Fact Sheet

ARK™ Voriconazole II Assay

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

Assay Characteristics

- Fast and efficient routine monitoring for voriconazole
- Cross-reactivity to Voriconazole-N-oxide ≤ 3,0%
- Liquid, ready to use reagents, calibrators and controls
- Storage at 2-8°C
- On-board stability for at least 60 days
- Does not contain any harmful preservatives, only ≤ 0.09% sodium azide

Background

Voriconazole (VFEND®, Pfizer) is a triazole antifungal agent, chemically designated as (2R,3S)-2-(2,4-difluorophenyl)-3-(5-fluoro-4-pyrimidinyl)-1-(1*H*-1,2,4-triazol-1-yl)-2-butanol. VFEND is indicated for use in the treatment of invasive aspergillosis, candidemia (non-neutropenic patients) and disseminated candidiasis in skin, abdomen, kidney, bladder wall, and wounds, of esophageal candidiasis as well as prophylactically in transplant patients. In addition, the drug is used to treat serious infections caused by *Scedosporium apiospermum* and *Fusarium spp*., including *Fusarium solani*, in patients intolerant of, or refractory to, other therapy.

Concentrations of ≥ 1-2 mg/L are recommended for Voriconazole prophylaxis and as a treatment target. Higher trough levels of ≥ 2 mg/L are advocated for severe infections or treatment of pathogens with elevated MICs (≥ 0.25 mg/L). Patients with trough levels > 5-6 mg/L have a higher probability of neurotoxic events and visual hallucinations during Voriconazole therapy. Steady state concentrations may be achieved after 5 to 7 days of treatment. Practice guidelines support TDM, and clinical application of TDM has been recommended due to the high inter-individual and intra-individual variation in the metabolism of voriconazole, non-linear pharmacokinetics and CYP2C19 polymorphisms. Consideration should be given to the requirements for pediatric use, since metabolism in children may be different than for adults.

Specialty Diagnostix

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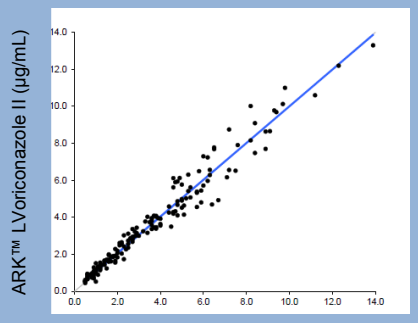
Properties of Voriconazole

Bioavailability	~ 96% (after oral dose)
Plasma protein binding	58%
Elimination	Less than 2% of a dose are excreted unchanged in urine; the main metabolite voriconazole-N-oxide only has minimal anti-fungal properties
Metabolization	In the liver; significant involvement of CYP2C19
Elimination half time	Dose dependent

Assay Precision

Sample	N	M (µg/ml)	Repeatability				Reproducibility	
			Within-Run		Between Day		Total	
			SD	CV (%)	SD	CV (%)	SD	CV (%)
ARK™ Voriconazole II Control								
LOW	160	1.03	0.047	4.6	0.030	2.9	0.051	4.9
MID	160	4.91	0.194	3.9	0.124	2.5	0.209	4.3
HIGH	160	9.39	0.394	4.2	0.242	2.6	0.426	4.5
Human serum								
LOW	160	1.02	0.043	4.2	0.029	2.8	0.047	4.6
MID	160	5.03	0.182	3.6	0.149	3.0	0.217	4.3
HIGH	160	9.80	0.334	3.4	0.286	2.9	0.407	4.2

Method Comparison



Order information

Product Description	Size	Order No.
ARK™ Voriconazole II Assay	28 mL R1 & 14 mL R2	5030-0001-00
ARK™ Voriconazole II Calibrator	1 x 4 mL & 5 x 2 mL	5030-0002-00
ARK™ Voriconazole II Control	6 x 4 mL	5030-0003-00

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