510k Submission
(K962721)
Evidence Pregnancy Test
Universal Diagnostics L.L.C.

OCT 1 1996

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510 (K) SUMMARY

Date of Summary: September 12, 1996

Product Name:

Evidence Pregnancy Test

Sponsor's Name:

Universal Diagnostics L.L.C.
P.O. Box 67635
Rancho Santa Fe, CA 92067

Manufactured by:

Veda Lab
Rue de l' Expansion - ZAT du Londeau - CERISE
B.P. 181 - 61006 Alencon Cedex, France

Correspondent:

MDC Associates
Fran White
Regulatory Consultant
15 Oak Street
Beverly Farms, MA 01915

Substantially Equivalent Devices:

Product: Pregnosis Pregnancy Test
Manufactured by: Hoffman - La Roche, Inc.

Product: Cards + Q.S. Pregnancy Test
Manufactured by: Pacific Biotech, Inc., a subsidiary of Quidel Corporation

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PRODUCT DESCRIPTION:

Evidence Pregnancy Test is a pregnancy test to be used for detecting human Chorionic Gonadotropin (hCG) in urine. The presence of hCG usually appears about the eighth or ninth day after fertilization. The Evidence Pregnancy Test will detect hCG in urine as early as the first day after a missed menses. The Evidence Pregnancy Test will be made available to the lay consumer.

INTENDED USE:

The Evidence Pregnancy Test is a qualitative, one-step assay for the detection of human chorionic gonadotropin (hCG) in urine. The Evidence Pregnancy Test is intended to be used by the lay consumer.

SUMMARY OF TECHNOLOGY:

The Evidence Pregnancy Test employs a unique combination of monoclonal-dye conjugate and polyclonal-solid phase antibodies to selectively identify human Chorionic Gonadotropin (hCG) in urine. As the urine flows through the absorbent portion of the device, the antibody-dye conjugate binds to the hCG forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose color band if hCG concentration is greater than 25 mIU/ml. In the absence of hCG, there is no line in the positive reaction zone. Unbound conjugate binds to the reagents in the control zone, producing a pink-rose color band, demonstrating that the reagents are functioning correctly.

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PERFORMANCE DATA:

A clinical trial was done to confirm the performance of the Evidence Pregnancy Test. These data clearly demonstrate that the performance of the Evidence Pregnancy Test is substantially equivalent to the Hoffman La-Roche Pregnosis Pregnancy Test.

Pregnosis vs. Evidence
(Professional User)

	PREGNOSIS +	PREGNOSIS -	Row Total
EVIDENCE +	95	2*	97
EVIDENCE -	0	3	3
Total	95	5	100

Sensitivity =	100.00%
Specificity =	60.00%
Accuracy =	98.00%
% Negative Predictive Value =	100.00%
% Positive Predictive Value =	97.94%

* Note: False positive results were tested with Pacific Biotech Cards + Q.S. and were confirmed positive. Both the Evidence Pregnancy Test and the Cards + Q.S. detect levels of hCG in urine at 25 mIU/ml. The Pregnosis Pregnancy Test will detect only 1.5 to 2.5 IU/ml of hCG in urine which is approximately 42 days after conception. The Evidence Pregnancy Test is more sensitive than the Pregnosis Test.

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Cards + Q.S. vs. Evidence
(Professional User)

Data Summary

	CARDS + Q.V. +	CARDS + Q.S. -	Row Total
Evidence +	2	0	2
Evidence -	0	0	0
Total	2	0	2

Sensitivity =	100.00%
Specificity =	100.00%
Accuracy =	100.00%
% Negative Predictive Value =	100.00%
% Positive Predictive Value =	100.00%

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Medical Technologist vs. Study Participant
(Lay Consumer)
To confirm that the Evidence Pregnancy Test can be used by the lay consumer. 100 people were asked to perform the test. Study participants were asked to read the insert and perform the test as instructed.

The following is a summary of the test results.

Data Summary

	Medical Technologist +	Medical Technologist -	Row Total
Study Participant+	31	0	31
Study Participant -	0	69	69
Total	31	69	100

Sensitivity =	100.00%
Specificity =	100.00%
Accuracy =	100.00%
% Negative Predictive Value =	100.00%
% Positive Predictive Value =	100.00%