

K964156

NOV 25 1996

510(k) Notification
Genzyme Diagnostics
Contrast[®] Strip hCG
October 15, 1996

**510(k) Summary of Safety and Effectiveness
Information Upon Which An Equivalence Determination Could Be Made**

Trade or Proprietary Name: *Contrast*[®] Strip hCG

Common or Usual Name: Human Chorionic Gonadotropin Test System

Product Classification Number: 21 CFR § 862.1155, Class II

Manufacturer: Genzyme Diagnostics
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San Carlos, CA 94070

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Equivalence Device: *Rapid* hCG[™] Urine/Serum Test
510(k) Number: **K952319**
Cleared June 20, 1995

Device Description: Rapid membrane based immunoassay for the qualitative detection of hCG using mouse monoclonal anti-hCG and sheep anti-alpha hCG polyclonal antibodies.

Intended Use: The qualitative detection of human chorionic gonadotropin (hCG) in urine or serum for the early determination of pregnancy in physician's office and clinical laboratories.

A multicenter clinical study was performed in four physician's offices/clinics (POL). The Genzyme Diagnostics *Contrast*[®] Strip hCG was provided to the sites. Each site also used the legally marketed *Rapid* hCG[™] Urine/Serum Test. The *Rapid* hCG[™] Urine/Serum Test is marketed for laboratory and professional use.

Urine specimens were tested in four physician's offices using both Genzyme tests. Clinical subjects included female patients seeking confirmation of pregnancy, those who were confirmed pregnant, post-menopausal women and assumed negatives.

Three physician's offices performed both Genzyme tests on serum specimens from female patients for either confirmation of pregnancy or non-pregnancy status prior to treatment (e.g. X-ray) for other disease states and post-menopausal women.

The results with both urine (209) and serum (177) samples demonstrate that the Genzyme Diagnostics *Contrast*[®] Strip hCG has 100% agreement with the *Rapid* hCG[™] Urine/Serum Test.

	Urine		Serum	
	Strip hCG	<i>Rapid</i> hCG [™]	Strip hCG	<i>Rapid</i> hCG [™]
Positive	75	75	Positive 72	72
Negative	134	134	Negative 105	105

At three POLs, eight individuals with various levels of training tested a blind reproducibility and sensitivity panel using the Genzyme Diagnostics *Contrast*[®] Strip hCG. The Genzyme Diagnostics *Contrast*[®] Strip hCG reproducibly detected hCG in urine at levels as low as 20 mIU/mL and as high as 1,000,000 mIU/mL and serum hCG at levels as low as 10 mIU/mL and as high as 1,000,000 mIU/mL.

These results establish that the Genzyme Diagnostics *Contrast*[®] Strip hCG is substantially equivalent to the *Rapid* hCG[™] Urine/Serum Test. The Genzyme Diagnostics *Contrast*[®] Strip hCG Test can detect hCG concentrations of 20 mIU/mL in urine and 10 mIU/mL in serum.

The intended use of the Genzyme Diagnostics *Contrast*[®] Strip hCG is the early determination of pregnancy by the qualitative detection of human chorionic gonadotropin (hCG) in human serum or urine. Our intent is to market this product for laboratory and professional use.