



CYTOCHROME P450 3A4 GENOTYPE, SALIVA
Test ID: 3A4O

USEFUL FOR: An aid to clinicians in determining therapeutic strategies for drugs that are metabolized by CYP3A4, including atorvastatin, simvastatin and lovastatin.

ADDITIONAL TESTS:

Test ID	Reporting Name	Available Separately	Always Performed
NPXTO	Rapid DNA extraction, Saliva	No	Yes

TESTING ALGORITHM: When this test is ordered, DNA extraction will always be performed at an additional charge; however, for multiple saliva genotype test orders, only a single specimen is needed. The DNA extraction will only be charged once.

METHODOLOGY: Polymerase Chain Reaction (PCR) 5'-Nuclease End-Point Allelic Discrimination Analysis

REFERENCE VALUES: An interpretive report will be provided.

SPECIMEN REQUIREMENTS:

NOTE: Multiple genotype tests can be performed on a single specimen after a single extraction. See Multiple Saliva Genotype Tests in Special Instructions for a list of tests that can be ordered together.

Collection Container/Tube: Oragene DNA Self-Collection Kit (Supply T651)

Specimen Volume: Full tube

Collection Instructions:

1. Fill tube to line.
2. Send specimen in original container per kit instructions.

FORMS: New York Clients-Informed consent is required. Please document on the request form or electronic order that a copy is on file. An Informed Consent for Genetic Testing (Supply T576) is available in Special Instructions.

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Saliva	Ambient	

FEE: Please contact your Regional Manager for your account's fee information.

CAUTIONS:

- This test does not detect polymorphism or mutations other than the specific intron 6 polymorphism.
- This test is not indicated for stand-alone diagnostic purposes.
- This test is not intended to be used to predict drug response.
- Drug-drug interactions and drug/metabolite inhibition must be considered.
- Drug/metabolite inhibition can occur, resulting in inhibition of CYP3A4 catalytic activity.
- Patients may also develop toxicity problems if liver and kidney function are impaired.
- CYP3A4 genotyping should not be ordered for managing patients receiving fluvastatin, rosuvastatin, or pravastatin since these drugs are NOT metabolized appreciably by CYP3A4.
- Saliva specimen type should be used on patients who have had blood transfusions or bone marrow transplantation. Blood transfusions or bone marrow transplantation prior to having blood drawn for DNA analysis can generate false results as DNA in the specimen may be a mix of patient and donor DNA.
- Rare polymorphisms exist that could lead to false-negative or false-positive results. If results obtained do not match the clinical findings, additional testing could be considered.

CPT CODE:**Cytochrome P450 3A4 Genotype, Saliva**

81401-CYP3A4 (Cytochrome P450, family 3, subfamily A, polypeptide 4) (e.g., drug metabolism), common variants (e.g., *2, *3, *4, *5, *6)

For nonparticipating payers: Cytochrome P450 3A4 Genotype, Saliva

83898-Amplification, target, each nucleic acid sequence

83896 x 2-Nucleic acid probe, each

83912-Interpretation and report

Rapid DNA Extraction, Saliva: 83890-Molecular extraction

Day(s) Set Up: Monday

Analytic Time: 1 day

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or Shirley Pokorski, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710