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genedrive plc
("genedrive" or the "Company")

Genedrive HCV ID Kit demonstrates high clinical accuracy in India study

Hepatitis C virus testing kit reveals 100% sensitivity and specificity when compared to Abbott Real time HCV test

Genedrive plc (AIM:GDR), the near patient molecular diagnostics company, announces the publication of the study data for the 'Evaluation of the Point of Care Molecular Diagnostic Genedrive HCV ID Kit for the detection of HCV RNA in clinical samples'.

The study[1] was led by Dr Ekta Gupta at ILBS, New Delhi, India. The objective of the study was to determine the diagnostic accuracy of the Genedrive HCV ID Kit, as a confirmatory test for seropositive hepatitis C virus (HCV) patients in Indian demographic settings.

Details of the study are published online here: https://tinyurl.com/y2pfylwo

The diagnostic accuracy of the Genedrive HCV ID Kit was evaluated by comparing the test with the Abbott Real time HCV test on the lab-based Abbott m2000 platform in an Indian demographic and across a range of different genotypes, to ensure suitability for introduction of the product to the Indian population. In India the circulation of HCV genotype is predominantly genotypes 3 and 1 with live infections of HCV estimated at between 6-12 million[2].

150 HCV RNA positive and 170 HCV RNA negative samples were tested using both methods. The comparison revealed 100% sensitivity (95% CI 97.9 - 100%) and 100% specificity (95% CI 97.9 - 100%). The overall diagnostic accuracy was 100% (95% CI 98.9 - 100%).

Overall, the study demonstrates that the Genedrive HCV ID Kit is suitable for use in India and can be used for decentralised testing of HCV thereby reducing the loss of patients to follow up.

David Budd, CEO of genedrive plc, said: *"These excellent clinical results for our HCV assay further validate the applicability of the test for a decentralised setting. India is a key target market for our assay and we are excited about the commercial prospects in the region."*

1 Unique publication reference: DOI 10.1017/S0950268820002812.
2 Ministry of Health and Family Welfare Government of India, 2019, https://tinyurl.com/y3box279

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About genedrive plc (http://www.genedriveplc.com)

genedrive plc is a molecular diagnostics company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need molecular diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications. The Company has assays on market for the detection of HCV, certain military biological targets, and has tests in development for tuberculosis (mTB). The Company recently released a high throughput SARS-CoV-2 assay and has in development a Genedrive® Point of Care version of the assay, both based on Genedrive® chemistry.

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