Genomadix

Molecular testing. Where and when you need it.

Is your DAPT optimized to reduce the risk of secondary strokes?

1-hour CYP2C19 genotyping results in your hands could help.

FDA 510(k) cleared CYP2C19 genotyping with Genomadix Cube™ can rapidly identify loss of function (LOF) patients.[1]

FDA CLEARED
- 510(k)
- Moderate complexity

FAST
1 hour turnaround time

ACCURATE
- Direct PCR results
- Most common and relevant alleles *2, *3, *17

EASY
- Buccal swab
- No sample prep

COST EFFECTIVE
CPT Code 81225

Recent studies have shown that rapid CYP2C19 genotyping allows for a tailored approach to dual anti-platelet therapy (DAPT) within 12 hours that can reduce secondary strokes in patients presenting with TIA or minor stroke.[2-3] The Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines recommend that minor stroke/TIA patients who are carriers of CYP2C19 LOF alleles (30% of the U.S. population) should receive alternate therapies to reduce the risk of secondary strokes.[4] The 510(k) cleared Genomadix Cube CYP2C19 System can help you identify LOF patients in 1 hour from a simple buccal swab.[1]

Genomadix.com/contact

Genomadix

Recurrent stroke stats

- 185,000 recurrent strokes annually in the U.S.[5]
- Over 17% will have a recurrent stroke after a high-risk TIA and 40% will be disabling or fatal.[5-6]
- Up to $53,696 in per-patient costs for recurrent stroke treatment.[7]
- CYP2C19 genotyping is cost-effective in patients with minor stroke or TIA.[8-10]

Prevention and therapy guidelines[4,5]

- DATP should be initiated in appropriate patients within 12-24 hours after first minor stroke and TIA.[5]
- Clopidogrel + aspirin isn't fully effective in approximately 30% of patients due to genetic variation.[11]
- Clopidogrel has a black box warning.[4]
- CPIC and other guidelines recommend alternative DAPT (aspirin + ticagrelor) for CYP2C19 LOF carriers and clopidogrel resistant patients.[5,12]

CHANCE-2 analysis

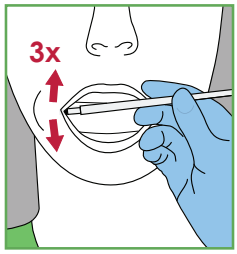
Recent studies on efficacy of early alternative DAPT showed reduced secondary strokes in LOF carriers identified using rapid CYP2C19 genotyping.[2-3]

—21% fewer secondary strokes in LOF carriers

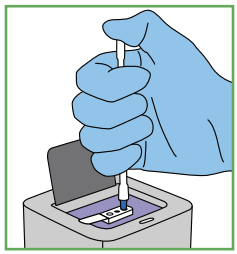
—Reductions at 1 week, 30 days, and 90 days

