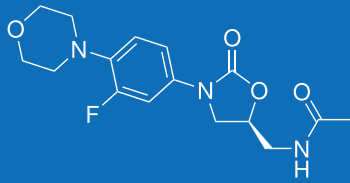


# ARK™ Linezolid Assay



The ARK Linezolid Assay is intended for the quantitative determination of linezolid in human serum on automated clinical chemistry analyzers. The measurements obtained are used in monitoring levels of linezolid to help ensure appropriate therapy.

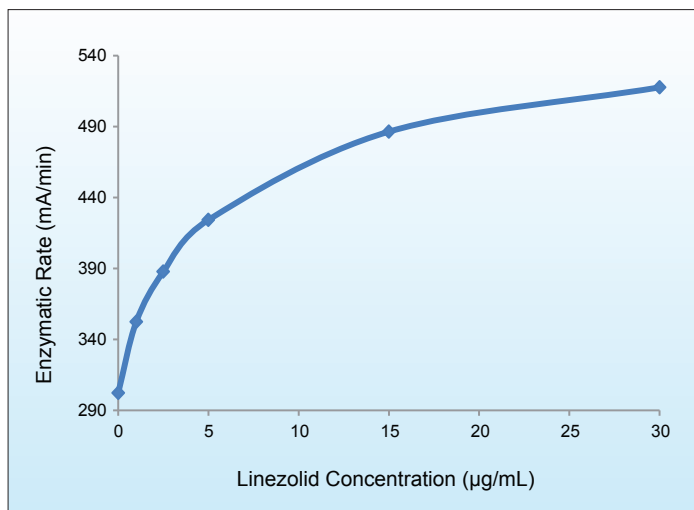


## KEY POINTS

- Homogeneous Enzyme immunoassay
- Applicable onboard automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use
- Excellent calibration range
- Tested drugs, endogenous substances and metabolites of linezolid do not interfere

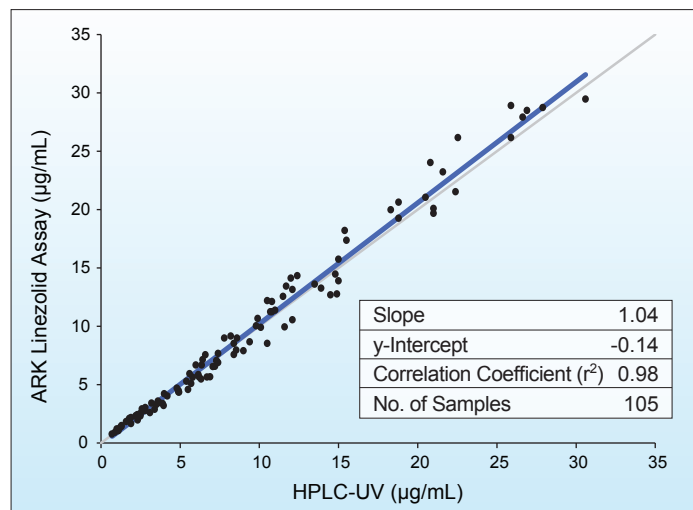
*Next Generation Assays*

## CALIBRATION RANGE



ARK Linezolid Assay Calibration Range: 0.0 to 30.0 µg/mL.  
LoQ: 0.75 µg/mL

## METHOD COMPARISON



ARK Linezolid Assay: Measurement Range: 0.8 to 30.0 µg/mL.

## ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery (%)	N
0.75	0.82	108.9	6
1.5	1.5	97.4	6
3.0	3.0	100.0	6
4.0	4.1	102.1	6
8.0	8.2	102.2	6
12.0	12.0	99.8	6
18.0	18.3	101.9	6
24.0	23.0	96.0	6
28.0	28.0	99.9	6

Accuracy (analytical recovery) was determined by adding concentrated linezolid drug into human serum negative for linezolid, representing drug concentrations across the assay range.

## PRECISION

Sample	Mean n = 160 (µg/mL)	REPEATABILITY WITHIN RUN		BETWEEN DAY		REPRODUCIBILITY TOTAL	
		SD	CV (%)	SD	CV (%)	SD	CV (%)
<b>ARK Linezolid Control</b>							
LOW	2.0	0.08	3.9	0.03	1.7	0.08	4.2
MID	10.4	0.41	4.0	0.19	1.9	0.45	4.3
HIGH	20.2	0.84	4.2	0.41	2.0	0.93	4.6
<b>Human Serum</b>							
LOW	1.9	0.08	4.1	0.04	2.2	0.09	4.6
MID	10.6	0.39	3.7	0.15	1.4	0.43	4.0
HIGH	20.7	1.03	5.0	0.50	2.4	1.14	5.5

Tri-level controls and sera containing linezolid were assayed in quadruplicate twice a day for 20 days. CLSI EP05-A3.

## INTERFERENCE

Tested endogenous substances and co-administered drugs do not interfere with ARK Linezolid Assay. The crossreactivity of linezolid metabolites PNU-142586 and PNU-142300 was not clinically significant ( $\leq 0.2\%$ ).

## SAFETY AND STABILITY

### Reagent on-board stability

Up to at least 60 days

### Shelf Life of Reagents, Calibrators, and Controls

30 months from date of manufacturing

### Safety

Nonhazardous preservatives  
Contains sodium azide  $\leq 0.09\%$

Results shown are typical and may vary among laboratory analyzers.

## ORDERING INFORMATION

ARK™ Linezolid Assay	5034-0001-00
ARK™ Linezolid Calibrator	5034-0002-00
ARK™ Linezolid Control	5034-0003-00

### ARK Diagnostics, Inc.

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