

510(k) Number: k051714

Device Name: Total Bile Acids Assay

Indications For Use:

Total Bile Acids Assay is intended for the *in vitro* quantitative determination of total bile acids (TBA) in human serum samples. Total bile acids are metabolized in the liver and serve as a marker for normal and abnormal liver function. Serum total bile acids are increased in patients with liver disease.

Total Bile Acids Assay contains a bile acid calibrator. The calibrator is design to be used with the assay for the quantitative determination of TBA in serum.

Total Bile Acids Assay has control design to be used with the assay for the quantitative determination of TBA in serum.

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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