

**New Test**

**3001518**

**CYP3A4 and CYP3A5**

**3A4/3A5**



Additional Technical Information



Supplemental Resources

**Methodology:** Polymerase Chain Reaction/Fluorescence Monitoring  
**Performed:** Varies  
**Reported:** 5-10 days

**Specimen Required:** Collect: **Whole Blood:** Lavender (EDTA), Pink (K<sub>2</sub>EDTA), or Yellow (ACD Solution A or B).  
**Saliva:** Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.  
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.  
Storage/Transport Temperature: **Whole Blood:** Refrigerated.  
**Saliva:** Room temperature.  
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.  
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month  
**Saliva:** Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

**Reference Interval:** By report

**Interpretive Data:**

**Background Information for CYP3A4 and CYP3A5:**

**Characteristics:** The cytochrome P450 (CYP) 3A subfamily of enzymes is involved in metabolism of many drugs. Variants in the genes that code for CYP3A4 and CYP3A5 may influence pharmacokinetics of CYP3A substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.

**Inheritance:** Autosomal co-dominant.

**Cause:** CYP3A4 or CYP3A5 gene variants affect enzyme expression or activity.

**Variants Tested:** See the “Additional Technical Information” document.

**Clinical Sensitivity:** Drug-dependent.

**Methodology:** Polymerase chain reaction (PCR) and fluorescence monitoring.

**Analytical Sensitivity and Specificity:** Greater than 99 percent.

**Limitations:** Only the targeted CYP3A4 and CYP3A5 variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically available sources such as the [www.pharmvar.org](http://www.pharmvar.org) or [www.pharmgkb.org](http://www.pharmgkb.org) provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP3A substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.

See Compliance Statement C: [www.aruplab.com/CS](http://www.aruplab.com/CS)

**Note:** Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.

**CPT Code(s):** 81230; 81231

New York DOH approval pending. Call for status update.

**HOTLINE NOTE:** Refer to the Test Mix Addendum for interface build information.