

Indications for Use

510(k) Number (if known): K042189

Device Name: Diazyme Sodium Enzymatic Assay Kit

Indications for Use:

Diazyme Sodium Enzymatic Assay Kit in conjunction with Diazyme Sodium Low and High Calibrators, are intended for the quantitative determination of sodium (NA) in serum.

Diazyme Sodium Enzymatic Assay Kit contains a low level standard and a high level standard. The standards are used to generate a linear graph that will be used in the calculation of sodium concentrations in unknown serum samples.

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

510(k) K042189