

# Assay Validation Report

Use this template to validation report for [assay\_name] performance characteristics.

## Template Metadata

Field	Details
Category	Life Sciences & Labs
Owner	[Team or owner]
Version	[Version number]
Effective Date	[Date]
Review Cycle	[Monthly / Quarterly / Annual / Event-based]
Status	[Draft / In Review / Approved]

## Objective

State assay name, intended use, matrix, and validation goal.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Method Summary

Summarize analytical principle, instrument platform, sample preparation, and readout.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

### Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Validation Design

Describe validation parameters such as accuracy, precision, specificity, linearity, range, robustness, and stability.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

### Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Results

Present result tables for each parameter with predefined acceptance criteria.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Deviations

List protocol deviations, impact assessment, and whether data remain valid.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Acceptance Summary

Compare all criteria to outcomes and identify any limitations.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Conclusion

State whether the assay is validated for intended use and any routine controls required. Use concise scientific language and tables for validation outcomes.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

## Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

## Review and Signoff

Document review conclusions, approvals, unresolved items, and next review date.

Role	Name	Date	Notes
Preparer	[Name]	[Date]	[Notes]
Reviewer	[Name]	[Date]	[Notes]
Approver	[Name]	[Date]	[Notes]