GeneChip™ Scanner 3000 System

IQ AND OQ SERVICES PROTOCOL

for use with:

GeneChip™ Scanner 3000

GeneChip™ AutoLoader

GeneChip™ Fluidics Station 450

GeneChip™ Hybridization Oven 645i

Select the service to be performed:

- ○ IQ and OQ Service
- ○ OQ Service

Protocol Execution Date:	
Scanner Serial Number:	
Organization / Lab Name:	
Lab Address:	
Contact Name:	
Contact Telephone Number:	
Contact E-mail:	

Pub. No. MAN0017103
Revision B.0

PART 1. General information

1.1. Definitions

1.1.1. **IQ**: Installation Qualification

1.1.2. **OQ**: Operation Qualification

1.1.3. **Customer:** The System Owner or a person designated by the System Owner to act on the System Owner's behalf to meet the requirements for this qualification service and to complete the approval sections.

1.1.4. **FSE**: A Thermo Fisher Scientific Field Service Engineer or an employee of a service provider authorized by Thermo Fisher Scientific.

1.2. Purpose

1.2.1. The IQ and OQ Services Protocol is designed to verify:

- The installation and operation of a newly manufactured or refurbished GeneChip™ Scanner 3000 System, which includes the GeneChip™ Scanner 3000 with GeneChip™ AutoLoader, up to four GeneChip™ Fluidics Station 450s, up to two GeneChip™ Hybridization Oven 645is, and workstation. Up to four GeneChip™ Fluidics Station 450s can be tested using this document, and up to four additional GeneChip™ Fluidics Station 450s can be tested using the *IQ and OQ Services Protocol Supplement for Additional GeneChip™ Fluidics Station 450 Qualification* (Pub. No. MAN0017107), for a total of eight GeneChip™ Fluidics Station 450s connected to a single workstation.
- The reinstallation and operation of a previously installed and previously qualified GeneChip™ Scanner 3000 System that has been relocated.
- The operation of a previously qualified GeneChip™ Scanner 3000 System that has subsequently undergone service, repair, preventative maintenance, or other maintenance that is critical to the performance of the GeneChip™ Scanner 3000 System.
- Additions or upgrades that may affect the instrument data results.

1.3. Scope

1.3.1. This IQ and OQ Services Protocol specifically applies to only the GeneChip™ Scanner 3000 System as configured and installed according to Thermo Fisher Scientific Acceptance Criteria. This IQ and OQ Services Protocol does not apply to any other products, processes, or optional components, unless specifically stated in this document.

1.3.2. This IQ and OQ Services Protocol does not address any Customer-specific analytical protocol, performance qualification, or method verification.

1.3.3. The execution of this IQ and OQ Services Protocol results in an IQ and OQ Services Protocol documentation package that includes completed verification tests and identified attachments.

1.3.4. Execution of this IQ and OQ Services Protocol verifies that, at the time of testing, the GeneChip™ Scanner 3000 System is installed and operational in accordance with Thermo Fisher Scientific Acceptance Criteria set forth in this IQ and OQ Services Protocol.

1.4. Customer responsibilities

1.4.1. The Customer is responsible for:

- Meeting the environmental requirements as outlined in the *GeneChip™ System 3000 Site Preparation Guide* (Pub. No. MAN0029136).
- Reviewing the entries made by the FSE and accepting these entries by signing under "Reviewed by" at the end of each section. This signifies Customer agreement with the entries made.
- Resolving exceptions arising from events outside of Thermo Fisher Scientific's control, such as misplaced user documentation or inability to comply with instrument site requirements.
- Completing the IQ and OQ Services Protocol final approval signatures according to the procedures of the Customer's organization.

1.4.2. If a new or refurbished GeneChip™ Scanner 3000 System in the process of installation does not meet the Acceptance Criteria or other requirements in this IQ and OQ Services Protocol, Thermo Fisher Scientific will be responsible for effecting repair of the GeneChip™ Scanner 3000 System to verify that operational specifications are met. If Thermo Fisher Scientific's execution of this IQ and OQ Services Protocol is interrupted by a GeneChip™ Scanner 3000 System or power failure due to power loss or disruption, Thermo Fisher Scientific may, at its option, terminate the execution of this IQ and OQ Services Protocol, and the Customer will be responsible for purchasing a new IQ and OQ Services Protocol for such GeneChip™ Scanner 3000 System. No refunds will be granted. Any damage to the GeneChip™ Scanner 3000 System caused by such power disruption will be repaired at the Customer's expense.

