

## MD017: Technical Review Application

### BACKGROUND

1. COVID-19 molecular test kit/s that have not been listed, registered or authorised for use in a jurisdiction recognised by SAHPRA or that have not been pre-qualified by the WHO, will be evaluated against the minimal acceptable key features outlined in the Specification Criteria for COVID-19 Molecular Test Kits (MD018).
2. Irrespective of a closed or open system or component, the overall specimen to result process must comply with the minimal acceptable key features outlined in MD018.
3. Only COVID-19 molecular test kit/s that meet the minimal acceptable key features (MD018) will be recommended to undergo a performance evaluation by the national reference laboratory.
4. The results of the performance evaluation will inform the decision of SAHPRA to issue the licence.

<b>Type of test</b>	
<b>Name of test</b>	
<b>Company name</b>	
<b>Source</b>	
<b>Provide a brief description of the test:</b>	

<i>Please answer the following questions based on the product information</i>		
<b>Characteristics</b>	<b>TO BE COMPLETED BY APPLICANT</b>	<b>LAB USE ONLY: Brief supporting evidence</b>
<b>Priority features</b>		
Is the intended use described for SARS-CoV2 diagnostics <i>(target population, target setting)</i>		
Is the kit for a closed or open system		
Is the test designed for a laboratory or POC		
Is the procedure safe <i>(level required, BSI1, 2, 3)</i>		
What is the gene target(s) <i>(Single or multiple, please list)</i>		
Is the result easy to interpret <i>(are Ct/Tm accessible)</i>		
What specimen type is required <i>(dry swab, NP, OP, saliva, sputum, other)</i>		
Can UVT/PBS/Saline be tested <i>(this is critical for inhibition/compatibility)</i>		
<b>Test Procedure</b>		
Is the test compatible with existing in-country laboratory testing footprint <i>(list extraction/amplification systems)</i>		
How many steps are performed by the operator ( $\leq 4$ or $< 6$ : label tube, add inactivator/extraction reagents, add RNA, add mastermix, interpret result)		
What type of operator is required to perform the test <i>(POC, Laboratory technician or Laboratory molecular scientist)</i>		
What minimal pipetting volume is transferred during the testing process <i>(&gt;20<math>\mu</math>l or &gt;5<math>\mu</math>l)</i>		
Is additional biosafety (more than standard PPE required) <i>(BSI2)</i>		
Does the test have an internal control <i>(Endogenous (RNaseP) or Synthetic)</i>		
Does the test have a positive and negative batch control <i>(included/not)</i>		
Does the result require interpretation (manual review of amplification curves or automated with no interpretation required)		
<b>Operational characteristics</b>		
What is the reagent storage stability <i>(24months @ Room temperature, or 12months @ -70C)</i>		

<i>Please answer the following questions based on the product information</i>		
<b>Characteristics</b>	<b>TO BE COMPLETED BY APPLICANT</b>	<b>LAB USE ONLY: Brief supporting evidence</b>
What are the training needs (<half day or <2days)		
How easy is the test to perform (hands on time <15 minutes or <60 minutes)		
What are the daily maintenance requirements (<15 minutes, or <30 minutes)		
Are additional consumables required <sup>a</sup> (are they provided)		
Additional equipment required <sup>a</sup> (are they provided) <sup>a</sup> over and above standard laboratory and in-country accessible		
Is there a connectivity option (Interface capability with in-country LIS or result file transferrable)		
Does the kit storage require space		
Is the waste disposal minimal (<5L/day or <20L/day and non-biohazard)		
Is there reagent wastage (Minimal and/not batch specific)		
Is the package Insert easy to follow		
Are the instructions for use comprehensive		
What is the automated time to result (<60 minutes or <4hrs)		
How many specimens/run (high ≥90 or ≥20 low throughput)		
How many specimens/8-hour shift (≥360 or ≥160)		
<b>Performance</b>		
What is the limit of detection (LOD) (is a value provided)		
Is there supporting data (lab or clinical) on the performance of the assay (accuracy, precision)		
<b>FOR LABORATORY USE ONLY</b>		
<b>This test/kit/reagent/system is suitable/not suitable for evaluation</b>		
<b>Add any comments if not approved for evaluation:</b>		

**DR B SEMETE-MAKOKOTLELA**  
**CHIEF EXECUTIVE OFFICER OF SAHPRA**  
**22 JULY 2020**