

# ADAZYME

## CONTROL CONTROL FOR QC & ASSAY VALIDATION

### SUMMARY

Clinical laboratories perform qualitative, semi-quantitative and quantitative assays for various biological analytes on various biological specimens. Quantitative tests determine the amount of a particular substance with the help of some instrument and express the results numerically. Most quantitative procedures involve several operations, or steps and each operation is subject to some degree of inaccuracy and imprecision. Monitoring and assessing the reliability and precision of methods and techniques form the fundamentals of good laboratory practices.

Adazyme controls are two level I (Cat. No. 203060012) Level II (Cat No. 203060021) assayed controls, useful for validating the calibration and performance of Adazyme assay (Cat. No. 203060025). Adazyme controls are useful for monitoring the precision of laboratory testing procedures with enzymatic ADA kits based on the enzymatic deamination of adenosine to inosine leading to formation of quinone dye measured in a kinetic manner.

One unit of ADA is defined as the amount of ADA that generates one  $\mu$ mole of inosine from adenosine per min at 37°C.

### PRESENTATION

REF	REF	203060012	203060011	203060021
Pack size		2 x 1 ml	1 ml	1 ml
Level I		1 ml	1 ml	-
Level II		1 ml	-	1 ml
Pack insert		1	1	1

### REAGENT

Adazyme controls (Level I and Level II) are bovine lyophilized serum, with ADA activity in the normal or pathologic range. The controls are intended for control of accuracy with enzymatic ADA kits on manual and automated analyzers. The controls are manufactured from Bovine serum with additives, bacteriostatic agents, etc. hence contamination due to HBsAg, HCV and HIV is practically excluded, however for GLP handle cautiously as potentially infectious.

### STORAGE AND STABILITY

The Control serum is stable until the expiration date on the label when stored tightly closed at 2-8°C

Do not use reagents over the expiration date or if there is visible evidence of microbial growth in the vial.

### PREPARATION

1. Bring control vial to room temperature before reconstitution.
2. Reconstitute with stated amount (described on vial label) of good quality of deionised / distilled water, wait for 10 minutes, dissolve by gently swirling the vial till the solution attains homogeneity, avoiding foam forming.
3. Avoid contamination during their use. Store tightly capped when not use.
4. Improper handling and / or storage can affect results. Inaccurate reconstitution and errors in assay technique can cause erroneous results.

After reconstitution the control is stable for:

15°C to 25°C for 24 hours

2°C to 8°C for 15 days

-15°C to -25°C for 1 month

### NOTE:

1. In vitro diagnostic reagent for laboratory and professional use only.
2. Adazyme control must be treated as a specimen and run strictly adhering to the instructions described by the manufacturer of reagents used for analysis.
3. The control can deteriorate due to microbial contamination or on exposure to elevated temperatures.
4. Usage of well calibrated equipment and accessories and procedures is critical for achieving correct results.
5. This product is not recommended for use as a calibrator or standard.

### VALUE ASSIGNMENT

The activity of the components are lot specific. The exact values and ranges valid for the specific lot of controls are given in the value sheet below.

**REMARKS**

Usage of well calibrated equipment and accessories and procedures is critical for achieving correct results. This product is not recommended for use as a calibrator or standard.











**WARRANTY**

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

**BIBLIOGRAPHY**

1. Clinical diagnosis and management by laboratory methods, 17<sup>th</sup> ed., edited by John Bernard Henry, Pg. 74-93.
2. Data on file: Tulip Diagnostics (P) Ltd.

**SYMBOL KEYS**

 Temperature Limitation	 Manufacturer	 Batch Number/ Lot Number	 Date of Manufacture	 This side up
 Use by	 Consult Instructions for use	 In vitro Diagnostic Medical Device	 Catalogue Number	 Production Site

Adazyme Control Assay Values		
Lot No.: ADC1016/5		
Control Level	Value (U/L)	Range (U/L)
Level I	25.3	+/- 4.6
Level II	81.7	+/- 14.7

0717/VER-01



Manufactured by:

**Coral Clinical Systems**

A Division of Tulip Diagnostics (P) Ltd.

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