

MD013: Process flow – Locally manufactured COVID-19 test kits

STEP A: PERFORMANCE EVALUATION OF COVID-19 TEST KITS

1. The performance of locally manufactured COVID-19 test kits must be evaluated by the National Reference Laboratory (NRL).
2. The results of the performance evaluation must be documented in a report prepared by the NRL. This report must accompany the application submitted to SAHPRA for a medical device establishment licence to manufacture medical devices including in-vitro diagnostics (IVDs).
3. COVID-19 test kits that do not meet the predetermined specifications for performance will not be considered by SAHPRA.
4. **COVID-19 test kits that have been evaluated by the NRL and do not meet the predetermined specifications for performance will not be re-evaluated by the NRL.**

STEP B: SUBMIT SAHPRA LICENCE APPLICATION

5. Local manufacturers of COVID-19 test kits are required to submit a licence application to manufacture medical devices to SAHPRA.
6. The regulatory requirements for the manufacture, distribution or wholesale of COVID-19 serological test kits are described in MD002.
7. The regulatory requirements for the manufacture, distribution or wholesale of COVID-19 molecular test kits are described in MD014.

STEP C: SAHPRA LICENCE AND SECTION 21 AUTHORISATION ISSUED

8. SAHPRA will issue a licence to manufacture medical devices to the applicant provided that all the regulatory requirements are met.
9. SAHPRA will issue a Section 21 Authorisation for the use of an unregistered medical device for locally manufactured COVID-19 test kits.
10. The licence conditions for unregistered COVID-19 test kits are described in MD011.

STEP D: AUTHORISATION FOR USE

11. Only medical device establishments that are licensed by SAHPRA may manufacture medical devices.
12. Only locally manufactured COVID-19 test kits that have been issued a Section 21 authorisation by SAHPRA may be made available for sale.
13. The use of COVID-19 tests kits will be limited for such purposes, in such a manner and during such a period as determined by SAHPRA.
14. The export of local manufactured COVID-19 test kits must be authorised by SAHPRA.

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ANNEX 1: PROCESS FLOW FOR LOCALLY MANUFACTURED COVID-19 TEST KITS

