

ASX Market Announcement



COVID-19 Risk Test Approved for Commercial Release

Melbourne, Australia, 26 April 2021: Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, "Company", "GTG"), a diversified Genomics and AI driven preventative health business provides an update to the market on the progress of the US commercial availability of the Company's COVID-19 Serious Disease Risk Test ('COVID-19 Risk Test') via US Based Infinity BiologiX LLC ('IBX'), (ref: ASX Announcement 3 March 2021).

The Company confirms the submission of the COVID-19 Risk Test regulatory pack to the regulators¹. In conjunction with prior correspondence with the regulators this submission enables the commercial release within the United States. Final steps in the technical interface are being built with additional capabilities for the telehealth platform to enable sales of GTG's COVID-19 Risk Test and further products² within markets outside of the United States. The Company will provide further updates on regional releases as and when they are confirmed.

The commercial release is expected to occur no later than the end of May once the technical interface for the United States telehealth platform is completed by IBX's telehealth partners.

Simon Morriss stated: "We are excited to be at the precipice of the commercial release of our COVID-19 Risk Test. With IBXs testing capacity of ~100,000 SARS CoV-2 Tests undertaken per day we look forward to seeing this rolled out and informing individuals of their risk of developing a serious case of COVID-19. Additionally, broadening the opportunity set by building a platform that can enable sales beyond the United States will be critical in streamlining market expansions and future product launches."

The Company will provide further details on the updated launch date for the COVID-19 Risk Test once confirmed between GTG, IBX and their telehealth partner.

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1. Regulators include the Centres for Medicare and Medicaid Services / Clinical Laboratory Improvement Amendments (CMS/CLIA) and New York State Department of Health (NYSDOH)/Clinical Laboratory Evaluation Program (CLEP). For COVID-19 testing, we are following a policy March 2020 FDA policy allowing laboratories to initiate patient testing once the assay has been:
 - a. Validated and approved by the laboratory director/ responsible Certificate of Qualification Holder; and
 - b. Submitted to CLEP via hard copy and digital.
2. COVID-19 Risk Test availability within expanded markets outside of the United States subject to regulatory approvals for each region.

Authorised by the Board of Genetic Technologies

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About Genetic Technologies Limited

Genetic Technologies Limited (ASX: GTG; Nasdaq: GENE) is a diversified molecular diagnostics company. GTG offers cancer predictive testing and assessment tools to help physicians proactively manage patient health. The Company's lead products GeneType for Breast Cancer for non-hereditary breast cancer and GeneType for Colorectal Cancer are clinically validated risk assessment tests and are first in class. Genetic Technologies is developing a pipeline of risk assessment products.

For more information, please visit www.gtglabs.com

About Infinity BiologiX LLC

Infinity BiologiX (IBX) is a market-disrupting central laboratory supporting academia, government, and industry. IBX provides global sample collection, processing, storage, and analytical services integrated with scientific and technical support in both the research and clinical arenas. As a leader in biomaterials, IBX provides support to the development of diagnostics, therapeutics, and research in the genomics, precision, and regenerative medicine arenas. IBX previously operated as RUCDR Infinite Biologics before spinning off from Rutgers University-New Brunswick in August 2020.

For more information, visit www.ibx.bio