

Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139

GlyPro™ Reagent, Calibrator  
Low Control and High Control  
October 5, 1998

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NOV 25 1998

## ATTACHMENT 1

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

**Trade or Proprietary Name:** GlyPro™ Reagent  
GlyPro™ Calibrator  
GlyPro™ Low Control  
GlyPro™ High Control

**Common or Usual Name:** Assay, Glycosylated Hemoglobin

**Classification Name:** Glycosylated Hemoglobin Assay

**Manufacturer:** Genzyme Diagnostics  
One Kendall Square  
Cambridge, MA 02139-1562

**Contact Person:** Barbara Pizza, Manager, Regulatory Affairs, (617) 252-7953

The use of the Genzyme GlyPro™ Reagent assay in the clinical laboratory setting is substantially equivalent to a currently marketed method for Fructosamine for the management of Diabetes.

The Genzyme GlyPro Assay System (consisting of Reagent, Calibrator, Low Control and High Control) is a quantitative method for the detection of glycated proteins in serum and plasma.

**PERFORMANCE STUDIES****Comparative Performance Studies**

A Comparative performance study was conducted using the Genzyme GlyPro Reagent, and predicate method (Roche Unimate Fructosamine).

The slope, intercept, correlation coefficient, and sample range for these comparisons are provided below.

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	GlyPro vs. Furosine n= 61	GlyPro vs. Roche n= 61
Slope	15.25	1.33
Intercept (µmol/L)	0.41	-127.45
Correlation Coefficient (r)	0.9881	0.9915
Sample Range	7.40 - 48.58 (peak area x 10 <sup>4</sup> )	169.0 - 675.5 (µmol/L)

The Genzyme method yielded acceptable correlation with the predicate and Furosine methods in samples across the usable range of the product.

**Linearity**

Linearity studies demonstrated that the GlyPro assay is linear up to 1734 µmol/L.

**Precision**

Both within-run and between-run studies were performed. Testing was done using frozen serum pools at three target levels of glycated serum protein for within-run precision and between-run.

**Within-Run**

Each serum pool was tested 20 times in one batch using the GlyPro Reagent assay. The mean, standard deviation (SD) and coefficient of variation (%CV) was calculated for each serum pool.

	Low	Medium	High
n	20	20	20
Sample Range (µmol/L)	179-182	403-408	656-670
Mean (µmol/L)	180.7	405.3	663.6
SD (µmol/L)	1.34	1.25	4.55
%CV	0.74	0.31	0.69

The GlyPro assay yielded excellent within-run precision with CVs of ≤ 1.0% and SD values of ≤ 5 µmol/L.

**Between-Run**

Each serum pool was tested twice per day, for ten days using the GlyPro assay for a total of 20 determinations. The mean, SD and %CV were calculated for each pool as follows:

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	Low	Medium	High
n	20	20	20
Sample Range (µmol/L)	175 - 185	396 - 408	644 - 665
Mean (µmol/L)	179.6	402.3	654.6
SD (µmol/L)	2.99	3.17	5.73
%CV	1.66	0.79	0.88

The GlyPro assay yielded excellent between-run precision with CVs  $\leq$  2.0% and SDs  $\leq$  6 µmol/L.

### Interference Studies

The effects of interfering substances was evaluated by adding varying levels of potential interferents to a specimen pool. These determined that triglyceride (Avian), ascorbic acid, bilirubin, hemoglobin, uric acid and glucose did not interfere with the performance of the Genzyme GlyPro assay at the levels up to and including those indicated below.

Interfering Substance	Concentration*
Triglyceride (Avian)	750 mg/dL
Ascorbic Acid	8 mg/dL
Bilirubin	29 mg/dL
Hemoglobin	200 mg/dL
Uric Acid	33 mg/dL
Glucose	1800 mg/dL

\*Different analyzer applications will have different interferences.

Additionally, a drug interference study was performed. Only the drugs listed below were found to interfere significantly at concentrations less than the therapeutic dose:

Drug	Interfering concentration
Dobesilate	10 mg/L
Gentisic Acid	25 mg/L
Methampyrone	100 mg/L

### Serum vs. Plasma

Matched sets of serum and EDTA plasma specimens were tested with the GlyPro Reagent. Data demonstrate that EDTA plasma results are 6% lower than serum results. It is preferable that the same sample type be used for all comparative analyses of the same patient.

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**Reference Range**

The reference range was calculated according to NCCLS C28-A using non-parametric analysis. The 95% reference range of the assay is: 122 - 238  $\mu\text{mol/L}$

**Conclusion**

Based on the results of the studies described above, the Genzyme GlyPro Reagent assay is substantially equivalent in performance to the predicate, Roche Unimate Fructosamine, a commercially marketed method for quantifying glycated proteins in serum and plasma.

**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.**



NOV 25 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Barbara Pizza  
Manager, Regulatory Affairs  
GENZYME CORPORATION  
One Kendall Square  
Cambridge, MA 02139

Re: K983726

Trade Name: GlyPro™ Reagent, GlyPro™ Calibrator,  
GlyPro™ Low Control, GlyPro™ High Control  
Regulatory Class: II  
Product Code: 81 LCP  
Dated: October 20, 1998  
Received: October 22, 1998

Dear Ms. Pizza:

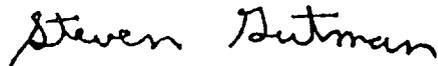
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) PREMARKET NOTIFICATION

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One Kendall Square  
Cambridge, MA 02139

GlyPro™ Reagent, Calibrator, Controls  
Reference No. K983726  
November 20, 1998

Confidential

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510(k) NUMBER (IF KNOWN): K983726

DEVICE NAME: GlyPro™ Reagent, Calibrator, Controls

INDICATIONS FOR USE:

**GlyPro Reagent**

For the quantitative determination of glycated proteins.

Measurement of glycated serum protein is representative of the mean blood glucose levels over the preceding 2-3 weeks

For In Vitro Diagnostic Use.

**GlyPro Calibrator**

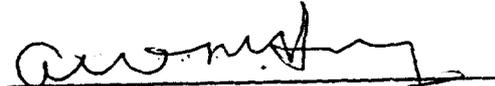
For calibration of the GlyPro™ assay.

For In Vitro Diagnostic Use.

**GlyPro Low and High Controls**

To monitor the performance of the GlyPro assay.

For In Vitro Diagnostic Use.



(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K983726

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED.)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)