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**FEMEXAM® TESTCARD™ pH AND AMINE TESTS
510(K) SUMMARY - SAFETY AND EFFECTIVENESS**

This summary of 510(k) safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR Section 807.92. Litmus Concepts, Inc. (LCI) hereby states that it will make available this safety and effectiveness information to any interested persons upon request.

1. Introduction:

The FemExam® TestCard™ contains two qualitative, colorimetric tests for use in the characterization of a vaginal fluid sample: (1) a pH test that differentiates vaginal fluid pH less than pH 4.7 from vaginal fluid pH equal to or greater than pH 4.7; and (2) a test that detects alkali volatilizable amines in vaginal fluid. Elevated vaginal fluid pH (pH 4.7 or higher) and the detection of a fishy odor upon adding 10% potassium hydroxide (KOH) to vaginal fluid represent two of the four Amsel criteria.

2. pH Test:

The FemExam® TestCard™ pH test system contains a traditional colorimetric pH indicator, nitrazine yellow, which produces a visual, geometric color change within two minutes of specimen application. When contacted with a vaginal fluid specimen at or above pH 4.7, the pH test produces a blue plus sign against a greenish-yellow background. When contacted with a vaginal fluid specimen below pH 4.7, the pH test produces a blue minus sign against a greenish-yellow background.

A narrow minus sign across the center of the pH test serves as the positive procedural control and is produced when the pH test is wetted with a vaginal fluid specimen. The positive control contains nitrazine yellow specifically formulated to change color (from greenish-yellow to blue) regardless of whether the pH of the vaginal fluid specimen is normal or elevated. Although the area surrounding the undeveloped plus sign within the pH test circle also contains nitrazine yellow, it is specifically designed not to change color, regardless of whether the pH of the vaginal fluid specimen is normal or elevated, and serves as the negative background control.

3. Amine Test:

The FemExam® TestCard™ amine test system contains a traditional colorimetric pH indicator, bromocresol green (BCG), which produces a visual, geometric color

change within two minutes of specimen application. When contacted with a vaginal fluid specimen that contains alkali volatilizable amines, the amine test produces a blue plus sign against a yellow background. When contacted with a vaginal fluid specimen that does not contain alkali volatilizable amines, the amine test produces a blue minus sign against a yellow background.

The TestCard™ amine test employs a very thin dried film of BCG in the yellow test circle which is surrounded by a thick black ring covered with a dried alkali, sodium aluminate. The BCG on the yellow amine test circle produces a visual color change (blue plus sign) in response to the pH elevation produced when the BCG is contacted with a vaginal fluid specimen containing amines volatilized by contact with the sodium aluminate on the thick black ring. The TestCard™ amine test detects volatile amines at concentrations above 0.5mM.

A narrow blue minus sign across the center of the TestCard™ amine test serves as the positive procedural control and is produced when the amine test is wetted with a vaginal fluid specimen. The positive control contains BCG specifically formulated to change color (from yellow to blue) regardless of whether the vaginal fluid specimen does or does not contain alkali volatilizable amines. Although the area surrounding the undeveloped plus sign within the test circle also contains BCG, it is specifically designed not to change color upon the addition of the vaginal fluid specimen, regardless of whether it contains alkali volatilized amines, and serves as the negative background control.

4. Performance Characteristics:

The FemExam® TestCard™ pH and amine tests were evaluated in a statistically designed clinical study. The results of the TestCard™ pH test were compared to the results of a commercial pH test strip (ColorpHast® pH test strip) routinely used in clinical studies to estimate vaginal fluid pH. The results of the TestCard™ amine test were compared to the results of the whiff test, an accepted clinical standard for ascertaining volatile vaginal fluid amines. The positive agreement, negative agreement and overall agreement were calculated. The TestCard™ pH test exhibited statistically significant overall agreement with the results of the pH test strip. The TestCard™ amine test exhibited statistically significant overall agreement with the results of the whiff test.