



Diazyme Total Bile Acid Control Set

Intended Use

The Diazyme Total Bile Acid Control Set is intended for use as quantitative quality controls for the Diazyme Total Bile Acid Assay. For *in vitro* diagnostic use only.

Summary

The Diazyme Total Bile Acid Control Set (REF DZ042A-CON) is a set of two levels. These two levels are to be used exclusively with the Diazyme Total Bile Acid Assay (REF DZ042A) which is an enzyme assay designed for quantify of the Total Bile Acid (TBA) levels in serum and plasma samples.

Control Content and Concentrations

The TBA Control Set is a two-level set (2 x 1 mL) prepared in bovine serum base and is supplied in lyophilized powder form. The TBA Control material is prepared in a bovine serum base.

Reactive components

- Bovine serum

Non-reactive components

- Stabilizers

Warnings and Precautions

The bovine source material used in this product originated in the USA. The origin of raw materials, type of tissue, and manufacturing process were deemed by the European Directorate of the Quality of Medicines to meet criteria concerning transmission of animal spongiform encephalopathies. Possible infectious agents in the materials have been inactivated. Because no method can offer complete assurance as to the absence of infectious agents, however, this material and all patient samples should be handled as though capable of transmitting infectious disease and disposed of accordingly.

Handling, Storage, and Stability

Open one vial of the bile acid control carefully to avoid any loss of material and reconstitute with exactly 1 mL of distilled H₂O. Close the vial and let stand for thirty (30) minutes at room temperature, dissolving contents completely by gently swirling or rotating.

The bile acid control is stable until the expiration date printed when stored properly at -20°C. Once reconstituted, the control is stable for 2 weeks at 2-8°C.

Instruments and Procedures

The TBA Control Set can be used with any platform running the Diazyme TBA Assay (reagents + calibrators).

The TBA Control Set is assayed by following the procedures and protocols of the Diazyme TBA Assay.

Results

Each control level is assigned an expected range of values printed on the certificate of analysis accompanying the TBA Control Set. The expected range of values is lot-dependent.

References

1. LaRusso, N.F. et al., Dynamics of Enterohepatic Circulation of Bile Acids, *New Engl J M*, 291, 689-692, (1974).
2. Skrede S. et al: Bile acids measured in serum during fasting as a test for liver disease, *Clin Chem* 24: 1095-1099, 1978
3. Wu, Alan H. B. *Tietz Clinical Guide to Laboratory Tests*. 4th ed. St. Louis, MO: Saunders/Elsevier, 2006. 170-171.



MDSS
Schiffgraben 41
30175 Hannover,
Germany



Diazyme Laboratories
12889 Gregg Court
Poway, CA 92064, USA
Tel: (858) 455-4754
Fax: (858) 455-4750