1.4.3. If a previously installed GeneChip™ Scanner 3000 System does not meet the Acceptance Criteria, the Customer is responsible for repairing the GeneChip™ Scanner 3000 System, or having it repaired, at the Customer's expense, except to the extent that the GeneChip™ Scanner 3000 System and the required repairs are covered by a Thermo Fisher Scientific warranty or service contract. If the execution of this IQ and OQ Services Protocol is interrupted by failure to meet such Acceptance Criteria, Thermo Fisher Scientific may, at its option, terminate the execution of this IQ and OQ Services Protocol, and the Customer will be responsible for purchasing a new IQ and OQ Services Protocol for such GeneChip™ Scanner 3000 System. No refunds will be granted.

1.4.4. The Customer is responsible for ensuring that the content and execution of this IQ and OQ Services Protocol are adequate to meet the Customer's quality, regulatory, and certification requirements.

1.4.5. If the Customer relocates the GeneChip™ Scanner 3000 System, the Customer is responsible for contacting Thermo Fisher Scientific to schedule the execution of an IQ and OQ Services Protocol, and is responsible for the cost of executing the IQ and OQ Services Protocol for the relocated GeneChip™ Scanner 3000 System.

1.4.6. The Customer may obtain certificates of analysis for qualification service reagents from **thermofisher.com**.

1.5. FSE responsibilities

1.5.1. The FSE is responsible for:

- Recording all findings and test results completely, reviewing all results with the Customer, and obtaining the Customer's approval signature at the end of each completed verification section.
- Verifying that the results were within specifications described or that Exceptions were recorded in an Exception Report and included with this completed IQ and OQ Services Protocol. If Exceptions were recorded, cross-referencing all Exception Reports in Section 5.1. Exception report cross-reference.
- Recording all supporting documentation attachments in Section 6.1. Attachment cross-reference.
- Obtaining the Customer's final approval signature in Section 4.3.2. System Owner or designee final approval when the IQ and OQ Services Protocol is complete.
- If applicable, obtaining any additional signer final approval signatures in Section 4.3.3. (Optional) Additional signer(s) when the IQ and OQ Services Protocol is complete.
- Signing, initialing, and dating in Section 4.3.1. FSE final approval when the IQ and OQ Services Protocol is complete.
- Providing the completed, signed, and locked IQ and OQ Services Protocol, any exception reports, and all supporting documentation to the Customer.

1.5.2. In the event of any discrepancies between the specified equipment parameters and those found on site, then the FSE is responsible for identifying them as Exceptions or Failures.

- Discrepancies identified as Exceptions are explained in an Exception Report that is included with this completed IQ and OQ Services Protocol, and all included Exception Reports are cross-referenced in Section N/A. Exception report cross-reference.
- Discrepancies identified as Failures are documented in the Optional Comments section at the end of the verification section where the discrepancy occurred. The FSE then proceeds directly to the IQ and OQ Services Protocol Completion page to complete the final pages of the IQ and OQ Services Protocol.

1.5.3. In the event that this protocol cannot be completed electronically, then the FSE is responsible for:

- Printing this document and completing this IQ and OQ Services Protocol as described above in clear handwriting and ink. The FSE may also complete all portions of the IQ and OQ Services Protocol except for the electronic signatures, then print the document to complete the signature fields by hand.
- Obtaining the Customer's final approval signature in Section 4.3.2. System Owner or designee final approval when the IQ and OQ Services Protocol is complete.
- If applicable, obtaining any additional signer final approval signatures in Section 4.3.3. (Optional) Additional signer(s) when the IQ and OQ Services Protocol is complete.
- Signing, initialing, and dating in Section 4.3.1. FSE final approval when the IQ and OQ Services Protocol is complete.
- Providing the completed, signed IQ and OQ Services Protocol with any exception reports and all supporting documentation to the Customer.

