

Analytical Characteristics ⁵

These performance characteristics were determined at BQ Kits using automated procedures unless otherwise stated.

Precision

The precision of the BQ Kits ADA assay evaluated on the Cobas Mira instrument according to a modified Clinical laboratory Standards Institute (formerly NCCLD) EP5-A guideline. In the study, two serum specimens containing 11 U/L and 30 U/L ADA were tested with 2 runs per day with duplicates over 15 working days.

No. of Data Points	Within Run Precision		Run to Run Precision	
	11 U/L	30 U/L	11 U/L	30 U/L
		30	30	30
Mean (µM)	11.11	30.74	9.63	29.62
SD	0.16	0.45	0.47	0.59
Cv %	1.47	1.45	4.90	2.00

Assay Linearity

The linearity of the procedure is from 0 - 200 U/L.

Interference

Assay is not affected by serum bilirubin up to 30mg/dL, hemoglobin up to 200mg/dL, triglycerides up to 750mg/dL, and ascorbic acid up to 4mg/dL.

Safety Precautions and Warnings

1. For Research Use Only in the USA. Not for use in diagnostic procedures.
2. Reagent R1 is light-sensitive. Store in a dark place.
3. Specimens containing human sourced materials should be handles as if potentially infectious using safe laboratory procedures, such as those Biosafety in Microbiological and Biomedical Laboratories (HHS publication Number [CDC] 93-8395).
4. Avoid ingestion and contact with skin and eyes. See Material Safety Data Sheet.
5. The reagents contain <0.1% sodium azide, NaN₃, as preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azide. On disposal, flush with a large volume of water to prevent azide buildup.
6. Do not use the reagents after the expiration date labeled on the outer box.

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 ADA Assay on the Cobas 6000 system. *Clinical Biochemistry* 43 (2010) 1468-1471.

Cobas Mira-S Parameters Temperature 37°C

Measurement Mode	Absorb
Reaction Mode	R-S-SR1
Calibration Mode	SLOPE AVG
Reagent Blank	Reag/DIL
Cleaner	No
Wavelength	550 nm
Decimal position	2
Unit	U/L
Sample Cycle	1
Sample Volume	5.0 uL
Sample dilution	H ₂ O
Dilution volume	0.0 uL
Reagent cycle	1
Reagent volume	180 uL
Dilution volume	0.0 uL
Start R1 cycle	7
Reagent volume	90 uL
Dilution volume	0.0 uL
Sample limit	No
Reaction Direction	Increase
Convers. Factor	1.0000
Offset	0.0000
Test range Low	0.000 U/L
Test range High	200.00 U/L
Number of steps	1
Calc. Step A	Kinetics
Readings first	19
Readings last	27
Calibration	
Cali. Interval	Each day
Time	No
Blank	
Reagent Range	Low -0.1
	High 0.3
Blank Range	Low -0.1
	High 0.1
STANDARD	POS 1
	STD-1 *
	STD-2 No

* Entered by operator

Hitachi 717 Parameters
Temperature 37°C

Test	ADA
Assay Code	Rate-A
Assay Point	(10) (27) (34)
Wavelength (Sub/Main)	(750) (546)
Calibration Type	Linearity
Sample volume (Normal)	(5) (0) (0)
Sample volume (Dec.)	(5) (0) (0)
Sample volume (Inc.)	(5) (0) (0)
Diluent	(water) (0)
Reagent vol. R1	(180) (0) (10008) (0)
Reagent vol. R2	(0) (0) (1000) (0)
Reagent vol. R3	(90) (10008) (0) (0)
Reagent vol. R4	(0) (0) (1000) (0)
ABS. Limit	(32000) (Increase)
STD. (1) CONC. – Position	(0)-(1)
STD. (1) CONC. – Pos	(*)-(2)
Expected value (normal value)	4-20
Tech. Limit	0-200

** Each cycle is 12 seconds.
 * Entered by operator

Beckman Synchron CX-7 Delta Parameters
Temperature 37°C

CHEMISTRY NAME: Adenosine Deaminase
 TEST NAME: [ADA]

REACTION TYPE: RATE 2 MATH MODEL: LINEAR
 REACTION DIRECTION: INCREASE CAL TIME LIMIT: Hrs
 UNITS: U/L DECIMAL PRECISION: X.XX
 CALCULATION FACTOR:
 NO. OF CALIBRATORS: 2 #1: USER DEFINED *

PRIMARY WAVELENGTH: 560 nm
 SECONDARY WAVELENGTH: 700 nm

SAMPLE VOLUME: 4µL
 PRIMARY INJECT RGT:
 A: 150 µL
 B: 75 µL
 SECONDARY INJECT RGT:
 None: 0 µL
 ADD TIME: 0 SEC

MULTIPOINT SPAN: 1-2: -0.001

REAGENT BLANK
 START READ: 288 SEC; END READ: 304 SEC
 LOW ABS LIMIT: -1.5; HIGH ABS LIMIT: 1.5

REACTION
 START READ: 300 SEC; END READ: 480 SEC
 LOW ABS LIMIT: -1.5; HIGH ABS LIMIT: 1.5

USABLE RANGE
 LOWER LIMIT: 0.00
 UPPER LIMIT: 99999.00

SUBSTRATE DEPLETION
 INITIAL RATE: 99.99
 DELTA ABS: 1.5

* Entered by operator

Olympus AU400 Parameters
Calibration Method - Temperature 37°C

General			
Test Name:	3. ADA	Type:	Serum
Operation:	Yes		
Sample Volume	5.0 µL	Dilution	0 µL
Pr-Dilution Rate	1		
Reagents :	Min OD	Max OD	
R1 volume	180 µL	Dilution	0 µL
L:	-2.000	H:	2.500
R2 volume	90 µL	Dilution	0 µL
Wavelength:	Pri. 540	Sec. 700	Reagent OD Limit:
Method:	Rate	First L:	-2.000; First H: 2.500
Reaction Slope:	+	Last L:	-2.000; Last H: 2.500
Measuring Point 1:	First 20; Last 27	Dynamic Range:	
Measuring Point 2:	First ;Last	L:0.0	H:200.0
Linearity	20%	Correlation Factor:	
No-Lag-Time:	No	A:1.0000	B:0.000
Onboard stability Period: 999			
Calibration Type	AB	Formula: Y=AX+B	
Counts	2	Process CONC	
Cal No.	OD	CONC	Factor/OD-L
Factor/OD-H			
Point 1	*		
Point 2			
Advanced Calibration: No			
MB Type Factor:	Calibration Stability Period: 999		

* Entered by operator

Hitachi 917 Parameters
Temperature 37°C

Test	ADA
Assay Code	Rate-A
Assay Point	(39)-(49) **
Wavelength	750/546
Calibration Method	LINEAR
Unit	U/L
Sample Volume	(5) (5)
Reagent vol. R1	(180)(100)(NO)
Reagent vol. R2	(90)(100)(NO)
STD. (1) CONC. – Position	(0)-(1)
STD (1) CONC. – POS	(*)-(2)
ABS Limit	32000-Increase
Expected value (normal value)	4-20
Tech. limit	0-200

* Entered by operator