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[510(k)] Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

ABBOTT Advisor® One-Step Pregnancy Test

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Trade Name	ABBOTT Advisor One-Step Pregnancy Test
Common Name	Consumer Use Home Pregnancy Test
Classification Name	Human Chorionic Gonadotropin (hCG) Test System
Device Classification	Class II
Predicate Device Name	FactPLUS® One Step Pregnancy Test (K962521)

The following information as presented in the 510(k) Notification for the ABBOTT Advisor One-Step Pregnancy Test constitutes data supporting a substantially equivalent determination.

Intended Use

The ABBOTT Advisor One-Step Pregnancy Test is a self-performing immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

Indications

The ABBOTT Advisor One-Step Pregnancy Test is an over-the counter *in vitro* test which can be used by the consumer to detect pregnancy as early as the first day of her missed period, using a direct urine stream sampling method. Some positive results appear as soon as three minutes, however, all results are confirmed when the Test Timer turns pink/red. The Test Timer will turn pink/red approximately 5 minutes after the urine has been added to the test device.

Device Description

The ABBOTT Advisor One-Step Pregnancy Test is an elongated device composed of two pieces of molded plastic which contain the internal test strip. The three openings on the device are the Urine Well, the Result Window and the Test Timer. The Result Window and the Test Timer are protected with a clear seal to prevent potential contamination caused by splashing urine.

The ABBOTT self-performing immunoassay for hCG in urine is based on the principle of a two site immunometric assay. Urine is added to the Urine Well, where it migrates through the Absorbent Pad to the Conjugate Pad portion of the test strip. As the urine moves through the Conjugate Pad, it mobilizes the mouse monoclonal anti-alpha hCG antibody coated colloidal particles. Any hCG present in the urine sample combines with the anti-alpha hCG antibody on the colloidal particle.

The urine, now containing an hCG-antibody-colloid complex and unbound colloid, continues to move up the test strip to the Result Window which contains immobilized polyclonal anti-βhCG on a vertical (Patient) bar and anti-mouse/anti-βhCG on a horizontal (Control) bar. The color generated is proportional to the concentration of hCG in the urine sample. Anti-hCG (mouse monoclonal) coated colloidal particles bind to the anti-mouse antibody immobilized on the Control Bar which indicates the assay is performing properly. A positive sign (+) indicates the presence of hCG. Low hCG concentration samples may display a "T" result, which is also interpreted as positive. The absence of detectable hCG will result in a negative sign (-). The assay is complete when the "Test Timer" indicator changes to pink or red, approximately three minutes after the start of the assay.

Statement of Substantial Equivalence

The ABBOTT Advisor One-Step Pregnancy Test is substantially equivalent to, and is the same device as the currently marketed FactPLUS® One Step Pregnancy Test (K962521) which is manufactured by Abbott Laboratories and distributed for over-the-counter sale by Direct Access Diagnostics, Bridgewater, New Jersey.

The intended use, technology, methodology, test chemistry, test analyte, component materials, sensitivity, specificity, and accuracy are the same for both the Abbott and the Direct Access Diagnostics devices. The devices can be used the first day of a missed period or menses, and at any time of the day.

The only differences between the Abbott and Direct Access Diagnostics devices are the name, the packaging and labeling format, and a modification to the labeled time to result requirement. Although some positive results may be seen as soon as 3 minutes from the start of the assay, customers are instructed to read the results when the Test Timer turns pink/red (approximately 5 minutes from beginning the test). A comparison of Similarities and Differences can be found in Table 1, page 9.

Table 1
Substantial Equivalence
Similarities and Differences

COMPARATORS	ADVISOR ONE-STEP PREGNANCY TEST (SUBJECT)	FACT PLUS ONE STEP PREGNANCY TEST (PREDICATE)
Visual Result Presentation Positive Signal Negative Signal	Plus (+) Sign Minus (-) Sign	Plus (+) Sign Minus (-) Sign
Urine Collection & Mode of Addition	Direct Urine Stream	Direct Urine Stream
Analyte hCG	Same	Same
Specimen Type Human Urine	Same	Same
Intended Use Home Pregnancy Test	Same	Same
Technology Qualitative - sandwich colloidal particle immunoassay	Same	Same
Time to Assay Result	5 minutes (some positives seen in 3 minutes)	3 minutes (some positives seen in 1 minute)
Components Single unit test device (all reagents contained on a test strip within)	Same	Same
End of Assay Color Change	Yes - Test Timer Shows adequate sample Wait to read results	Yes * Do not wait for signal before reading results
Strip Chemistry Conjugate - Monoclonal Anti-αhCG Antibody	Same	Same
Patient Bar Polyclonal Anti-βhCG Antibody	Same	Same
Control Bar Polyclonal Anti-βhCG Antibody and Polyclonal Anti-Mouse	Same	Same
Consumer Use Accuracy	98%	98%
Laboratory Use Accuracy	100%	100%

* Do not need to wait for signal before reading results

Performance Data

Accuracy testing was perfomed by Advanced Care Products using hCG-positive and hCG-negative female clinical urine specimens across three different lots of the Abbott device, which is currently marketed under the brand name of FactPLUS® One Step Pregnancy Test.

The device correctly identified 50/50 hCG-positive and 50/50 hCG-negative specimens. Tests were read immediately after the Test Timer turned pink/red, approximately 5 minutes after the start of the test. The hCG-positive samples were confirmed to be positive with the Hybritech ICON pregnancy test. The hCG-negative specimens were confirmed to be negative with the FactPLUS® Cup and Dropper Pregnancy Test. At three minutes agreement was 100% with the ICON and FactPLUS devices.

Consumer Testing

A clinical study was conducted to verify that consumers could obtain accurate test results when using the Abbott manufactured device according to the provided instructions. The consumer population consisted of 149 female volunteers recruited from a central New Jersey location. The volunteers were between the ages of 18 to 45, from various income, educational and employment backgrounds. Correct results were obtained by one hundred forty six (146) of one hundred forty nine (149) subjects for an overall accuracy of 98%. Subjects reported little difficulty with understanding the test instructions. Ninety-two percent reported that the instructions were "very easy to understand" and all subjects (100%) indicated that the instructions were "somewhat" or "very easy to understand.

Conclusion

The ABBOTT Advisor One-Step Pregnancy Test is substantially equivalent, and is in fact the same device as the FactPLUS® One Step Pregnancy Test, distributed by Direct Access Diagnostics. Laboratory testing indicates accuracy of 100%, sensitivity and specificity of 100% each.

Results of consumer clinical testing demonstrated that the Abbott device can be performed and correctly interpreted by consumers with an overall accuracy rate of 98%.

Prepared and Submitted January 8, 1997 by:

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