
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Silver Factory Technology Pte Ltd
<i>Name of test</i>	TracieX Breathalyzer
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The TracieX Breathalyzer is an in-vitro diagnostic (IVD) device used in screening for rapid qualitative detection of COVID-19 infection. Using breathomics assay with human breath specimen, it measures the volatile biomarkers in breath and detects based on the biomarker compositions. The device is intended for near-subject use with trained personnel. It is not a confirmatory test.</i></p> <p><i>Positive results do not rule out infection with bacteria or other viruses. Any positive results from this test should be confirmed by PCR testing.</i></p> <p><i>Negative results must be combined with clinical observations, patient history, and epidemiological information and should not be used as a sole basis of patient management.</i></p>
<i>Date of Provisional Authorisation</i>	27 May 2021
