



**Product:** A test kit for detecting ketone bodies in cow milk.

## A. Kit & Storage Specifications

<b>Test Strip</b>	<ul style="list-style-type: none"><li>• 0.48 cm x 7.62 cm: 0.19 in x 3.00 in — consisting of plastic support material, adhesive, and membrane with dried reagents.</li><li>• Contains no biological materials.</li></ul>
<b>Test Principle</b>	<ul style="list-style-type: none"><li>• The reagent pad on the test strip contains an enzyme that converts BHB (beta-hydroxybutyrate) to acetoacetate. This reaction generates hydrogen ions that reduce nitrotetrazolium blue to formazan, which is purple in color.</li><li>• The darker the purple color, the higher the concentration of BHB.</li></ul>
<b>Color Chart</b>	<ul style="list-style-type: none"><li>• Printed on label for estimating results using color comparison.</li></ul>
<b>Package Insert</b>	<ul style="list-style-type: none"><li>• List of kit contents, and instructions.</li></ul>
<b>Storage</b>	<ul style="list-style-type: none"><li>• Store at 2° – 25° Celsius (36° – 77° Fahrenheit).</li><li>• Store refrigerated whenever possible.</li><li>• Product is supplied in black desiccated vials.</li><li>• Keep vials tightly closed. Product is sensitive to light and humidity.</li></ul>
<b>Shelf Life</b>	<ul style="list-style-type: none"><li>• 2 years from the date of manufacture if stored at room temperature (unopened product).</li></ul>

## B. Test Specifications

<b>Assay Temperature</b>	<ul style="list-style-type: none"><li>• 7° – 35° Celsius (45° – 95° Fahrenheit)</li></ul>
<b>Reaction Time</b>	<ul style="list-style-type: none"><li>• 1 (one) minute</li></ul>

## C. Performance Specifications

<b>Analytical Ranges:</b>	<ul style="list-style-type: none"><li>•   0   50   100   200   500   <math>\mu\text{mol/L}</math> BHB</li></ul>
<b>Sensitivity</b>	Initial studies show: <ul style="list-style-type: none"><li>• <b>89%</b> at 100 <math>\mu\text{mol/L}</math> BHB in milk — compared to a concentration of 1.4 mg/dL BHB in blood.</li></ul>
<b>Specificity</b>	<ul style="list-style-type: none"><li>• <b>80%</b> at 100 <math>\mu\text{mol/L}</math> BHB in milk — compared to a concentration of 1.4 mg/dL BHB in blood.</li></ul>