**System Name**

**Testing Summary**



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# Introduction

## Purpose

This document summarizes the outcomes of the validation testing activities. Its focus is on the results of the tests and any problems identified during text execution.

## Scope

Define the scope of the system and/or project that is covered by this Testing Summary. If multiple Testing Summaries are prepared for different portions of the system’s testing, note the portion(s) of the testing included in this document.Define the scope of the Validation Testing that is covered within this Validation Testing Summary. Note any portion(s) of the validation testing that is excluded from this document.

## Definitions, Acronyms and Abbreviations

| **Term** | **Definition** |
| --- | --- |
| FRS | Functional Requirements Specification |
| IQ | Installation Qualification |
| OQ | Operational Qualification |
| PQ | Performance Qualification |
| SDS | System Design Specification |
| SOP | Standard Operating Procedure |
| URS | User Requirements Specification |
| FRS | Functional Requirements Specification |
|  |  |
|  |  |

# Test Preparation

## Test Environment

Describe the technical environment(s) within which the tests were executed. For example, a Development environment might have been used for coding and unit testing, and another environment for execution of the Validation Protocols.

Describe the data that was used in each testing environment. For example, you might have populated the validation testing environment with a copy of production data.

Example Text: Testing was conducted on the Validation System. This environment was established using approved system architecture design documentation, as well as approved Installation Qualification (IQ) documentation for all hardware and software components. A copy of production data was loaded into the Validation System to provide data for validation testing.

## Test Resources

Identify the human resources that were used to execute the validation tests. For example, the testers might have been from the organization that would eventually use the validated system or from the IT organization.

Describe any training that was provided to the testers. For example, testers might need to be trained in documentation procedures prior to requirements verification.

Example Text: The testing team consisted of 2 testers and 2 verifiers from the Laboratory Department. All testers and verifiers were trained in the testing process before they were permitted to execute or verify tests. The scope of the tester training included:

* A brief overview of the system provided by the software vendor
* 2 hours of hands-on system practice using the system
* Instruction on the validation testing process SOP
* Instruction on the Good Documentation Practices SOP

# Test Execution

## Test Protocol Preparation

Describe the process for preparing the validation protocols for execution.

Example Text: The validation test protocols from the previous version of the system were reviewed and revised as needed to align with the functionality of the new version of the system. Protocols were approved by Quality Assurance, the IT Director, and the Head of Laboratory Operations prior to execution of the tests.

## Test Approach

Describe the approach to test structure as well as documentation and verification practices.

Example Text: Validation testing consisted of executing test protocols that were pre-approved per the approval matrix in the Validation Plan. The tests were organized into four main categories:

* Hardware IQ Tests
* Software IQ Tests
* OQ Tests
* PQ Tests

The testers executed the test steps as documented in test protocols. When the actual results matched the expected results the step was passed. When the actual results did not match, the testers were instructed to notify the test administrator. The test administrator then classified the error, per the approved Validation Plan, and made a decision as to whether the test should be stopped or continued. For each completed test protocol, the tester provided:

* Test Result (Pass/Fail) for each step
* Initial & date for each step
* Signature & date for the test protocol

The test administrator reviewed the executed test protocols per the guidance in the approved Validation Plan, then on the final page of the protocol, documented the protocol's status (Pass/Fail) and signed and dated.

## Test Execution Results

Describe the results of the validation testing and list the protocols.

Example Text: The following tables define in detail the validation test protocols and test results. An incident reports was created for each failing test. All test protocols that were given an initial FAIL status were re-executed. The re-executed protocol line item follows the original failed line item.

### Hardware IQ Tests

**Protocols**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Protocol ID** | **Title** | **Date Executed** | **Incident Reports** | **Protocol Status** |
|  |  |  |  |  |
|  |  |  |  |  |

**Validation Incidents Reports**

|  |  |  |  |
| --- | --- | --- | --- |
| **Incident Report ID** | **Failure Date** | **Resolution Date** | **Status** |
|  |  |  |  |
|  |  |  |  |

### Software IQ Tests

**Protocols**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Protocol ID** | **Title** | **Date Executed** | **Incident Reports** | **Protocol Status** |
|  |  |  |  |  |
|  |  |  |  |  |

**Validation Incidents Reports**

|  |  |  |  |
| --- | --- | --- | --- |
| **Incident Report ID** | **Failure Date** | **Resolution Date** | **Status** |
|  |  |  |  |
|  |  |  |  |

### OQ Tests

**Protocols**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Protocol ID** | **Title** | **Date Executed** | **Incident Reports** | **Protocol Status** |
|  |  |  |  |  |
|  |  |  |  |  |

**Validation Incidents Reports**

|  |  |  |  |
| --- | --- | --- | --- |
| **Incident Report ID** | **Failure Date** | **Resolution Date** | **Status** |
|  |  |  |  |
|  |  |  |  |