1.6. Reporting data

1.6.1. The completed qualification service documentation will consist of this IQ and OQ Services Protocol, signed by the appropriate persons, with appended documents as listed in the data sheet sections.

1.7. Product use

1.7.1. Customers should refer to the (Pub. No.) for this information.

PART 2. Pre-execution verification

2.1. Pre-execution verification procedure

2.1.1. For any service type selected to be performed on page 1:

- All sections in **Part 1. General information** have been read.
- Perform each test in the sections below.

2.2. Field service order verification

Test No.	2.2.1.
Test Procedure	Verify that the Field Service Order for this qualification service has been created and the service order number has been recorded. The Field Service Order number allows Thermo Fisher Scientific to access records for this completed qualification service.
Acceptance Criteria	The Field Service Order is created and recorded.
Actual Results	Field Service Order number:
	○ Pass ○ Fail ○ Exception
Optional Comments	If there are no comments, enter "Not applicable" below.

2.3. Service identification

Test No.	2.3.1.
Test Procedure	Identify the qualification service being performed and the reason for the qualification service.
Acceptance Criteria	The qualification service and the reason for its execution is identified.
Actual Results	○ IQ and OQ Service ○ OQ Service

IQ and OQ Service

Component	Event
☐ GeneChip™ Scanner 3000 ☐ GeneChip™ AutoLoader ☐ GeneChip™ Fluidics Station 450 ☐ GeneChip™ Hybridization Oven 645i	○ New installation ○ Reinstallation/Move ○ Replacement ○ Workstation replacement/ upgrade ○ Not applicable

OQ Service

Component	Event
Complete GeneChip™ Scanner 3000 System	○ Post PM service ○ Annual requalification ○ Software/firmware update/upgrade ○ Not applicable
GeneChip™ Scanner 3000 component(s): ☐ Power supply ☐ Laser module ☐ Win Sys/CCT boards ☐ Chip transport assy ☐ Optics assy	○ Repair/Replacement ○ Realignment ○ Not applicable
GeneChip™ AutoLoader component(s): ☐ Carousel assy ☐ Cooler assy ☐ Insulated disk ☐ Feeder assy ☐ Warmer assy ☐ Controller PCB	○ Repair/Replacement ○ Realignment ○ Not applicable
GeneChip™ Fluidics Station 450 component(s): ☐ Power supply ☐ Sensors ☐ Fluidics module ☐ Pump assy ☐ Valves ☐ Peristaltic tubing ☐ Wash block assy	○ Repair/Replacement ○ Not applicable
GeneChip™ Hybridization Oven 645i component(s): ☐ Power supply ☐ Heater assy ☐ Circulating fan ☐ Carousel assy ☐ CCT boards ☐ Door gasket ☐ Grabber catch/keeper	○ Repair/Replacement ○ Recalibration ○ Not applicable

If the reason for this qualification service is not listed in either section above, enter the information in the blank fields below. Otherwise, enter "Not applicable."

2.3. Service identification *[continued]*

Test No.	2.3.2.
Test Procedure	Identify if the Customer purchased any optional add-on services to test one or more additional GeneChip™ Fluidics Station 450(s) connected to this workstation to follow this qualification service.
Acceptance Criteria	The add-on services status is recorded. If the Customer purchased any optional add-on services to test one or more additional GeneChip™ Fluidics Station 450(s) connected to this workstation, then the add-on service order number(s) are recorded. If the Customer did not purchase any optional add-on services, then select "Not applicable" in the Actual Results section below.
Actual Results	If optional instrument add-on services were purchased to follow this qualification service, record the service order number(s): Additional instrument: — Service order number: ☐ First GeneChip™ Fluidics Station 450 ☐ Second GeneChip™ Fluidics Station 450 ☐ Third GeneChip™ Fluidics Station 450 ☐ Fourth GeneChip™ Fluidics Station 450 Complete the protocol supplement for each additional GeneChip™ Fluidics Station 450 to be tested following the completion of this IQ and OQ Services Protocol: • *IQ and OQ Services Protocol Supplement for Additional GeneChip™ Fluidics Station 450 Qualification* (Pub. No. MAN0017107)
	○ Pass ○ Fail ○ Exception ○ Not applicable *Include each completed protocol supplement with this completed IQ and OQ Services Protocol.*
Optional Comments	If there are no comments, enter "Not applicable" below.

