

Clinical performance of the **Genedrive CYP2C19** Genotyping platform



Reference: Development and Validation of a Rapid Point-of-Care CYP2C19 Genotyping Platform

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KEY FINDINGS:

100% ACCURACY:

Genedrive CYP2C19 ID Kit delivers exceptional sensitivity and specificity.

SUPERIOR TO LAB REFERENCE TEST:

Faster, more accurate, and with fewer test failures.

- Genedrive Correctly Identified **99.02%** of patients tested
- Agena Correctly Identified **92.65%** of patients tested

ENHANCED DETECTION:

Identifies 5 LOF variants, detecting 7 patients missed by other POC or lab platforms targeting *2 & *3 alone.

AIM:

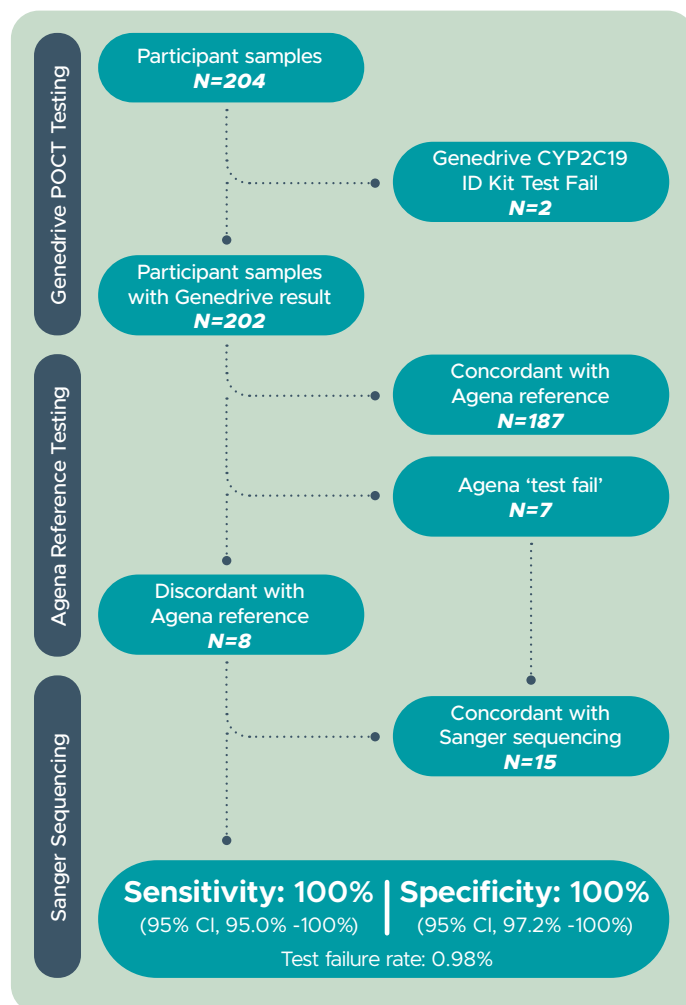
To evaluate the performance and accuracy of the **Genedrive CYP2C19 ID Kit** as a rapid, point-of-care genotyping tool for guiding antiplatelet treatments in stroke and TIA patients.

METHOD:

A total of 204 patients were tested at two sites using buccal samples (Genedrive) and DNA extracted from Blood (Agena), collected and prepared by healthcare professionals.

COMPARISON WITH THE AGENA VERIDOSE CORE V1.0 PANEL:

- Genedrive had **2** failed tests (**0.98%**) compared to **7** by the Agena panel (**3.5%**)
- Agena panel had 8 Discordant results (Genedrive confirmed accurate in all cases by sanger sequencing):
 1. **Agena errors:** Small peaks missed or falsely identified.
 2. ***35 Detection:** Agena lacked detection of the *35 allele which was correctly identified by the Genedrive test in 3 patients.



CONCLUSIONS:

- The **Genedrive CYP2C19 ID Kit** is NICE's choice of POCT platform.
- **POCT provides significant advantages** over lab testing and in this study the **Genedrive CYP2C19 ID Kit** has been shown to **outperform a widely used laboratory test**.



ADDITIONAL BENEFITS OF POINT-OF-CARE TESTING (POCT):

- The National Stroke clinical guideline recommends that dual antiplatelet therapies are administered in <24 hours of the event.
1. POCT eliminates delays caused by centralised labs, enabling faster treatment adjustments.
 2. POCT streamlines patient pathways, minimising recall and reducing the need for outpatient follow-up.
 3. Having immediate, actionable results improves secondary prevention and reduces the risk of further strokes within the critical 90-day window.



Scan QR code or click [HERE](#) to view the NICE guidance.



Scan QR code or click [HERE](#) to view Sales Flyer.



“Implementation of the Genedrive CYP2C19 ID Kit in clinical practice could provide an accurate, rapid, cost-effective, and non-invasive alternative to standard laboratory testing and ensures results are available in a clinically relevant format and time frame to guide patient care.”

GPM-166 V2

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