### PQ Tests

**Protocols**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Protocol ID** | **Title** | **Date Executed** | **Incident Reports** | **Protocol Status** |
| PQ-001 | Lab Trainee Set Up | 01-JUN-2011 | None | PASS |
| PQ-002 | Training Curriculum Creation | 02-JUN-2011 | VIR-PQ-002-01 | FAIL |
| PQ-002 | Training Curriculum Creation | 04-JUN-2011 | None | PASS |
| PQ-003 | Training Notification | 04-JUN-2011 | None | PASS |

**Validation Incidents Reports**

|  |  |  |  |
| --- | --- | --- | --- |
| **Incident Report ID** | **Failure Date** | **Resolution Date** | **Status** |
| VIR-PQ-002-01 | 02-JUN-2011 | 04-JUN-2011 | Resolved |
|  |  |  |  |

# Test Metrics

Provide summary metrics and statistics of the test results. Examples are provided below.

## Hardware IQ Metrics

**Protocol Execution**

|  |  |  |  |
| --- | --- | --- | --- |
| **Executed** | **Passed** | **Failed** | **Re-executed** |
| 2 | 2 | 0 | 0 |

**Incident Report Status**

|  |  |  |
| --- | --- | --- |
| **Incident Reports** | **Resolved** | **Not Resolved** |
| 0 | 0 | 0 |

**Unresolved Incident Severity**

|  |  |  |
| --- | --- | --- |
| **Minor** | **Moderate** | **Major** |
| 0 | 0 | 0 |

**Incident Type**

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol Error** | **Execution Error** | **Defect** | **Requirement Error** |
| 0 | 0 | 0 | 0 |

## Software IQ Metrics

**Protocol Execution**

|  |  |  |  |
| --- | --- | --- | --- |
| **Executed** | **Passed** | **Failed** | **Re-executed** |
| 3 | 2 | 1 | 1 |

**Incident Report Status**

|  |  |  |
| --- | --- | --- |
| **Incident Reports** | **Resolved** | **Not Resolved** |
| 1 | 1 | 0 |

**Unresolved Incident Severity**

|  |  |  |
| --- | --- | --- |
| **Minor** | **Moderate** | **Major** |
| 0 | 0 | 0 |

**Incident Type**

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol Error** | **Execution Error** | **Defect** | **Requirement Error** |
| 0 | 1 | 0 | 0 |

## OQ Metrics

**Protocol Execution**

|  |  |  |  |
| --- | --- | --- | --- |
| **Executed** | **Passed** | **Failed** | **Re-executed** |
| 18 | 15 | 3 | 3 |

**Incident Report Status**

|  |  |  |
| --- | --- | --- |
| **Incident Reports** | **Resolved** | **Not Resolved** |
| 3 | 2 | 1 |

**Unresolved Incident Severity**

|  |  |  |
| --- | --- | --- |
| **Minor** | **Moderate** | **Major** |
| 0 | 1 | 0 |

**Incident Type**

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol Error** | **Execution Error** | **Defect** | **Requirement Error** |
| 1 | 1 | 0 | 1 |

## PQ Metrics

**Protocol Execution**

|  |  |  |  |
| --- | --- | --- | --- |
| **Executed** | **Passed** | **Failed** | **Re-executed** |
| 12 | 12 | 0 | 0 |

**Incident Report Status**

|  |  |  |
| --- | --- | --- |
| **Incident Reports** | **Resolved** | **Not Resolved** |
| 0 | 0 | 0 |

**Unresolved Incident Severity**

|  |  |  |
| --- | --- | --- |
| **Minor** | **Moderate** | **Major** |
| 0 | 0 | 0 |

**Incident Type**

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol Error** | **Execution Error** | **Defect** | **Requirement Error** |
| 0 | 0 | 0 | 0 |

# Testing Summary

Provide a brief summary of the validation testing effort.

Example Text: The testing team has completed the testing of all system modules. Testing was conducted and documented as required by company SOPs and the system Validation Plan. Issues identified during the testing have been disposed as documented on each test protocol and in the validation incident reports.

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Document Version Number** | **Document Revision Date** | **Revisions Made By:** | **Revision Summary**  *(Reference section[s] changed)* |
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# Approvals

Signature(s) below indicate agreement with the contents of this Testing Summary as an accurate representation of testing preparation, execution, and results.

|  |  |  |  |
| --- | --- | --- | --- |
| Document Prepared by: | | | |
| Function | Name | Signature | Date |
|  |  |  |  |

Signatures below additionally signify approval of this Testing Summary.

| Document Approvals: | | | |
| --- | --- | --- | --- |
| Function | Name | Signature | Date |
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