2.4. FSE training verification

Test No.	2.4.1.
Test Procedure	Verify that the FSE is certified by Thermo Fisher Scientific to perform this qualification service on the GeneChip™ Scanner 3000 System.
Acceptance Criteria	The FSE is identified and has been certified by Thermo Fisher Scientific to perform this qualification service on the GeneChip™ Scanner 3000 System.
Actual Results	FSE Name: FSE initials: FSE Employee Number: ○ Pass ○ Fail ○ Exception *Include a copy of the GeneChip™ Scanner 3000 System training certificate and the Global Compliance Services Overview and Affymetrix Qualification Protocol Training certificate with this completed IQ and OQ Services Protocol.*
Optional Comments	If there are no comments, enter "Not applicable" below.

2.5. Site requirements verification

Test No.	2.5.1.
Test Procedure	Verify that the Customer represents that they have read the environmental and electrical site requirements listed in the *GeneChip™ System 3000 Site Preparation Guide* (Pub. No. MAN0029136) and can comply with the site requirements.
Acceptance Criteria	The Customer represents that they have read the environmental and electrical site requirements listed in the *GeneChip™ System 3000 Site Preparation Guide* (Pub. No. MAN0029136) and can comply with the site requirements.
Actual Results	If “OQ Service” is selected for the service to be performed on page 1, enter "Not applicable" in both fields below. The Customer has read the environmental and electrical site requirements and can comply with the site requirements. Customer name: _____ Title/Role: _____
	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	2.5.2.
Test Procedure	Verify that the user reference documents are available on site.
Acceptance Criteria	The user documents for the GeneChip™ Scanner 3000 System are available on site, as specified in the *GeneChip™ Scanner 3000 System Software Compatibility and User Documents Reference* (Pub. No. MAN0017185).
Actual Results	Pub. No. MAN0017185 document revision letter: _____
	○ Pass ○ Fail ○ Exception *Include a copy of the GeneChip™ Scanner 3000 System Software Compatibility and User Documents Reference with this completed IQ and OQ Services Protocol.*

2.5. Site requirements verification *[continued]*

Test No.	2.5.3.
Test Procedure	Verify that the digital volt meter used to check the power receptacle voltage is identified and the calibration is valid. Use the calibrated digital volt meter to verify that the installation site meets the electrical requirements.
Acceptance Criteria	The tool is identified and the calibration is valid. **Note:** The calibration expiration date is 12 months from the calibration date recorded on the calibration certificate.
Actual Results	**Note:** Record the serial number located on the digital volt meter, not the serial number of the calibration certificate. Digital volt meter serial number: Digital volt meter calibration date: Digital volt meter calibration expiration date: ○ Pass ○ Fail ○ Exception *Include a copy of the digital volt meter calibration certificate with this completed IQ and OQ Services Protocol.*
Acceptance Criteria	The voltage that is measured at the power receptacle designated to supply power to the instrument meets the electrical requirements listed in the *GeneChip™ System 3000 Site Preparation Guide* (Pub. No. MAN0029136).
Actual Results	The voltage measured is ±10% of the nominal local voltage. Voltage reading: Nominal local voltage: ○ Pass ○ Fail ○ Exception
Optional Comments	If there are no comments, enter "Not applicable" below.

2.6. System identification

Test No.	2.6.1.
Test Procedure	Record the GeneChip™ Scanner 3000 information.
Acceptance Criteria	The GeneChip™ Scanner 3000 information is recorded.
Actual Results	Instrument part number: Instrument serial number:
	○ Pass ○ Fail ○ Exception

Test No.	2.6.2.
Test Procedure	Record the optional GeneChip™ AutoLoader information. If the Customer does not have the GeneChip™ AutoLoader, enter and select "Not applicable" in the Actual Results section.
Acceptance Criteria	The GeneChip™ AutoLoader information is recorded.
Actual Results	Instrument part number: Instrument serial number:
	○ Pass ○ Fail ○ Exception ○ Not applicable

