



Indications for Use

510(k) Number: k060619

Device Name: Diazyme Carbon Dioxide Enzymatic Assay Kit
Diazyme Carbon Dioxide Control Set

Indications For Use: Diazyme Carbon Dioxide Enzymatic Assay Kit, in conjunction with Diazyme Carbon Dioxide Calibrator, are intended for the quantitative determination of carbon dioxide (CO₂) in serum and plasma.

Diazyme Carbon Dioxide Enzymatic Assay Kit contains a single-point calibrator. The calibrator, along with 0.9% saline as a zero reference, is used to generate a linear graph that will be used in the calculation of carbon dioxide concentrations in unknown samples.

Diazyme Carbon Dioxide Control Set has controls for normal carbon dioxide level and abnormal carbon dioxide level. The controls are used as reference samples for checking the functionality of the Diazyme Carbon Dioxide Enzymatic Assay.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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

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Evaluation and Safety

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