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www.miravistalabs.com

L. Joseph Wheat, M.D., Director

Clinical Consults: x452
Result Inquires: x450

Current licensure available on our website

MVista[®] HPLC Assays

Posaconazole test code: 311

Voriconazole test code: 313

Intended Use

- The proposed target concentrations are based upon limited data suggesting an association between blood level and response, and are thus provided as mere guidelines. Formal studies of drug level monitoring with dose adjustment based upon level would be needed to prove the utility of drug level monitoring and to establish the levels predictive of response or toxicity. Accordingly, recommendations in this document should be regarded only as guidelines, and do not established a standard of care.
- To be used as an aid in monitoring antifungal therapy. Guidelines have not been rigorously proven by clinical trial.
- Follow-up testing may be necessary if there are changes in treatment, including starting or stopping interacting medications, or suspicion of treatment failure.

Methodology

- MVista[®] azole therapeutic drug monitoring is conducted by an HPLC method. In each assay a standard curve, controls and patient samples are extracted and run on a Shimadzu high pressure system. The patient result is released in µg/ml quantities between the clinical Lower Limit of Quantitation (LLOQ) and the ceiling of the assay.

Specimen Requirements

- Acceptable samples include serum, plasma, and CSF.
- 2.0 ml is preferred, 1.5 ml is required.
- Serum/plasma should be separated from the clot.
- FREEZE on day of collection and remain frozen during shipment. Frozen cold packs or dry ice are recommended.
- Recommended supplementary information:
 - Ideally specimens should be taken at the trough time just before the next dose, but the timing is less important for posaconazole because of its long half-life.
 - Name of co-administered antifungal agent.
- Specimens cannot be tested if the volume is not sufficient, if they are of a type not listed above or if the information on the container and requisition do not match.

Limitations of the Method

- Therapeutic and toxic concentrations have not been accurately defined in clinical trials correlating drug concentration with outcome.
- Concentration determined on a single specimen may not reflect future concentrations because of changes in adherence, drug dosage, and route of administration, absorption, or receipt of other medications affecting absorption or metabolism of the azole.
- MVista[®] Posaconazole HPLC assay: LLOQ = 0.045 µg/ml and LOD = 0.016 µg/ml.
- MVista[®] Voriconazole HPLC assay: LLOQ = 0.05 µg/ml and LOD = 0.022 µg/ml.

CAP 7182293
CLIA 15D0996282
Medicare Part B 190460
NPI 1588600456

CA COS800133
FL L800017215
MD 1077
NY 8036

NJ 25ms00007800
PA 028127
RI 00360



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Reporting and Expression of Results

- Results are reported as numeric values ($\mu\text{g/ml}$) or non-numeric as stated below:
 - None Detected is released as a result when either there is no peak at the designated retention time or if the amount detected is below the clinical Limit Of Detection (LOD).
 - Levels above the LOD but less than the LLOQ have drug detected but the level is lower than the clinical Lower Limit Of Quantitation. Report states the drug level is Below the Threshold of Quantitation.
- Therapeutic Ranges have not been established.
- The assays are performed Mondays, Wednesdays and Fridays with most results released the same day.
- Results will be sent to Facilities and Physicians Only. Due to HIPAA regulations, reports will only be sent to the FAX number listed on the requisition.

Shipping

- Frozen cold packs or dry ice is recommended. Specimens must be frozen on the day of collection and remain frozen during shipment.
- Shipment requirements: Leak-proof containers sent according to Federal Regulations.
- Specimen Labeling: Patient's name or ID# must be visible on the specimen.
- Shipping Address: 4444 Decatur Blvd., Suite 300, Indianapolis, IN 46241
- MiraVista is closed every weekend and on National Holidays.

Billing

- Referring facility will be billed. MiraVista does not bill patients or insurance.
- CPT Code is 82491 for any HPLC azole assay.
*Provided CPT codes are to be used as a guideline only. Billing is the responsibility of the ordering facility. Any questions should be reviewed with your Medicare carrier.

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