

New York State clinical test approval of CARDIO inCode-Score®

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[GENinCode](#) US Inc the Irvine based predictive genetics company focused on the prevention of coronary heart disease ("CHD" or "Heart Disease") and risk assessment of ovarian cancer, announces today the test approval by the New York State Department of Health, Clinical laboratory Evaluation Program, of [CARDIO inCode-Score®](#) Polygenic Risk Score ("PRS") for the prediction and prevention of coronary heart disease.



The approval of CARDIO inCode-Score® test by New York State now enables full state coverage under US Centers for Medicare and Medicaid Services (CMS) with the test included in the 2025 Clinical Laboratory Fee Schedule at an average reimbursement of ~\$500.00 per test.

New York State clinical test approval requires rigorous analytical and clinical test validation, extensive quality documentation and the completion of a comprehensive application and laboratory audits. Test approval of CARDIO inCode-Score® allows GENinCode to collect patient samples from New York State physicians, clinics, and health institutions for testing at its Irvine, California lab facility which has also received a New York State clinical test permit.

CARDIO inCode-Score® is a clinically validated, commercially available polygenic risk score based on DNA extracted from a simple saliva or blood sample. The extracted DNA is scored to identify an individual's inherited genetic risk of heart disease thereby enabling prevention through lifestyle change and/or therapeutic treatment. The test has been designed and optimized for population-based risk prediction and primary prevention of heart disease.

GENinCode continues to progress discussions with the FDA and expects to submit additional data requested to complete its De Novo assessment in Q1. 2026. Approval by the FDA is required to sell the test in a medical device/kit format that can be used across a broad range of US laboratories.

Matthew Walls, GENinCode Chief Executive Officer said: "Following careful evaluation by the New York State Department of Health, we are delighted to receive CARDIO inCode-Score® test approval to commercially promote CARDIO inCode-Score® for genetic risk prediction of heart disease in the New York State. The approval also provides further support for our FDA De Novo assessment."

For more information visit www.genincode.com

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