Pariksha Biotech
A game changer in IVD

HIGH Q®
Command on Quality

High-Q Adenosine Deaminase(ADA)
PNP-XOD Method

Features and Advantages

- For the determination of Pulmonary and Extra Pulmonary Tuberculosis
- High Specificity: 98%
- Liquid Stable, ready to use two liquid reagents
- Liquid Calibrator provided.
- Liquid Low and High controls are available (Optional)
- Kinetic reaction time 150 sec (30 Sec Delay+ 120 Sec Measuring).
- Linearity: 250 IU/L.
- Measuring Wavelength 546nm.
- Assay is not affected by serum bilirubin up to 31 mg/dl, Hemoglobin up to 220 mg/dl,triglycerides up to 1000 mg/dl and ascorbic acid up to 4 mg/dl.
- Serum, Plasma Pleural Fluid, Ascitic Fluid (Peritoneal Fluid), Pericardial Fluid, Cerebrospinal Fluid are to be used as specimens based on the clinical condition.
- Available as multipurpose reagents and dedicated system packs.

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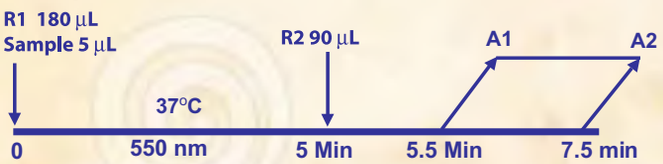
Assay Method



Within-run Precision	Level 1	Level 2
Mean (U/L)	11.11	30.74
SD	0.16	0.45
CV%	1.47	1.45

Between-Run Precision	Level 1	Level 2
Mean (U/L)	9.63	29.62
SD	0.47	0.59
CV%	4.90	2.00

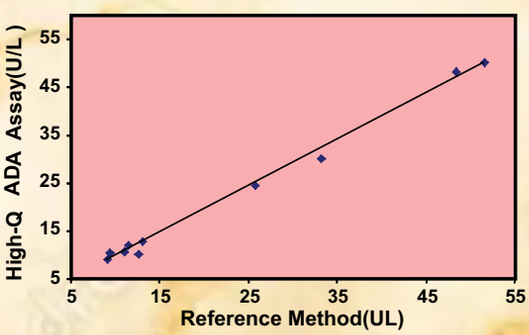
Performance

Method Comparison

To demonstrate accuracy, the High-Q Adenosine Deaminase Enzymatic Assay was tested with individual serum samples with comparison to results obtained by an accredited reference clinical laboratory using their analyte specific reagents based upon the reference method for ADA activity in serum.

The individual patient serum or plasma samples used for this study were from a certified commercial source. A small sample of ten (10) patient samples ranging from 13 – 48 U/L were tested which gave a correlation coefficient of 0.966. This study yielded a linear regression equation of y = 0.9662x - 0.02 U/L.

High-Q ADA Method Comparison



Precision

The precision of the High-Q Adenosine Deaminase Enzymatic Assay was evaluated according to a modified Clinical and Laboratory Standards Institute (formerly NCCLS) EP5-A protocol. In the study, two specimens containing 11.0 ± 2.75 and 30.0 ± 5.4 U/L Adenosine Deaminase were tested with 2 runs per day with duplicates over 15 working days.

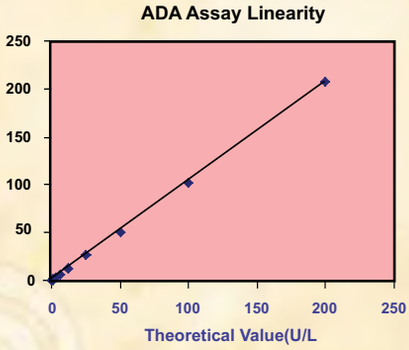
Analytical Sensitivity

To demonstrate the limit of detection (LOD) of High-Q Adenosine Deaminase Enzymatic Assay, Adenosine Deaminase zero calibrator was tested on 12 replicates on Cobas Mira. The LOD is defined as mean + 3SD.Based on these studies the LOD = 0.003 + 0.03 = 0.033 U/L Adenosine Deaminase.

Linearity

Ten levels of samples with ADA activity were prepared by serially diluting a serum control containing 250 U/L Adenosine Deaminase with distilled H_2O. Based on this study the assay is linear to 200 U/L.

ADA Assay Linearity



Interference

To determine the level of interference from the substances normally present in the serum, High-Q Adenosine Deaminase Enzymatic Assay was evaluated by running three (3) replicates each of a control sample in the absence and presence of various potential interference substances at indicated concentrations. Assay is not affected by interfering substances such as serum bilirubin up to 30 mg/dL, hemoglobin up to 500 mg/dL, triglycerides up to 500 mg/dL, ascorbic acid up to 20 mg/dL, and ammonia up to 800 µmol.

Interfering substances	Interfering substance concentration	Concentration of ADA (U/L)	Nonspiking (control)	% Interference
Ammonia	800 µmol	22.38 ± 0.10	22.76 ± 0.14	1.6
Ascorbic Acid	4.0 mg/dL	8.70 ± 0.17	9.20 ± 0.21	5.4
Bilirubin	30 mg/dL	41.0 ± 0.18	41.15 ± 0.19	2.6
Hemoglobin	200 mg/dL	123.0 ± 0.36	117.9 ± 0.16	4.2
Triglycerides	500 mg/dL	17.53 ± 0.20	18.05 ± 0.26	2.9

Assay Specifications

Linearity	0 to 250 U/L
LOD	0.0333 U/L
Calibration Levels	1-Point Calibration
Reagent On-Board Stability	Opened: Four weeks when stored at 2-8°C

Pariksha Biotech Pvt Ltd,
Plot no.1/B-14,SVICE,
Balanagar,
Hyderabad-500037
Telangana State
CIN No: U24232TG2011PTC072118
An ISO 13485 Certified Company

+91 70757 06709
info@parikshabio.com
www.parikshabio.com