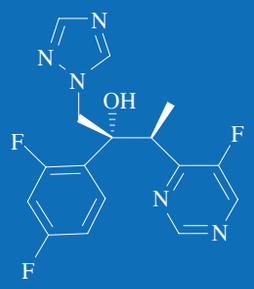


ARK™ Voriconazole II Assay

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

KEY POINTS

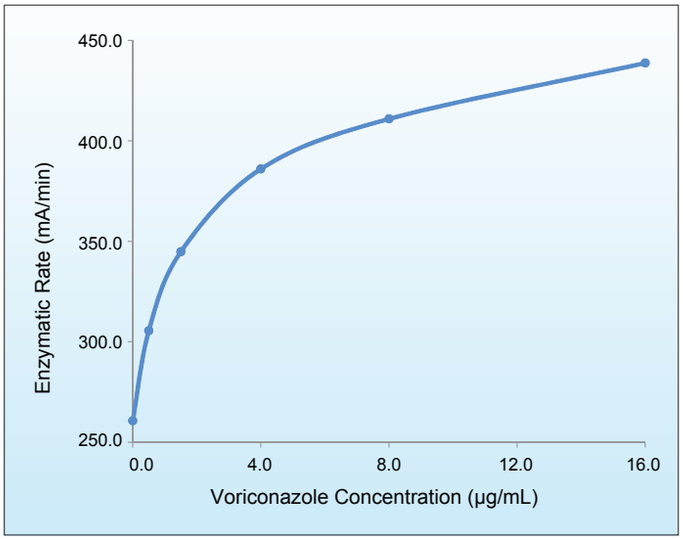
- Homogeneous Enzyme immunoassay
- Applicable onboard automated clinical chemistry analyzers
- Convenient, liquid-stable, ready-to-use
- Excellent calibration range
- Tested drugs and endogenous substances do not interfere
- The crossreactivity of N-oxide voriconazole metabolite (5.0 µg/mL or 10.0 µg/mL) was not clinically significant (≤ 3.0% crossreactivity)

Next Generation Assays

ARK Diagnostics, Inc.

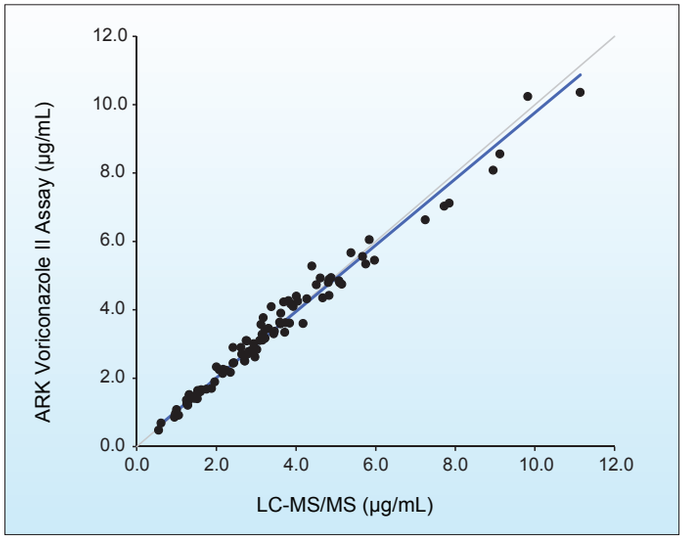
CE Mark, Not FDA Cleared

CALIBRATION RANGE



ARK™ Voriconazole II Assay Calibration Range: 0.0 to 16.0 µg/mL.
LOQ: 0.5 µg/mL

METHOD COMPARISON



ARK™ Voriconazole II Assay Range: 0.5 to 16.0 µg/mL

PRECISION

			WITHIN-RUN		BETWEEN DAY		TOTAL	
Sample	N	Mean (µg/mL)	SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK Voriconazole Control								
LOW	160	1.04	0.048	4.7	0.028	2.7	0.055	5.3
MID	160	5.09	0.196	3.8	0.158	3.1	0.255	5.0
HIGH	160	9.83	0.541	5.5	0.303	3.1	0.641	6.5
Human Serum								
LOW	160	1.02	0.045	4.4	0.035	3.4	0.062	6.0
MID	160	5.05	0.225	4.5	0.175	3.5	0.293	5.8
HIGH	160	9.91	0.493	5.0	0.395	4.0	0.633	6.4

Tri-level controls and sera containing voriconazole were assayed in quadruplicate twice a day for 20 days. CLSI/NCCLS Protocol EP5-A2.

ACCURACY

Theoretical Concentration (µg/mL)	Mean Recovered Concentration (µg/mL)	Percent Recovery
0.5	0.45	90.0
1.2	1.19	99.2
3.0	3.05	101.7
6.0	5.86	97.7
9.0	8.74	97.1
12.0	11.44	95.3
15.0	15.75	105.0

Accuracy (analytical recovery) was determined by adding concentrated voriconazole drug into human serum negative to produce across the assay range.

INTERFERENCE

Tested endogenous substances and co-administered drugs do not interfere with ARKTM Voriconazole II Assay. The crossreactivity of major metabolite N-oxide voriconazole was not clinically significant (≤ 3.0% crossreactivity).

SAFETY AND STABILITY

Reagent on-board stability
At least 60 days

Shelf Life of Reagents, Calibrators, and Controls
18 months from data of manufacturing

Shelf Life of Reagents, Calibrators, and Controls
Nonhazardous preservatives
Contains sodium azide ≤ 0.09%

Results shown are typical and may vary among laboratory analyzers.

Available Upon request: UK NEQAS Proficiency Testing for Antifungal Drugs.

ORDERING INFORMATION

ARK™ Voriconazole II Assay	5030-0001-01
ARK™ Voriconazole II Calibrator	5030-0002-01
ARK™ Voriconazole II Control	5030-0003-01

ARK Diagnostics, Inc.
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