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FDA approves genetic test to highlight drug metabolism

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The test is designed to provide information about particular genetic mutations that may be associated with a patient's ability to metabolize certain drugs.

Singapore - The FDA approves a consumer-targeted molecular diagnostic test from privately held 23andme, the Personal Genome Service Pharmacogenetic Reports, that detects 33 variants for multiple genes from a saliva sample.

The test is designed to provide information about particular genetic mutations that may be associated with a patient's ability to metabolize certain drugs, although it is not intended to determine the appropriateness of any drug for a patient, a decision that should be made by a physician.

The agency says it approved the test based on data that showed it to be accurate and reproducible. The report delivered to the customer provides information about what the results might mean, what the test does not do and how to interpret the results.