iSeq™ 100 Sequencing System

Performance Qualification

|  |  |
| --- | --- |
| Customer/Institution Name | Type here. |
| iSeq 100 System Serial Number | Type here. |
| Date of Service | Click or tap to enter a date. |

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# Introduction

The iSeq 100 Performance Qualification (PQ) protocol describes the process to verify the successful performance of the iSeq 100 System. Successful completion of this protocol confirms that the iSeq 100 System is operating in accordance with Illumina specifications.

Complete this PQ protocol after any major repair that can impact instrument performance. Such events can include service maintenance or part replacement.

Illumina service specialists can perform the iSeq 100 PQ and provide a certified version of this document. For more information, refer to the Products section of the Illumina website.

When Illumina service personnel complete the PQ Service, they use this protocol for certification purposes. The Illumina Certification fields at the end of this document are for Illumina service personnel use only.

# Instructions

To execute this PQ, perform a 100% PhiX run as described in the “PhiX Troubleshooting Run” section of the *iSeq 100 Sequencing System Guide*, Document #1000000036024. The PhiX run serves as a control that can assess instrument performance.

Configure the run for a read length of 2 x 150 base pairs (bp). The read length refers to the length of each sequenced DNA fragment and whether it is sequenced from one end or both ends. A 2 x 150 bp run performs two reads (forward and reverse) of the 150 base pairs in each DNA fragment.

After the PhiX run completes, do the following:

1. Access the metrics for the PhiX run.

**NOTE:** Refer to “Appendix C Real Time Analysis” in the *iSeq 100 Sequencing System Guide*, Document #1000000036024, for instructions on accessing these metrics on the iSeq system.

1. Record these results in section 8 of the PQ Document.
2. Compare your results to the specifications listed in section 8 of the PQ Document.
3. Check the appropriate box in the “Result” column in section 9 of the PQ Document.

You can find the specifications for this run in the *iSeq 100 Sequencing System Spec Sheet*, Document #1000000036024. Note that the PhiX specifications for the PQ are based on cluster densities between 174 K/mm² and 200 K/mm².

# Roles and Responsibilities

If you request Illumina certification of the PQ service, the following roles and responsibilities apply:

1. The sole purpose of this Performance Qualification Service (“**PQ Service**”) and this Performance Qualification Document (“**PQ Document**”) is to verify and certify that the system referenced by the serial number listed on the cover page (“**System**”) is operating in accordance with Illumina specifications. This PQ Service and PQ Document are not to be used, or relied upon, by you or a third party for any other purpose.
2. The PQ Document and Illumina’s certification that the PQ Service has been completed does not guarantee the performance of the System or constitute any warranty with respect to the System.
3. Illumina’s terms and conditions of sale provided to you when you acquired the System solely govern any applicable performance guarantees and warranties for the System (“**Illumina Warranties**”).
4. You irrevocably accept the System; provided that, Illumina’s obligations to you under the Illumina Warranties shall survive acceptance.
5. Only an Illumina certified copy of this PQ Document is valid. Certified copies of this PQ Document can be obtained exclusively from Illumina and you may incur additional charges for this. Copies from other sources and electronic copies are invalid.
6. You have read the PQ Document in its entirety, have been given the opportunity to ask questions, and understand this PQ Document including these terms and conditions and the Legal Notices.
7. Once the PQ Service is initiated, you are responsible for the entire cost of the PQ Service even if you cancel the PQ Service or stop Illumina from performing it.
8. You certify, represent, and warrant that you have read and understand the Illumina Site Preparation Guide for the System (“**ISPG**”).
9. The System may not perform properly if the requirements set forth in the ISPG are not strictly followed.
10. The physical location where the System is/has been installed meets the physical space requirements set forth in the ISPG.
11. The site meets the environmental considerations set forth in the ISPG including those concerning temperature, humidity, altitude, and ventilation.
12. The electrical requirements for the System set forth in the ISPG have been met and will be maintained.
13. Illumina recommends running the System off an Uninterruptible Power Supply (UPS).
14. The site meets the network requirements for the System set forth in the ISPG.
15. You consent to the performance of the PQ Service.

# Contact and Instrument Location Information

Customer/Institution Information

|  |  |
| --- | --- |
| Customer/Institution Name | Type here. |
| Contact Name | Type here. |
| Address | Type here. |
| Telephone | Type here. |
| Email | Type here. |

Instrument Location

|  |  |
| --- | --- |
| City | Type here. |
| Building | Type here. |
| Floor and Room | Type here. |

Illumina Personnel Information (for Illumina personnel only)

|  |  |
| --- | --- |
| Name | N/A |
| Title | N/A |
| Telephone | N/A |
| Email | N/A |

# Performance Qualification Protocol

|  |  |
| --- | --- |
| IQ Segments | Description |
| Software Identification | Verifies the software installed on the instrument. |
| Record Lot Number | Record the lot numbers and expiration dates of the consumables used to perform the PhiX run. |
| PhiX Run Data | Verifies that the instrument meets Illumina PhiX run specifications. |
| Summary Performance Qualification Result | Verifies that the instrument meets all Illumina specifications. |

# Software Identification

Record the software version number in the field below.

|  |  |
| --- | --- |
| Software | Version |
| iSeq 100 Control Software (in the menu at the top left, select About) | Type here. |

# Record Lot Numbers

| Reagent Kit | Consumable | Part Number\* | Lot Number | Expiration Date |
| --- | --- | --- | --- | --- |
| PhiX Control v3 | PhiX Control v3 | 15017397 | Type here. | Click here to enter a date. |
| HP3 (NaOH) | 11324596 | Type here. | Click here to enter a date. |
| Elution Buffer | 15025394 | Type here. | Click here to enter a date. |
| PW1 Finishing Reagent | 11298922 | Type here. | Click here to enter a date. |
| iSeq 100 i1 Reagent | iSeq 100 Flow Cell | 20009555 | Type here. | Click here to enter a date. |
| Assay, iSeq 100 Cartridge | 20009712 | Type here. | Click here to enter a date. |

\*Part Numbers are listed for Illumina service personnel reference.

# PhiX Run Data

## Projected Yield Total

| Reagent Kit | Specification | Yield Total (Gb) |
| --- | --- | --- |
| iSeq 100 i1 (2 x 150) | >= 1.2 Gb | Type here. |

## Data Quality

| Reagent Kit | Specification | % > Q30\* |
| --- | --- | --- |
| iSeq 100 i1 (2 x 150) | 80% > Q30 | Type here. |

\*A quality score (or Q-score) is a prediction of the probability of an error in base calling. Higher Q-scores indicate a smaller probability of error. A quality score of 30 represents an error rate of 1 in 1000, with a corresponding call accuracy of 99.9%.

# Summary Performance Qualification Result

|  |  |  |
| --- | --- | --- |
| Qualification Type | Specification | Result |
| Performance Qualification | Meets all specifications | Pass Fail |

| Comments (Enter N/A if no comments) |
| --- |
| Type here. | |

Illumina Certification

I certify that all information I have provided in this document is true and accurate. I certify that all tests I have performed were conducted in accordance with published Illumina procedures that apply to the instrument listed on this form.

|  |  |
| --- | --- |
| Illumina Personnel Signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Printed Name | Type here. |
| Printed Title | Type here. |
| Date | Click or tap to enter a date. |