2.6. System identification *[continued]*

Test No.	2.6.3.
Test Procedure	**IMPORTANT!** Up to eight GeneChip™ Fluidics Station 450s can be connected to a single workstation, and up to four can be tested using this document. Identify the GeneChip™ Fluidics Station 450s to be tested in Tests 2.6.3 - 2.6.6, and use this document to verify the GeneChip™ Fluidics Station 450s identified in these tests. If the Customer has more than four GeneChip™ Fluidics Station 450s connected to this workstation, use the *IQ and OQ Services Protocol Supplement for Additional GeneChip™ Fluidics Station 450 Qualification* (Pub. No. MAN0017107) to document and test the remaining instruments. Record the information for the first GeneChip™ Fluidics Station 450 to be tested.
Acceptance Criteria	The information for the first GeneChip™ Fluidics Station 450 to be tested is recorded.
Actual Results	Instrument part number: _____ Instrument serial number: _____ Fluidics module 1 serial number: _____ Fluidics module 2 serial number: _____ Fluidics module 3 serial number: _____ Fluidics module 4 serial number: _____ ○ Pass ○ Fail ○ Exception

Test No.	2.6.4.
Test Procedure	If applicable, record the information for the second GeneChip™ Fluidics Station 450 to be tested. If the Customer does not have a second GeneChip™ Fluidics Station 450, enter and select "Not applicable" in the Actual Results section.
Acceptance Criteria	If applicable, the information for the second GeneChip™ Fluidics Station 450 to be tested is recorded.
Actual Results	Instrument part number: _____ Instrument serial number: _____ Fluidics module 1 serial number: _____ Fluidics module 2 serial number: _____ Fluidics module 3 serial number: _____ Fluidics module 4 serial number: _____ ○ Pass ○ Fail ○ Exception ○ Not applicable

2.6. System identification *[continued]*

Test No.	2.6.5.
Test Procedure	If applicable, record the information for the third GeneChip™ Fluidics Station 450 to be tested. If the Customer does not have a third GeneChip™ Fluidics Station 450, enter and select "Not applicable" in the Actual Results section.
Acceptance Criteria	If applicable, the information for the third GeneChip™ Fluidics Station 450 to be tested is recorded.
Actual Results	Instrument part number: _____ Instrument serial number: _____ Fluidics module 1 serial number: _____ Fluidics module 2 serial number: _____ Fluidics module 3 serial number: _____ Fluidics module 4 serial number: _____ ○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	2.6.6.
Test Procedure	If applicable, record the information for the fourth GeneChip™ Fluidics Station 450 to be tested. If the Customer does not have a fourth GeneChip™ Fluidics Station 450, enter and select "Not applicable" in the Actual Results section.
Acceptance Criteria	If applicable, the information for the fourth GeneChip™ Fluidics Station 450 to be tested is recorded.
Actual Results	Instrument part number: _____ Instrument serial number: _____ Fluidics module 1 serial number: _____ Fluidics module 2 serial number: _____ Fluidics module 3 serial number: _____ Fluidics module 4 serial number: _____ ○ Pass ○ Fail ○ Exception ○ Not applicable

2.6. System identification *[continued]*

Test No.	2.6.7.
Test Procedure	**IMPORTANT!** Up to two GeneChip™ Hybridization Oven 645is can be used with a single system. Identify the GeneChip™ Hybridization Oven 645is to be tested in Tests 2.6.7 - 2.6.8, and use this document to verify the GeneChip™ Hybridization Oven 645is identified in these tests. Record the information for the first GeneChip™ Hybridization Oven 645i to be tested.
Acceptance Criteria	The information for the first GeneChip™ Hybridization Oven 645i to be tested is recorded.
Actual Results	Instrument part number: _____ Instrument serial number: _____ ○ Pass ○ Fail ○ Exception

Test No.	2.6.8.
Test Procedure	If applicable, record the information for the second GeneChip™ Hybridization Oven 645i to be tested. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, enter and select "Not applicable" in the Actual Results section.
Acceptance Criteria	If applicable, the information for the second GeneChip™ Hybridization Oven 645i to be tested is recorded.
Actual Results	Instrument part number: _____ Instrument serial number: _____ ○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	2.6.9.
Test Procedure	Verify that the workstation connected to the instrument is on site and is supplied by Thermo Fisher Scientific.
Acceptance Criteria	The workstation is on site and is supplied by Thermo Fisher Scientific, and the workstation information is recorded.
Actual Results	Thermo Fisher Scientific part number: _____ Model: _____ Manufacturer: _____ Service tag number: _____ ○ Pass ○ Fail ○ Exception

