Clinical Pipeline Database  
and Clinical Dashboard v2.0

**Validation Summary Report**

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# PURPOSE

**This Validation Summary Report** provides an overview of the results of the Clinical Pipeline Database/Dashboard v2.0 validation. The information in this report was obtained from the test results produced during Performance Qualification testing. The purpose of the validation procedure was to ensure the Clinical Pipeline Database/Dashboard v2.0 meets the defined User Requirement Specifications and is an appropriate system to be used for Clinical Use.

# SYSTEM DESCRIPTION

The Clinical Pipeline database is a system that stores sequencing results, quality control data, and annotation information for the reporting of variants in any samples processed via the clinical pipeline. The Clinical Dashboard is a system that allows users to perform quality control checks, variant annotation, and report generation for clinical specimens.

# VALIDATION APPROACH

The validation model at Mount Sinai Genetic Testing Lab-Connecticut for version 2.0 of the Clinical Pipeline Database/Dashboard v2.0 system includes User Requirement Specifications and Performance Qualification (PQ). User representatives approved changes to the User Requirement Specifications and received a demonstration of the changes in a test environment prior to approval. PQ protocol was developed based on the URS changes. The Subject Matter Experts then ran the PQ protocol in the test environment. After all users are trained in the relevant changes for their work, the change will be released to production. Any change to the system will follow a documented change control procedure and before the system is retired all quality and compliance relevant records generated on the system shall be successfully migrated to the new system.

# PERFORMANCE QUALIFICATION (PQ)

The Performance Qualification testing was designed to assure that the system performs as configured at Mount Sinai Genetic Testing Lab-Connecticut. The test plan simulates user workflow in the user environment and intended use of the system. Any failures were reported in a Validation Error Report and Resolution form(s). All tests were successfully completed, confirming the Clinical Pipeline Database/Dashboard v2.0 is in conformance with Mount Sinai Genetic Testing Lab-Connecticut requirements.

# VALIDATION DELIVERABLES

|  |  |  |
| --- | --- | --- |
| Document Type | Version & Creation Date | Prepared by |
| Validation Project Plan | Version 1.0  07OCT2016 | Yirong Wang |
| TRS | Version 1.0  07OCT2106 | Yirong Wang |
| URS | Version 1  07OCT2016 | Yirong Wang |
| PQ Protocol | Version 1  07OCT2016 | Yirong Wang |
| Validation Summary Report | Version 1  17OCT2016 | Yirong Wang |

# CLINICAL PIPELINE DATABASE/DASHBOARD v2.0 SYSTEM PQ TRACEABILITY MATRIX

|  |  |  |  |
| --- | --- | --- | --- |
| **URS Changes** | **Name** | **# Linked Cases** | **Test Cases** |
| **QI-001** | Fluidigm results shall be uploaded to the QCAR database on a per chip basis | 1 | TC-1.7 |
| **QI-002** | NGS sequencing data for each sample shall be processed resulting in a final VCF file | 1 | TC-2.6 |
| **QI-003** | NGS sequencing quality matrix data shall be uploaded to the QCAR database | 1 | TC-2.10 |
| **QI-004** | Sample level QC (sequence QC, Identity QC) and plate level QC (Control QC) shall be performed for all NGS sequencing data after all related data are available in the QCAR database | 4 | TC-2.14-17 |
| **CD-001** | All sequencing samples need to pass sequencing QC, control run QC and identity QC using pre-set QC matrix and manual check prior to the Variant QC step | 1 | TC-3.5 |
| **CD-002** | Any sample failing any step of QC could be sent back to a re-queue list which can be entered into LIMS for re-sequencing in the lab | 2 | TC-3.4, TC-4.6 |
| **CD-003** | Clinical Directors can withdraw samples during Sample QC and Variant QC steps for quality or other reasons | 1 | TC-5.4 |
| **CD-004** | Any samples that pass sequencing QC, control QC and identity QC shall be subject to variant QC during which time, each variant shall be checked for quality which sets a status for the sample to move into variant annotation | 3 | TC-6.5,6,8 |
| **CD-005** | Any variants identified by the Clinical Director requiring confirmation by Sanger technology shall be queued in a list where the confirmation results can later be uploaded to the Clinical Dashboard for evaluation | 3 | TC-7.3,6,9 |
| **CD-006** | Any variants identified by the Clinical Director requiring confirmation by qPCR technology shall be queued in a list where the confirmation results can later be uploaded to the Clinical Dashboard for evaluation | 3 | TC-6.9, TC-8.6,9 |
| **CD-007** | Any clinical patient samples shall have their variants annotated using the combined sources of commercial databases (e.g., iCMDB) and any other public database and information sources that the Clinical Director deems necessary | 2 | TC-9.7-8 |
| **CD-008** | Any annotated samples can be configured to report any or all of the annotated variants | 2 | TC-9.8, TC-10.3 |
| **CD-009** | The Clinical Director can digitally sign the final report | 1 | TC-10.6 |
| **CD-010** | Administrator of the system can assign users to different roles: | 2 | TC-11.3,7 |

CLINICAL PIPELINE DATABASE/DASHBOARD v2.0 SYSTEM PQ VALIDATION RESULTS

|  |  |  |  |
| --- | --- | --- | --- |
| Test Case # | Overall Results (P/F) | Notes (Please describe any incidents of failed tests) | Resolution Report # Opened as a Result of Failed Test |
| TC-1 | P |  |  |
| TC-2 | P |  |  |
| TC-3 | P |  |  |
| TC-4 | P |  |  |
| TC-5 | P |  |  |
| TC-6 | P |  |  |
| TC-7 | P |  |  |
| TC-8 | P |  |  |
| TC-9 | P |  |  |
| TC-10 | P |  |  |
| TC-11 | P |  |  |

# Conclusion

Each error is associated with a priority for resolution as follows:

|  |  |
| --- | --- |
| Priorities |  |
|  | Definition |
| High | The issue poses a significant risk to patient reporting outcomes. |
| Medium | The issue poses a low risk to patient reporting outcomes. |
| Low | There is no risk to patient reporting outcomes (such as a cosmetic change). |

There were no reported errors.

The Clinical Pipeline Database/Dashboard v2.0 software has met the acceptance criteria.

# APPROVAL

All tasks have been performed as defined in the Validation Project Plan. All errors have been addressed and documented in the Validation Testing Error Report and Resolution form(s). The validation of the Clinical Pipeline Database/Dashboard v2.0 System has been completed according to the documented procedures and this software is approved for use in clinical pipeline operations.

|  |  |
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| Summary Report Signatures: | |
| Approver  Quality Reviewer  Clinical Lab Director | I indicate that I approve this Validation Report for the Clinical Pipeline Database/Dashboard v2.0 System and find it meets all applicable business requirements and that it reflects the procedure described. I approve it for use.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have reviewed this Validation Report for the Clinical Pipeline Database/Dashboard v2.0 System and find it meets all applicable quality requirements and company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I indicate that I have reviewed this Validation Report for Clinical Pipeline Database/Dashboard v2.0 and find that it meets all applicable clinical requirements and company standards.  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

VERSION HISTORY:

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| --- | --- | --- | --- |
| Date | Version | Description of Document Updates | Author |
| 21-OCT-16 | 01 | Initial Version | Yirong Wang |