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Diazyme Adenosine Deaminase Control Set

Intended Use

Diazyme Adenosine Control Set are intended to be used as reference samples for checking the functionality of the Diazyme Adenosine Deaminase Assay.

Summary

The Diazyme Adenosine Deaminase (ADA) Control Set **CONTROL** is a set of two serum levels. These two levels are to be used exclusively with the Diazyme ADA Assay (**REF** DZ117A). The Diazyme ADA Assay is based on the enzymatic deamination of adenosine and after many reactions quinone dye is generated, which is monitored in a kinetic manner

Reagents – working solutions

Reactive components

- Bovine serum and additives

Non-reactive components

- Sodium azide (NaN_3) <0.1%

CONTROL are a two-level set that is supplied in lyophilized form (2 x 1 mL). **CONTROL** are manufactured from bovine serum. The concentrations of the controls are lot specific and ADA concentrations are expressed in U/L.

Target values and ranges

Lot specific target values and ranges are stated in the Certificate of Analysis. Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

Precautions and Warnings

1. USA: For Research Use Only. Not to be used in diagnostic procedures.
2. EU: CE IVD
3. For use with Diazyme Adenosine Deaminase Assay (**REF** DZ117A).
4. For Laboratory Reagent Use Only. Do Not Feed to Cattle or Other Ruminants.
5. Product contains highly purified bovine source material from non-BSE countries. The manufacturing facility does not receive, store or process ruminant materials from restricted countries.
6. Possible infectious agents in the materials have been inactivated. Because no method can offer complete assurance as to the absence of infectious agents, this material should be handled as though capable of transmitting infectious disease and disposed as biohazard waste or medical waste according to applicable local and national laws.
7. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product. To obtain an MSDS, please contact our customer service department at 858-455-4768.

8. Avoid contact with skin and eyes.

9. Contains sodium azide, which may react with lead or copper plumbing to form explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.

Handling

Reconstitute contents of each vial with exactly 1.0 mL of distilled water very carefully avoiding any loss of material. Close vial and let stand at room temperature for 30 minutes, dissolving contents completely by gently swirling. Make sure all the contents are dissolved before use.

Storage and Stability

Store at -20°C. *Note:* Store controls tightly capped when not in use.

Stability

- Unopened vials: stability is up to the expiration date on label when stored at -20°C
- After reconstitution: stability is 7 days when stored at 2 to 8°C

Materials Provided

CONTROL consists of 2 lyophilized vials.

Materials required (but not provided)

- Diazyme Adenosine Deaminase Assay reagents (**REF** DZ117A)
- Distilled water
- General laboratory equipment

Assay

Prepare **CONTROL** 1 and 2 as stated in the Handling section. The use of a 1.0 mL pipette is recommended. Take care to avoid the formation of bubbles. Use in the same way as a sample. The control intervals should be adapted to each laboratory's individual requirements. Follow the applicable government regulations and local guidelines for quality control.

References

1. Kobayashi F, Ikeda T, Marumo F, Sato C: Adenosine deaminase isoenzymes in liver disease. *Am. J. Gastroenterol.* 88: 266-271 (1993)
2. Kallkan A., Bult V., Erel O., Avci S., and Bingol N. K.: Adenosine deaminase and guanosine deaminase activities in sera of patients with viral hepatitis. *Mem Inst. Oswaldo Cruz* 94(3) 383-386 (1999)
3. Burgess LJ, Maritz FJ, Le Roux I, et al. Use of adenosine deaminase as a diagnostic tool for tuberculous pleurisy. *Thorax* 50: 672-674 (1995)
4. Lakkana B., Sasisopin K: Use of Adenosine Deaminase for the Diagnosis of Tuberculosis: A review *J. Infect. Dis Antimicrob Agents* 2010; 27:111-8
5. Delacour H., Sauvanet C., Ceppa F., Burnat P.: Analytical performances of the Diazyme ADA assay on the Cobas 6000 system. *Clinical Biochemistry* 43 (2010) 1468-1471.



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