Testing procedure is as simple as 1, 2, 3

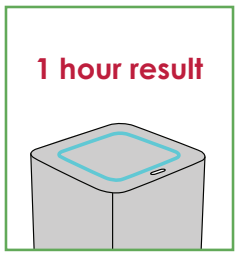
1
Collect



2
Load



3
Start



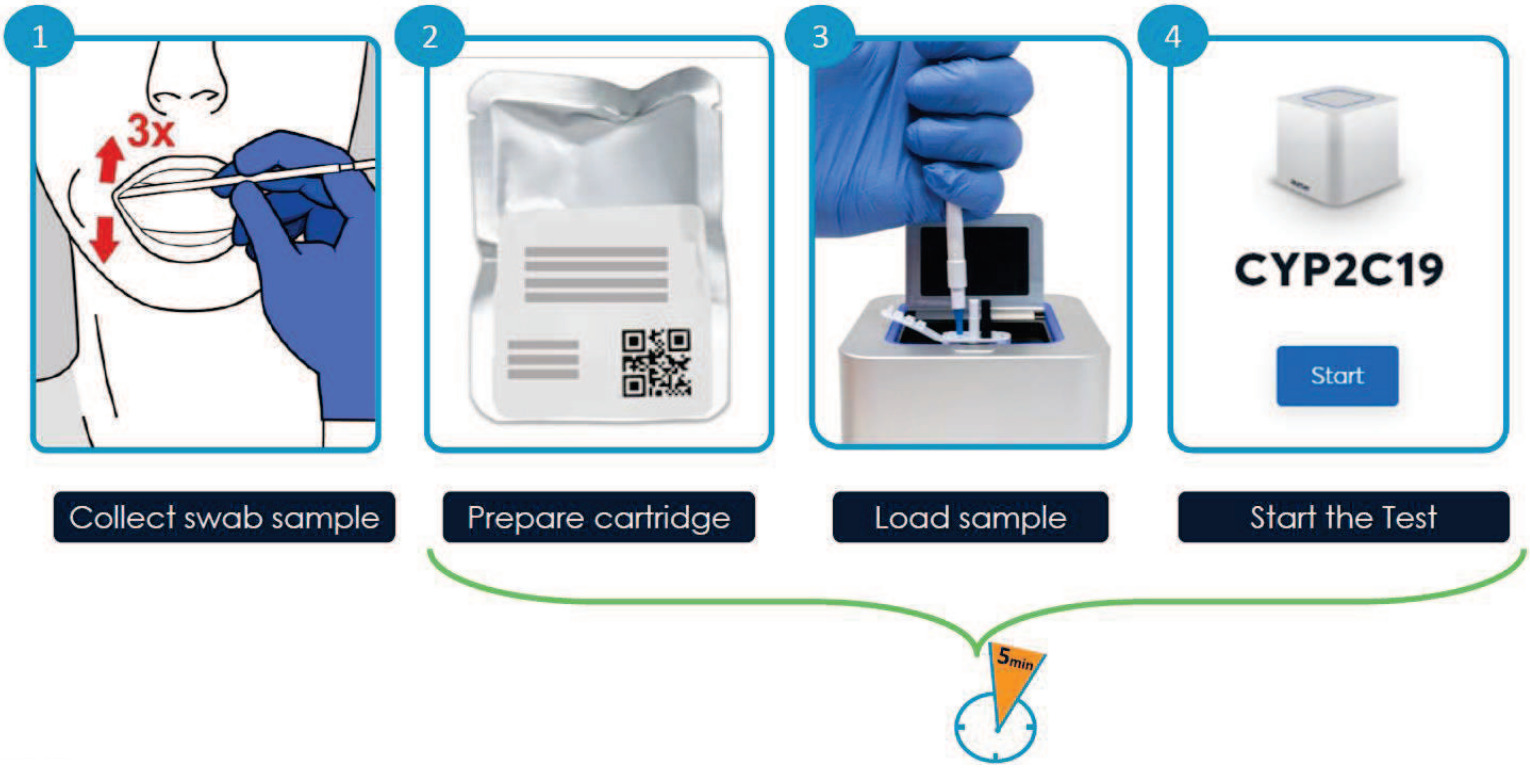
Learn how rapid CYP2C19 testing may help optimize your approach to DAPT.

