

K964108

Direct Access Diagnostics Division
Premarket Notification [510(k)]
FactPlus® Pregnancy Test (modification)

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APPENDIX

510(k) SUMMARY

510(k) SUMMARY per 21 CFR 807.92(c)

Trade name Fact PLUS Pregnancy Test
Common name Consumer Use Home Pregnancy Test
Classification name Human chorionic Gonadotropin (hCG) Test System

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule... "510(k) Summaries and 510(k) Statements." (21CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

- Modified device name: Fact PLUS Pregnancy Test
- Predicate device name(s): currently marketed Fact PLUS Pregnancy Test and Fact PLUS One Step Pregnancy Test

Intended Use

The modified Fact PLUS Pregnancy Test (Cup and Dropper) is an over-the counter *in vitro* diagnostic immunoassay intended for the qualitative detection of human chorionic gonadotropin (hCG), in urine. A labeling modification to the currently marketed Fact PLUS® Pregnancy Test enables the test results to be read in three minutes or less without altering the accuracy, sensitivity or specificity of the test.

Indications

The Fact PLUS Pregnancy Test is indicated for consumer use to detect pregnancy as early as first day of a missed period, any time of the day. Negative test results are confirmed after three minutes, some positives results can be read as soon as one minute.

Safety

Home pregnancy tests for detection of hCG in urine have been safely used and in commercial distribution for over twenty years. *In vitro* diagnostic hCG urine tests which do not come in contact with the body are not generally associated with safety issues. Home-use pregnancy tests are categorized as "waived" status under the 1988 Clinical Laboratory and Improvement Amendment (CLIA).

510(k) SUMMARY (continued)

Device Description

The modified Fact PLUS Pregnancy Test is a disk-shaped ("*Test Disk*") device constructed of two pieces of molded plastic. The test chemistries are coated on a test strip housed within the test disk. The test strip contains three reactive sites: a conjugate site, an antibody site and a control site. Three openings on the upper surface of the test disk correspond to these sites: "*Urine Well*," "*Result Window*," "*Control Window*" (*CW*) respectively.

When urine is added via the *Urine Well* it wets the conjugate (anti- α hCG antibody) mobilizing it. If hCG molecules are present in the urine specimen, an hCG/conjugate complex is formed. This complex and any remaining unbound conjugate migrate along the strip attaching to the anti- β hCG antibody contained on the vertical bar (positive) and also to the polyclonal antibodies on the intersecting horizontal bar (negative) causing a pink reaction. The appearance of pink color on the horizontal and vertical bars forms the "plus" sign or positive "pregnant" result.

When no hCG molecules are present in the urine specimen, the conjugate remains unbound and attaches only to the horizontal or "minus" bar causing it to turn pink. The appearance of only one pink horizontal bar constitutes the negative or ("not pregnant") result.

The urine flow continues on to the *Control Window* where it activates a special dye causing a red color to appear. The red color in the *CW* tells the user that enough urine was added. It can also play an important role in helping the Consumer Service representatives on our toll free number to evaluate consumer reported problems. It takes approximately five minutes for the urine to reach the *Control Window*. The appearance of a "plus" or a "minus" in the *Result Window* however, appears sooner usually within three minutes or less. Some positive results can appear as soon as one minute. The appearance of a plus or minus in the *Result Window* and red color in the *Control Window* are the built-in controls which indicate the test chemistries worked properly and that a sufficient volume of urine was added.

Substantial Equivalence

The modified Fact PLUS Pregnancy Test is substantially equivalent to the marketed version of Fact PLUS[®] Pregnancy Test with a labeling modification for reading the results sooner. Additionally modified Fact PLUS (Cup & Dropper) is substantially equivalent to Fact PLUS[®] One Step (Direct) Pregnancy test which also provides results within 3 minutes.

The proposed and the marketed devices have the same intended use, performance characteristics, and utilize the same chemistries, materials, and test analyte. All three pregnancy tests can be used the first day of missed period, at any time of day.

510(k) SUMMARY (continued)

Performance Data

Substantial equivalence was demonstrated in laboratory validation testing. Fact PLUS Pregnancy Test when performed according to the modified instructions was compared to the currently marketed Fact PLUS Pregnancy Tests for accuracy, specificity, and sensitivity.

Percent laboratory accuracy was determined by testing hCG-positive and hCG-negative female clinical urine specimens across three different lots of Fact PLUS Pregnancy Test and one lot of Fact PLUS One Step. Data compared test results read according to the modified labeling instructions (three minutes) to test results read according to the current labeling instructions (End of Test Window /approximately 5 minutes). There was 100% agreement for all four lots at the three minute and five minute time frames.

Consumer Testing

A single-blind, consumer, clinical study was conducted to verify that consumers could obtain accurate test results when performing the Fact PLUS Pregnancy test and reading the results according to the modified directions. The consumer population consisted of 150 evaluable female volunteers recruited from a Central New Jersey location. One hundred and fifty-two subjects had been enrolled, however two subjects were dropped from the study for protocol violations. The participants were between 18 to 45 years of age, from various income levels, and educational and employment backgrounds.

Subjects were provided with a randomized hCG positive or hCG negative urine sample, the Fact Pregnancy Test and the modified instructions. All subjects who tested positive specimens recorded the results as positive and all subjects who tested negative specimens recorded the results as negative. The overall consumer accuracy rating was 100% for this study.

Conclusion

The Fact PLUS Pregnancy Test with modified directions has been shown to be substantially equivalent to the currently marketed Fact PLUS® and the Fact PLUS® One Step Pregnancy Test in laboratory validation testing demonstrating 100% agreement for accuracy, sensitivity, specificity. Additionally, consumer testing demonstrated that the FactPLUS Pregnancy Test can be performed according to the modified directions and correctly interpreted by consumers with an overall accuracy rating of 100%.