2.6. System identification *[continued]*

Test No.	2.6.10.
Test Procedure	Identify and record any additional equipment.
Acceptance Criteria	Any additional equipment is identified and recorded.
Actual Results	**Additional Equipment** *Uninterruptible power supply (UPS)* — Manufacturer: ____ Model: ____ Serial number: ____ ○ Yes ○ No *Pre-amp workstation* — Manufacturer: ____ Model: ____ Serial number: ____ ○ Yes ○ No *Post-amp workstation* — Manufacturer: ____ Model: ____ Serial number: ____ ○ Yes ○ No *Hand-held barcode reader* — Manufacturer: ____ Model: ____ Serial number: ____ ○ Yes ○ No ○ Pass ○ Fail ○ Exception
Optional Comments	If there are no comments, enter "Not applicable" below.

2.7. Maintenance verification

Test No.	2.7.1.
Test Procedure	Record whether the GeneChip™ Scanner 3000 System is covered by a warranty or service contract.
Acceptance Criteria	The GeneChip™ Scanner 3000 System warranty or service contract status is recorded. If the GeneChip™ Scanner 3000 System is not covered by either a warranty or a service contract, select "Not applicable" in the fields below.
Actual Results	The GeneChip™ Scanner 3000 System is covered by a warranty or service contract. ○ Yes ○ No Warranty or Service Contract expiration date, if applicable: ☐ Not applicable Warranty or Service Contract number, if applicable: ☐ Not applicable
Optional Comments	If there are no comments, enter "Not applicable" below.

2.8. Pre-execution verification completion

Test No.	2.8.1.
Test Procedure	Verify that all required pre-execution verification tests have been completed, and all exceptions have been recorded.
Acceptance Criteria	All required pre-execution verification tests have been completed, and all exceptions have been recorded.
Actual Results	All required pre-execution verification tests have been completed: ○ Yes ○ No
	All exceptions have been recorded on an exception report: ○ Yes ○ No ○ Not applicable
	FSE initials: Date:
	○ Pass ○ Fail The Customer must review the entries in the pre-execution verification tests and sign below to indicate acceptance. **Reviewed by:** Customer name: Title/Role: Signature: Date:
Optional Comments	If there are no comments, enter "Not applicable" below.

PART 3. Installation Qualification (IQ)

3.1. IQ execution procedure

3.1.1. If "IQ and OQ Service" is selected for the service to be performed on page 1:

- All sections in **Part 2. Pre-execution verification** have been successfully completed.
- Perform each test in the sections below.

3.1.2. If "OQ Service" is selected for the service to be performed on page 1:

- All sections in **Part 3. Installation Qualification (IQ)** are not applicable.
- **It is not necessary to mark all tests in Part 3. Installation Qualification (IQ) as not applicable.**

3.2. GeneChip™ Scanner 3000 System order verification

Test No.	3.2.1.
Test Procedure	*New GeneChip™ Scanner 3000 System installations only.* Verify that the product received matches the product ordered. If this is not a new installation, then select "Not applicable" below.
Acceptance Criteria	There is recorded evidence that the system on site is as ordered.
Actual Results	This IQ and OQ Service is for a: ○ New installation ○ Reinstallation of a previously installed and previously qualified system **System order reference** If this is not a new GeneChip™ Scanner 3000 System installation, then enter "Not applicable" in the fields below. Document title/type: Document number:
	○ Pass ○ Fail ○ Exception ○ Not applicable *Include supporting documentation with this completed IQ and OQ Services Protocol.*
Optional Comments	If there are no comments, enter "Not applicable" below.

