

**INDICATIONS FOR USE**

K032161

**Device Name:** pHEM-ALERT

**Indications For Use:**

The pHEM-ALERT® test measures vaginal pH and is intended for use by women who have any of the following vaginal symptoms:

Itching – Burning - Unpleasant odor - Unusual discharge

This test may help decide if these symptoms are caused by an infection that may require follow-up by your healthcare provider. This test is only intended for women who have normal menstrual periods (periodic vaginal bleeding) or who may currently be pregnant. If you are pregnant, always discuss your symptoms and the result of this test with your healthcare provider and NEVER treat yourself.

Jean Cooper  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

§10(k) K032161

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:  
(Per 21 CFR 801.109)

OR

Over-The-Counter:

(Optional Format 1-2-96)

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