Genomadix.com/contact

References

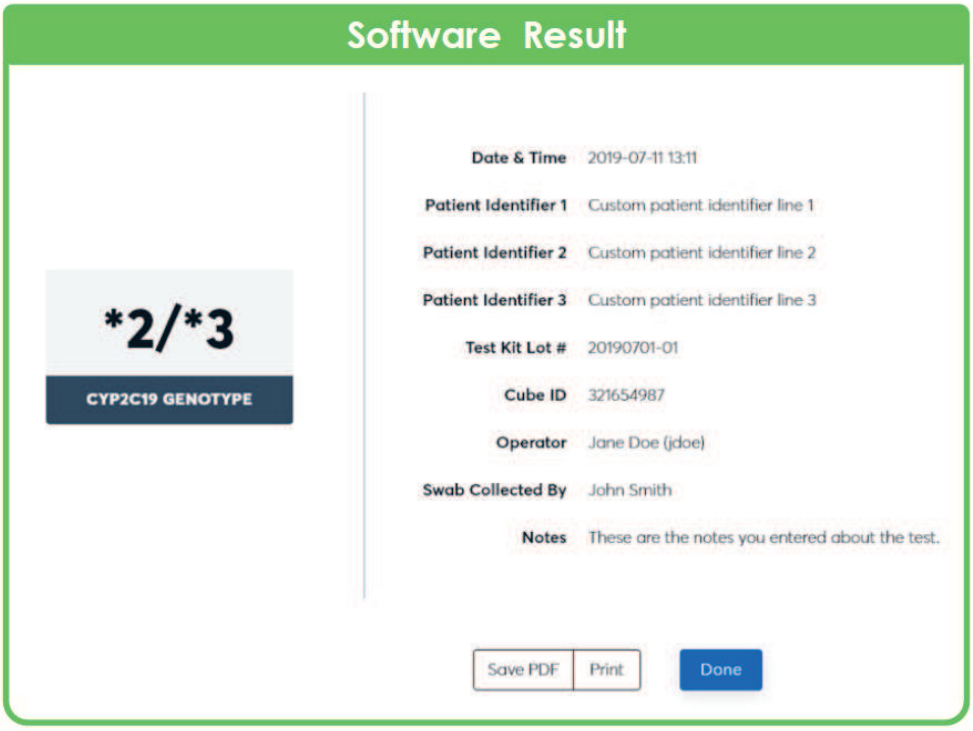
1. Genomadix Cube CYP2C19 System 510(k) Decision Summary. https://www.accessdata.fda.gov/cdrh_docs/reviews/K220026.pdf. Accessed December 22, 2023.
2. Wang Y, Meng X, Wang A, et al. Ticagrelor versus clopidogrel in CYP2C19 loss-of-function carriers with stroke or TIA. *N Engl J Med*. 2021;385:2520-2530.
3. Pan Y, Meng X, Jin A, et al. Time course for benefit and risk with ticagrelor and aspirin in individuals with acute ischemic stroke or transient ischemic attack who carry CYP2C19 loss-of-function alleles: A secondary analysis of the CHANCE-2 randomized clinical trial. *JAMA Neurol*. 2022;79(8):739–745.
4. Lee CR, Luzum JA, Sangkuhl K, et al. Clinical Pharmacogenetics Implementation Consortium Guideline for CYP2C19 genotype and clopidogrel therapy: 2022 update. *J Clinical Pharmacol Therapeutics*. 2022;122(5):959-967.
5. Amin HP, Madsen TE, Bravata DM, et al. Diagnosis, workup, risk reduction of transient ischemic attack in the emergency department setting: a scientific statement from the American Heart Association. *Stroke*. 2023;54:e109–e121.
6. Hobeanu C, Lavallée PC, Charles BST H,et al. Risk of subsequent disabling or fatal stroke in patients with transient ischaemic attack or minor ischaemic stroke: an international, prospective cohort study. *Lancet Neuro*l. 2022;21:889–898.
7. Ferrone SR, Boltyenkov AT, Lodato Z, et al. Clinical outcomes and costs of recurrent ischemic stroke: a systematic review. *J Stroke Cerebrovasc Dis*. 2022;31(6):106438.
8. Micieli A, Singh N, Jahn B, et al. Cost-effectiveness of testing for CYP2C19 loss-of-function carriers following transient ischemic attack/minor stroke: A Canadian perspective. *Int J Stroke*. 2023;18(4):416-425.
9. Wright S, McDermott J, Sen D, Smith C, Newman W, Payne K. Development of a point-of-care genetic test for effective treatment of patients with ischaemic stroke and transient ischaemic attacks: an early model-based cost-effectiveness analysis 2022. *Welcome Open Res*. 2023;8:183.
10. National Institute of Health and Care Excellence. Evidence overview of clopidogrel genotype testing after ischemic stroke of transient ischemic attack. *NICE*. March 2023.
11. Kang HG, Lee SJ, Heo SH, Chang D, Kim BJ. Clopidogrel resistance in patients with stroke recurrence under single or dual antiplatelet treatment. *Front Neurol*. 2021;12:652416.
12. Dawson J, Merwick A, Webb A, et al. European Stroke Organisation expedited recommendation for the use of short-term dual antiplatelet therapy early after minor stroke and high-risk TIA. *European Stroke J*. 2021;6(2):CLXXXVII-CXCI.

Genomadix Cube CYP2C19 System
Workflow



Genomadix Cube CYP2C19 System
Result

Software Result



PDF Result Report