3.3. Installation Qualification

Test No.	3.3.1.
Test Procedure	**Note:** If **Workstation replacement/upgrade** was selected as the reason for qualification in Test 2.3.1, choose "Not applicable" in the tests in this section that are not applicable to the computer workstation. Verify that the components of the GeneChip™ Scanner 3000 are unpacked and positioned appropriately, according to the instructions in the *GeneChip™ System 3000 Service Manual* MAN0026695.
Acceptance Criteria	The components of the GeneChip™ Scanner 3000 are unpacked and positioned appropriately.
Actual Results	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.2.
Test Procedure	Verify that the shipping restraints for the GeneChip™ Scanner 3000 have been removed, according to the instructions in the *GeneChip™ System 3000 Service Manual* MAN0026695.
Acceptance Criteria	The shipping restraints for the GeneChip™ Scanner 3000 have been removed.
Actual Results	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.3.
Test Procedure	Verify that all packing kit components for the GeneChip™ Scanner 3000 are available, according to the instructions in the *GeneChip™ System 3000 Service Manual* MAN0026695.
Acceptance Criteria	All packing kit components for the GeneChip™ Scanner 3000 are available.
Actual Results	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.4.
Test Procedure	Verify that the connections between the GeneChip™ Scanner 3000 and the workstation are correctly configured, according to the instructions in the *GeneChip™ System 3000 Service Manual* MAN0026695.
Acceptance Criteria	The connections between the GeneChip™ Scanner 3000 and the workstation are correctly configured.
Actual Results	○ Pass ○ Fail ○ Exception

Test No.	3.3.5.
Test Procedure	Verify that the components of each GeneChip™ Fluidics Station 450 are unpacked and positioned appropriately, according to the instructions in the *GeneChip™ Fluidics Station Service Manual*. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	The components of each GeneChip™ Fluidics Station 450 are unpacked and positioned appropriately.
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable ○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.6.
Test Procedure	Verify that the shipping restraints for each GeneChip™ Fluidics Station 450 have been removed, according to the instructions in the *GeneChip™ Fluidics Station Service Manual*. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	The shipping restraints for each GeneChip™ Fluidics Station 450 have been removed.
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable ○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.7.
Test Procedure	Verify that all packing kit components for each GeneChip™ Fluidics Station 450 are available, according to the instructions in the *GeneChip™ Fluidics Station Service Manual*. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	All packing kit components for each GeneChip™ Fluidics Station 450 are available.
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable ○ Pass ○ Fail ○ Exception ○ Not applicable

3.3. Installation Qualification *[continued]*

Test No.	3.3.8.
Test Procedure	Verify that the connections between each GeneChip™ Fluidics Station 450 and the workstation are correctly configured, according to the instructions in the *GeneChip™ Fluidics Station Service Manual*. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	The connections between each GeneChip™ Fluidics Station 450 and the workstation are correctly configured.
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

Test No.	3.3.9.
Test Procedure	Verify that each GeneChip™ Hybridization Oven 645i has been unpacked and set up appropriately according to the instructions in the *GeneChip™ Hybridization Oven Service Manual*. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	Each GeneChip™ Hybridization Oven 645i has been unpacked and set up appropriately.
Actual Results	First GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail Second GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.10.
Test Procedure	Verify that the shipping restraints for each GeneChip™ Hybridization Oven 645i have been removed, according to the instructions in the *GeneChip™ Hybridization Oven Service Manual*. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	The shipping restraints for each GeneChip™ Hybridization Oven 645i have been removed.
Actual Results	First GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail Second GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.11.
Test Procedure	Verify that all packing kit components for each GeneChip™ Hybridization Oven 645i are available, according to the *GeneChip™ Hybridization Oven Service Manual*. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	All packing kit components for each GeneChip™ Hybridization Oven 645i are available.
Actual Results	First GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail Second GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	3.3.12.
Test Procedure	Verify that the voltage selector on each GeneChip™ Hybridization Oven 645i is set correctly, and record the selected voltage. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	The voltage selector on each GeneChip™ Hybridization Oven 645i is set correctly, and the selected voltage is recorded.
Actual Results	Voltage setting: First GeneChip™ Hybridization Oven 645i: ○ 115V ○ 230V Second GeneChip™ Hybridization Oven 645i: ○ 115V ○ 230V ○ Not applicable
	○ Pass ○ Fail ○ Exception ○ Not applicable
Optional Comments	If there are no comments, enter "Not applicable" below.

