

KENYA PLANT HEALTH INSPECTORATE SERVICE			Page 1 of 777
Quarantine and Plant Health Laboratory-Muguga			
TITLE AND ID.	SOP FOR Ensuring the Validity of Results SOP-GE-09		
DEPARTMENT	Quality Management Unit		
EFFECTIVE DATE	1st February 2020	Version Number: 01	

Approval and authorizations.

Completion of the below signature blocks signifies the review and approval of this document.

Name	Job title/role	Signature	Date
Authored by	Deputy Quality Manager	<i>Approved</i>	1 st February 2020
Checked by	Quality Manager	<i>Approved</i>	1 st February 2020
Approved by	Officer In Charge	<i>Approved</i>	1 st February 2020

Periodic reviews, approvals and authorizations

Required by: 1st March 2021

Name /	Job title/role	Signature	Date
Checked by			
Approved by			

Periodic reviews, approvals and authorizations

Required by: 1st March 2024

Name	Job title/role	Signature	Date
Checked by			
Approved by			

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1.0 Purpose

The purpose of this procedure is to guide on the process of monitoring ensuring validity of test results generated at the Quarantine and Plant Health Laboratory. ies

2.0 Scope

This SOP applies to all results generated -from the laboratory. from accredited methods.

3.0 Responsibilities

Laboratory manager

- Planning and ensuring for the monitoring of validity of -review of results is done on an annual-quarterly basis.
- Recommends improvements on tests to ensure validity where necessary.

Officer in Charge

- Provide resources necessary for carrying out quality checks on results.
- Authorizes competent staff to undertake review of test results.
- Authorizes test results before they are sent to the customer

Procedures

The following quality control procedures shall be used for monitoring the validity of results for tests undertaken by the Quarantine Plant Health Laboratories.

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Annual monitoring of Validity of results:

1. Quality control is a continuous process. The laboratory manager shall plan on an annual basis a monitoring and review of results generated by the laboratory.
2. This monitoring shall be planned and reviewed and shall include, where appropriate but not be limited to, the following bullets labeled (a) through (k):
 - a) Use of reference materials or quality control materials.
 - b) Use of alternative instrumentation that has been calibrated to provide traceable results.
 - c) Functional check(s) of measuring and testing equipment.
 - d) Use of check or working standards with control charts, where applicable.
 - e) Intermediate checks on measuring equipment.
 - f) Replicate tests using the same or different methods.
 - g) Retesting of retained items
 - h) When a verification of a result is carried out, it shall be conducted by an individual who is currently authorized to perform testing; a record of the

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verification shall be made and the record shall identify who performed the verification, when it was performed, and the results of the verification; and the resolution of any discrepancy shall be recorded.

- i) Correlation of results for different characteristics of an item.

This review shall be documented in form of a checklist SOP-GE-aa -01

Technical review of reports prior to release

- a) All reports generated by the laboratory shall undergo a technical review before the test report is released to customers.
- b) Laboratory analysts approved to perform review may perform technical reviews if they are authorized.
- c) Analysts shall not technically review their own work. Technical review shall not be conducted by the author or the co-author(s) of the examination records or test report under review.

A technical reviewer shall ensure the following :

- Conformance with proper technical and/or analytical procedures.
- Accuracy of test reports and that the data supports the results and/or conclusions in the test report.

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- Results, opinions, and interpretations shall be accurate, properly qualified, and supported by the technical record.
- The test report contains all required information.

d) The reviewer will assent his/her signature on the report upon satisfaction that the report meets requirements of (d) above.

j. Intralaboratory comparison

h. Testing of blind sample(s).

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CHECKLIST FOR CHECKING VALIDITY OF TEST RESULTS (SOP-GE-09-01)

Sample details

- ☐ Samples numbers are consistent with the request, bear unique identity, indicate test laboratory and client details match with sample contract form.
- ☐ The person collecting the samples is correctly identified
- ☐ Sample was labeled correctly and clear
- ☐ The request form contains correct and clear contact details of the requester
- ☐ The date and time of collection is indicated on the request form
- ☐ The sample was received in acceptable condition

Analytical

- ☐ Reagents and test kits used were within expiry date.
- ☐ Quality controls associated with the result were acceptable
- ☐ There were no flags on the analyzer's results that need investigation
- ☐ Correct method was used
- ☐ Appropriate standards or controls are used.
- ☐ Equipment's used are functional and in good state.

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Post Analytical

- ☐ The report shows an appropriate result including test and result match for each test requested
- ☐ Proper grammar is used.
- ☐ The opinion and interpretations are consistent with the identified pathogen management.
- ☐ The persons performing the tests are identified.
- ☐ All results and documentation are legible
- ☐ The release of the results is dated.
- ☐ The report format is as specified in relevant procedures.

Remarks:

Authorizer's name, signature and date for completion of validation and correctness of results:

Name: _____ **Date:** _____ **Signature:** _____