALP Test

Refer to the ALP Test Swabs instruction manual.

5. Storage and Shelf Life

2–8°C, protect from light, valid for 12 months.

For Positive Controls, check the expiration date on the box label. Do not use it after the expiration date.

The Negative Control should be used within 48 hours when stored at 2 – 8 °C.

Reconstituted Positive Controls must be used within 7 days when stored at 2 – 8 °C.

6. Cautions and User Responsibility

The components of the Positive Control Kit for ALP 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.

a. Ensure proper incubation time and temperature for Negative Control preparation.

b. Ensure Positive Controls are reconstituted with the Negative Control made with milk type to be tested (whole, 2%, 1% or non-fat).

c. Ensure proper storage temperature of Negative and reconstituted Positive Controls. If Negative Controls are stored frozen, aliquot into single-use volumes before freezing. Do not use after one freeze/thaw cycle. The use of freshly made Negative Control is recommended.

d. High RLU results may be produced by reactivated phosphatase and microbial phosphatase. Reactivated phosphatase is a natural phenomenon of ALP when not cooled quickly after pasteurization and/or pasteurized product is stored at temperatures above 8 °C. It is important to maintain samples at chilled temperatures when not being tested. Microbial phosphatase can survive pasteurization when raw milk is contaminated and/or abused prior to pasteurization.

7. Scigiene Liability

Scigiene 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, Scigiene's sole obligation will be to replace the product or at its discretion, refund the purchase price. Promptly notify Scigiene within 5 days of discovery of any suspected defect and return the product to Scigiene.