



ANNEXURE A: TECHNICAL SPECIFICATION

BID NUMBER RT63-2022

**SUPPLY AND DELIVERY COVID-19 TEST KITS TO THE STATE FOR THE PERIOD OF
24 MONTHS**

**NATIONAL TREASURY
TRANSVERSAL CONTRACTING**



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TECHNICAL SPECIFICATION

1. TECHNICAL MANDATORY REQUIREMENTS

- 1.1. Rapid antigen test –SAHPRA test kit approval for use in South Africa. Evidence: SAHPRA letter of authorisation.
- 1.2. Suppliers must supply a batch from each new lot number for verification at the national reference laboratory Evidence: Commitment in writing to supply each new lot number for verification
- 1.3. All required consumables should be supplied within or with the kit. Evidence: Brochure and/or package insert
- 1.4. Published validation data produced through a recognised regulatory authority (FDA, CE, or WHO) or through a report from the national reference laboratory should indicate that the sensitivity of the test exceeds 85% and the specificity >98%. Evidence: must submit a formal validation report produced by a regulatory authority indicated and authorised by a pathologist.
- 1.5. The item awarded should be able to adapt to the detection of novel COVID-19 variants as outlined by the National Institute for Communicable Diseases. The state reserve the right to suspend procurement of the awarded testing kits which no longer serve effectively to detect the Covid-19 variant during the contract period. Evidence: Validation data to show that the test kit can detect alpha, beta, delta and omicron variants with sensitivity >85%

2. TECHNICAL COMPLIANCE REQUIREMENTS

- 2.1. Item offered must comply to the following minimum technical specification.

#	REQUIREMENTS	DETAILS
1.	Assay sensitivity	85% or greater
2.	Assay specificity	>98%
3.	Ease of kit use	Closed system (EXCLUDING addition of buffer by dropper) but requires minimal preanalytical processing (swab cutting, addition of buffer without a dropper e.g., via a pipette or other processing)
4.	Requirement for analyser or reader	Must be supplied with analyser or have a lateral flow assay.



#	REQUIREMENTS	DETAILS
5.	Training	Must have access to online training material and must be able to provide onsite technical training for up to 3 technical persons (phlebotomist or phlebotomy technician, nurse)
6.	Specimen type	Can be utilised on sputum (for use on an early morning sample prior to eating/drinking/brushing teeth), nasopharyngeal swabs and oropharyngeal swabs

END