Validation Report *(Notes in Red Underline)*

Title	
Document Reference	
Division/Study Area	

Document Approval

Author			
Name	Position	Signature	Date
Technical Approval			
Name	Position	Signature	Date
Management Approval			
Name	Position	Signature	Date
Quality Approval			
Name	Position	Signature	Date

Contents

1. Introduction

XXX…

Provide an outline and context for the validation i.e. what was validated and why. [Can copy from the Validation Plan]

2. Validation Criteria

XXX…

Re-state the validation criteria described in Validation Plan. [Can copy from the Validation Plan]

3. Assessment of Performance Against Criteria

Include detailed results with a section for each validation acceptance criteria.

3.1 Acceptance Criterion 1 [edit heading]

XXX…

Each section should include results tables and discussion related to the specific criterion. If any aspect is not fully met this must be discussed with appropriate actions and/or recommendations made.

Sample ID	Observed results			±3SD
	Replicate 1	Replicate 2	Replicate 3	
e.g. 123456	*e.g. 28.2*	*e.g. 33.1*	*e.g. 37.4*	*e.g. 21.3 – 39.7*

XXX…

Reference to the location of original raw data should be included e.g. report appendix, hard copy file locations, soft copy network drive locations.

XXX…

Conclude each section with a statement on whether the acceptance criterion has been met

Acceptance criteria [XXXX] – **Pass/Fail**

3.2 Acceptance Criterion 2 ect

XXX…

4. Conclusions

XXX…

Conclude whether all validation acceptance criteria have been met. If not what has not been fulfilled? What impact does that have on the validity of the assay and the veracity of results? e.g. will a particular sample type be invalid or does the whole test method need to be further optimised / re-designed?

Include a concluding statement on the fitness for purpose of the test method

All validation acceptance criteria have been met and [test method] deemed fit for purpose for the [identification of X/determining the relative potency of Y/…] for use within the [Study Area/Group] of [Division].

5. Recommendations

XXX…

Describe any actions which need to be taken as a result of the validation exercise, number the recommendations to aid identification and subsequent follow-up.

No.	Recommendation	Target Date	Assigned To
1	*e.g. finalise SOP, test forms*	*e.g. 01/01/2020*	*e.g. John Doe*
2			
3			
4			

Suggest including a general statement approving the implementation of the validated test method.

The validation exercise has been successfully completed and following [close-out of the above recommendations and] authorisation of this report the validated test method will be implemented for routine use following change control procedures.

6. Impact of Validation

XXX…

Based on the impacts stated in the Validation Plan describe what actions have been taken:

- *what documents have been revised e.g. SOPs, forms, study plans. Reference CRQ raised and version numbers issued.*

- *what records have been created or updated e.g. equipment records, training records, critical reagents list. Reference storage location of new/updated records.*
- *what training schedules have been created/updated, which staff have undergone (re)training.*
- *has a review of data monitoring method taken place and been documented. Reference location of authorised review*
- *has uncertainty of measurement been re-accessed and documented. Reference location of authorised re-assessment*
- *have required CT-LIMS changes been made. Reference record of changes made.*

Appendix A

XXX…

Appendices can be added and deleted as required to include details of items referred to in the body of the Validation Report

Sample ID	Test parameter	Observed result	Acceptance criteria (Pass / Fail)
e.g. 123456	*e.g. Accuracy*	*e.g. 2.2 RPU*	*e.g. Pass*

Completed by			
Name	Position	Signature	Date
Checked by			
Name	Position	Signature	Date