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Platform OneStep Pregnancy Test Summary of Safety and Effectiveness

Platform OneStep pregnancy test is Syntron Bioresearch, Inc. name for OTC use of solid phase immunoassay in vitro diagnostic test kit for the qualitative determination of human Chorionic Gonadotropin (hCG) in urine. Platform OneStep pregnancy test is based on comparative data with Besure OneStep immunoassay, an assay for human Chorionic Gonadotropin currently being marketed.

The Principle of Platform and Besure Pregnancy Test is as follows:

The Platform and Besure pregnancy test is a sandwich solid phase dye-conjugate non-enzyme immunoassay. As the specimen is added to the reaction device, the gold-sol-antibody conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a purple-pink color band when hCG concentration is greater than 25 mIU/ml. In the absence of hCG, there is no purple-pink line in the positive reaction zone. The reaction mixture continues to flow through the absorbent device, pass the positive reaction zone, producing a purple-pink color band, demonstrating that the reagents and device are functioning correctly.

The Differences Between the Two Protocols

	Platform	Besure
Specimen Volume	6 drops of urine	4 drops of urine
Incubation Time	5minutes	5minutes
Reagent	No	No
Steps	1 Step	1 Step
Threshold	25 mIU/ml	25 mIU/ml
Time to Result	Yes	Yes