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ATTACHMENT 1

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

Trade or Proprietary Name: Genzyme N-geneous™ HDL Cholesterol Kit

Common or Usual Name: Homogeneous assay for high density lipoprotein cholesterol
Calibrator for high density lipoprotein cholesterol

Classification Name: High density lipoprotein cholesterol test
Calibrator, Primary

Manufacturer: Genzyme Diagnostics
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Cambridge, MA 02139-1562

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The use of the Genzyme N-geneous™ HDL Cholesterol Kit in the clinical laboratory setting is substantially equivalent to the use of the Phosphotungstic Acid MgCl₂ (PTA) precipitation method.

The Genzyme N-geneous™ HDL Cholesterol Kit, is a two-reagent homogenous method for use in the direct quantitative determination of high density lipoprotein cholesterol (HDL-C) in human serum and plasma.

The first reagent contains a mixture of polymers and polyanions that bind to the surface of low-density lipoproteins (LDL), very low-density lipoproteins (VLDL) and chylomicrons. These complexed lipoproteins are stabilized, even in the presence of detergent which is added as part of the second reagent, together with cholesterol enzymes. HDL particles, on the other hand, are not stabilized by the polymers and polyanions and become solubilized by the detergent. Consequently, only the HDL cholesterol is subject to cholesterol measurement.

Comparative performance studies were conducted at three sites using the N-geneous™ HDL Cholesterol Kit and two reference methods: Phosphotungstic Acid MgCl₂ and the Center for Disease Control (CDC) reference method. Based on the Lipid Research Clinics (LRC) population studies, patient serum samples with HDL values between 27-91 mg/dL (5th and 95th percentile, respectively) were used for these comparative studies.

One hundred fourteen serum samples, with HDL values between 24 and 94 mg/dL, were tested at three sites with the N-geneous™ HDL test method. Of these 114 samples, 108 had sufficient volume

510(k) PREMARKET NOTIFICATION

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June 5, 1996

for testing with the PTA predicate method. Additionally, a subset of at least 25 serum samples were to be analyzed by the CDC reference method and the results compared.

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	N-geneous™ vs. Phosphotungstic Acid (n = 108)	N-geneous™ vs. CDC Method (n = 26)
Correlation Coefficient (r)	0.96	0.96
Regression Equation	$y = 0.81x + 7.82$	$y = 1.01x - 3.39$

Precision studies were conducted using the N-geneous™ HDL Cholesterol Test Kit. Both within-run and between-run studies were performed using fresh and frozen serum pools at three target levels of HDL Cholesterol as determined by the NCEP: <35 mg/dL (low); 35-60 mg/dL (mid); and >60 mg/dL (high).

Within-Run	Low (<35 mg/dL)	Mid (35-60 mg/dL)	High (>60 mg/dL)
n	20	20	20
Mean (mg/dL)	30.2	42.7	75.6
SD (mg/dL)	0.45	0.50	0.79
%CV	1.50%	1.18%	1.04%

Between-Run	Low (<35 mg/dL)	Mid (35-60 mg/dL)	High (>60 mg/dL)
n	80	80	80
Mean (mg/dL)	29.4	41.9	73.2
SD (mg/dL)	1.11	1.10	2.03
%CV	3.79%	2.64%	2.78%

These data demonstrate that the performance of the N-geneous™ HDL Cholesterol Kit in the clinical laboratory is substantially equivalent to the performance of the PTA and CDC Reference methods.

In lieu of a 510(k) statement under 513(i) of the Act, this information is provided as a 510(k) summary for disclosure to any other persons/companies without the specific written authorization from Genzyme Corporation.