

Seraseq® DPYD DNA Mutation Mix

Assay validation and daily-run QC material for DPYD pharmacogenomics testing

INTRODUCTION

DPYD genetic testing is a critical component in the realm of personalized medicine, providing insights that help optimize chemotherapy regimens for cancer patients. This test analyzes the DPYD gene, which encodes the enzyme dihydropyrimidine dehydrogenase (DPD). The enzyme plays a crucial role in the metabolism of fluoropyrimidines, a class of chemotherapeutic agents including 5-fluorouracil (5-FU) and capecitabine. However, approximately 3-5% of patients have variations in the DPYD gene that lead to reduced or absent DPD enzyme activity. These genetic variations can result in severe, and sometimes fatal, toxicity when standard doses of fluoropyrimidines are administered.

Seraseq DPYD DNA Mutation Mix is a highly multiplexed and comprehensive reference material to help clinical labs develop, characterize, validate and routinely assess their pharmacogenomics assays performance in compliance with quality standards as set by many regulatory bodies, such as the College of American Pathologists (CAP) and the Clinical Laboratory Improvement Amendments (CLIA). It contains 39 clinically important mutations as recommended by clinical consortium and experts around the world.

The product can be used alongside clinical samples to validate and monitor assay performance across the entire workflow. It can also help in identifying systematic errors and sources of variability within the testing process, such as issues with reagents, instruments, or human error.

By aiding test accuracy assessment, this reference material can increase healthcare providers' confidence in their patient test results, thus enhancing the safety and effectiveness of cancer treatments, paving the way for more personalized and precision medicine.

FEATURES AND BENEFITS

- Develop and validate DPYD assays with confidence using a highly multiplexed reference material containing 39 clinically important DPYD mutations.
- Variants are present within a single well-characterized genomic background (GM24385) at clinically relevant allele frequencies, precisely quantitated by digital PCR and orthogonally verified by NGS.
- Manufacturing of large batches with long shelf-life allows for repeated use of the same lot for validation, or assay performance assessment over time.

ORDERING INFORMATION

Material #	Product	Concentration*	Fill Volume	Total Mass
0750-9502	Seraseq DPYD DNA Mutation Mix	30 ng/μL	1 vial x 20μL	600 ng

HIGHLIGHTS

High-quality third-party QC material to develop, validate, monitor, and troubleshoot your assay

Convenient highly multiplexed material in a single vial format to save time, cost, and increase QC consistency

Ensure lot-to-lot consistency and a reliable supply with materials manufactured in GMP-compliant and ISO 13485-certified facilities

*Not for In Vitro Diagnostic Use. Research Use Only.



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