

Indications for Use

510(k) Number (if known): K042193

Device Name: Diazyme Glycated Serum Protein Enzymatic Assay Kit

Indications for Use:

Diazyme Glycated Serum Protein Enzymatic Assay Kit in conjunction with Diazyme Glycated Serum Protein single calibrator, are intended for the quantitative determination of glycated serum proteins (fructosamine) in serum. The measurement of glycated serum proteins (fructosamine) is useful for monitoring diabetic patients.

Diazyme Glycated Serum Protein Enzymatic Assay Kit contains a single calibrator. The calibrator is used in the calculation of glycated serum protein concentrations in unknown serum samples.

Diazyme Glycated Serum Protein Enzymatic Assay has controls for normal glycated serum protein level and abnormal glycated serum protein level. The controls are used as reference samples for checking the functionality of the Diazyme Glycated Serum Protein Enzymatic Assay.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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