K963425

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

Trade or Proprietary Name:	*Contrast*® Mono Test
Common or Usual Name:	Infectious Mononucleosis Test for Human IgM antibodies to Heterophile Antigen
Product Classification Number:	21 CFR § 866.5640, Class II
Manufacturer:	Genzyme Diagnostics 1531 Industrial Road San Carlos, CA 94070
Contact Person:	Delia R. Bethell, Ph.D. Director of Research and Development Phone: (415) 594-0513 Fax: (415) 594-0571
Predicate Device:	Quidel CONCISE® PLUS™ MONO
Device Description:	Rapid membrane based immunoassay for the qualitative detection of human IgM antibodies to heterophile antigen using mouse monoclonal anti-IgM antibodies and heterophile antigen from bovine red blood cells.
Intended Use:	The qualitative detection of human IgM antibodies to heterophile antigen in serum, plasma or whole blood as an aid in the diagnosis of acute infectious mononucleosis for use in the physician's office laboratory and the clinical laboratory.

A multicenter clinical study was performed in three physician's office laboratories, POL, (including two university student health clinics) and one clinical laboratory. The Genzyme Diagnostics Infectious Mono Test was provided to the sites. Each site also used the legally marketed Quidel Concise® Plus™ Mono Test. The Quidel test is marketed for laboratory and professional use.

The clinical laboratory performed the Genzyme and Quidel tests on serum and plasma specimens submitted for infectious mononucleosis. The university student health centers tested whole blood and plasma from students presenting with symptoms consistent with a diagnosis of infectious mononucleosis. A total of 480 serum, plasma and whole blood specimens were tested and compared with the reference method.

The results demonstrate that the Genzyme Diagnostic Infectious Mono Test has a 99.2% agreement with the Quidel Concise® Plus™ Mono (476/480). There was no difference in performance between the university student health centers and the clinical laboratory.

		Contrast® Mono	
		Positive	**Negative**
Concise® Plus™ Mono	**Positive**	58	3
	Negative	1	418

Individuals with various levels of training tested a blind reproducibility panel using the Genzyme Diagnostics *Contrast®* Mono Test. Panel samples in replicates of 5 were tested on three different days. The *Contrast®* Mono Test demonstrated reproducible results at three physician's office laboratories.

These results establish that the Genzyme Diagnostic *Contrast®* Mono Test is substantially equivalent to Quidel Concise® Plus™ Mono Test. The *Contrast®* Mono Test can detect human IgM antibodies to heterophile antigen in serum, plasma, and whole blood samples.

The intended use of the Genzyme Diagnostic *Contrast®* Mono Test is for the detection of human IgM antibodies to heterophile antigen as an aid in the diagnosis of acute infectious mononucleosis. This product will be marketed for laboratory and professional use.