Indications for Use

510(k) Number: k091455

Device Name: Diazyme Liquid Stable Enzymatic Potassium Assay Kit

Indications for Use:

For in vitro quantitative determination of potassium in human serum. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. For IVD use only.

Calibrator:

The Diazyme Liquid Stable Enzymatic Potassium Assay Calibrator Kit is intended for use in the calibration of quantitative Diazyme Liquid Stable Enzymatic Potassium Assay Kit (DZ113C). For IVD use only.

Controls:

The Diazyme Liquid Stable Enzymatic Potassium Assay Control Kit is intended for use as quality controls for the Diazyme Liquid Stable Enzymatic Potassium Assay (DZ113C). For IVD use only.

Prescription Use (Part 21 CFR 801 Subpart D)	X	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

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K091455