

Indications for Use

510(k) Number: K042448

Device Name: Diazyme Homocysteine Enzymatic Assay Kit

Indications for Use:

Diazyme Enzymatic Homocysteine Assay is intended for the *in vitro* quantitative determination of total L-homocysteine in serum and heparin plasma. The reagents can assist in diagnosis and treatment of patients suspected in having hyperhomocysteinemia and homocystinuria.

Diazyme Homocysteine Enzymatic Assay Kit contains a single calibrator. The calibrator is used to generate a calibration point that will be used in the calculation of homocysteine concentrations in unknown serum samples.

Diazyme Homocysteine Enzymatic Assay has controls for normal serum homocysteine level and abnormal serum homocysteine level. The controls are used as reference samples for checking the functionality of the Diazyme Homocysteine Enzymatic Assay.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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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