

# Interim guidance for monitoring of GeneXpert testing quality and supplies of testing cartridges in Pacific Island Countries

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## Overview

This interim guidance is intended to assist the Pacific COVID-19 Joint Incident Management Team Laboratory Cell monitor the quality of COVID-19 SARS-COV-2 GeneXpert testing and the status of cartridge supplies in Pacific Island Countries. Information gathered will be used to improve the quality of SARS-COV-2 testing, inform countries of the possibility of another coronavirus infection and guide the Laboratory Cell with the distribution of GeneXpert cartridges to countries.

## Background

As countries prepare to increase testing capacity it is vital the quality and volume of testing are monitored by the Laboratory Cell. This will allow issues detected in the countries' testing system to be addressed and rectified in a timely manner, through the prompt provision of corrective measures, timely communication with the supplier and dialogue with partner organization in particular UNDP who have supported countries tuberculosis programmes with the procurement of GeneXpert equipment.

GeneXpert equipment captures real-time testing data that are considered as key performance indicators of the testing process. Laboratory scientists are required to send the information either by taking a picture of the equipment's quick-stat screen or downloading the information and submit electronically on a monthly basis.

The overall quality of tests is reflected by 3 indices; error rate, invalid results and number of tests with no results. A high number of these indices or increase in trend indicates deterioration in the quality of testing and test results. This will warrant the provision to in country laboratory managers and scientists appropriate measures and guidance on how to improve test performance. Furthermore, an increase in presumptive positive results would indicate the presence of other strains of coronavirus and the need for surveillance and referral of sample to a reference laboratory for further testing.

In-country stock of GeneXpert cartridges will be monitored through test statistics i.e. one cartridge per test. This information will be used by the Laboratory Cell to guide the development of GeneXpert cartridge distribution plans to ensure there is an adequate supply to meet testing needs and countries do not overstock which may result in cartridges to expiring on the shelves.

The 9 Key Performance Indicators (KPIs) that will be monitored using equipment Quickstat results are:

1. Total number Xpert SARS-COV-2 tests run in the monitoring period
2. Total number of successful Xpert tests
3. Total number of unsuccessful Xpert tests
4. Total number of Xpert SARS-COV-2 positive
5. Total number of Xpert SARS-COV-2 Presumptive positive
6. Total number of Xpert SARS-COV-2 negative
7. Total number of error results
8. Total number of invalid results
9. Total number of no results

## Advise

- Each country to appoint senior technicians or scientists to be in-charge of SARS-COV-2 testing, overlooking monitoring of the quality SARS-COV-2 GeneXpert testing.
- SARS-COV-2 testing scientists or technicians to undergo training by Cepheid on how to access quick-stat screen and extract COVID-19 SARS-COV-2 testing information.
- Countries scientist or technician in-charge of testing to obtain SARS-COV-2 quick stat information either by taking a picture of the quick-stat screen or upload quick stat and email to JIMT Laboratory Cell focal person.
- The JIMT to appoint a focal person who has experience in GeneXpert testing and data analysis to receive and collate information from the laboratory using the Monitoring Tool (**Annex 1**) and assist countries in implementing corrective measures.
- JIMT Laboratory Cell focal person will;
  - acknowledge receiving information from countries,
  - check and upload information onto the Excel spreadsheet,
  - check the error pattern, invalid results and no results and complete countries assessment summary
  - advise countries and JIMT Laboratory Cell on the quality of in-country testing and corrective measures
  - advise JIMT Laboratory Cell on testing cartridge usage based on test statistics
  - communicate with partners; supplier and UNDP regarding any issues with SARS-COV-2 testing as the needs arises

**Annex 1:** Country Monitoring Report tool for GeneXpert testing for SARs-CoV-2 (electronic copy to be provided to countries)

*This document has been developed in accordance with global guidance and contextualized to the Pacific context by the, Pacific Island Health Officers Association (PIHOA), Pacific Community (SPC), United Nations Development Programme (UNDP) and the World Health Organization (WHO) from the COVID-19 Pacific Joint Incident Management Team*