3.4. Installation Qualification (IQ) completion

Test No.	3.4.1.
Test Procedure	Verify that all required IQ tests have been completed, and all exceptions have been recorded.
Acceptance Criteria	All required IQ tests have been completed, and all exceptions have been recorded.
Actual Results	All required IQ tests have been completed: ○ Yes ○ No
	All exceptions have been recorded on an exception report: ○ Yes ○ No ○ Not applicable
	FSE initials: Date:
	○ Pass ○ Fail The Customer must review the entries in the IQ tests and sign below to indicate acceptance. **Reviewed by:** Customer name: Title/Role: Signature: Date:
Optional Comments	If there are no comments, enter "Not applicable" below.

PART 4. Operation Qualification (OQ)

4.1. OQ execution procedure

4.1.1. If "IQ and OQ Service" is selected for the service to be performed on page 1:

- All sections in **Part 2. Pre-execution verification** have been successfully completed.
- All sections in **Part 3. Installation Qualification (IQ)** have been successfully completed.
- Perform each test in the sections below.

4.1.2. If "OQ Service" is selected for the service to be performed on page 1:

- All sections in **Part 2. Pre-execution verification** have been successfully completed.
- All sections in **Part 3. Installation Qualification (IQ)** are not applicable.
- **It is not necessary to mark all tests in Part 3. Installation Qualification (IQ) as not applicable.**
- Perform each test in the sections below.

4.2. Power on verification

Test No.	4.2.1.
Test Procedure	Power on the computer workstation to launch the GeneChip™ Command Console™ (GCC) Software, then verify that the self-test completes successfully.
Acceptance Criteria	When the GeneChip™ Command Console™ (GCC) Software is launched, the following occurs: **1.** A system self-test is performed to confirm the operational status of the system and ensure that all components are connected and operating correctly. **2.** Housekeeping tasks are performed to ensure that all test requests are in known states and can be processed. **3.** When the self-test is complete, the GCC User Logon window opens.
Actual Results	○ Pass ○ Fail ○ Exception

Test No.	4.2.2.	
Test Procedure	Power on each GeneChip™ Fluidics Station 450 and verify that they power on properly. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section.	
Acceptance Criteria	When each GeneChip™ Fluidics Station 450 is powered on, the LCD screen displays the following: • Power-on done • NOT PRIMED 25°C	
Actual Results	First GeneChip™ Fluidics Station 450:	○ Pass ○ Fail
	Second GeneChip™ Fluidics Station 450:	○ Pass ○ Fail ○ Not applicable
	Third GeneChip™ Fluidics Station 450:	○ Pass ○ Fail ○ Not applicable
	Fourth GeneChip™ Fluidics Station 450:	○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception	

Test No.	4.2.3.
Test Procedure	Power on the GeneChip™ Scanner 3000 and verify that it powers on properly.
Acceptance Criteria	When the GeneChip™ Scanner 3000 is powered on, the following occurs: **1.** During initial bootup, the embedded PC takes control and the blue scanner indicator light is illuminated. **2.** During scanner bootup, the embedded PC takes control of the scanner boot up and the green light, yellow light, and blue scanner indicator light are illuminated. **3.** While the laser warms up, the software is enabled and the yellow light and blue scanner indicator light are illuminated. **4.** When the system is ready for use, the scanner door is unlocked waiting to receive a carousel and the green light and blue scanner indicator light are illuminated.
Actual Results	○ Pass ○ Fail ○ Exception

4.2. Power on verification *[continued]*

Test No.	4.2.4.
Test Procedure	Power on each GeneChip™ Hybridization Oven 645i and verify that they power on properly. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, select "Not applicable" as appropriate in the Actual Results section.
Acceptance Criteria	When each GeneChip™ Hybridization Oven 645i is powered on, there will be an audible beep. The two alphanumeric displays will illuminate, briefly display status information, then scroll **PAUSE**.
Actual Results	First GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail Second GeneChip™ Hybridization Oven 645i: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception
Optional Comments	If there are no comments, enter "Not applicable" below.

4.3. Software and firmware identification

Test No.	4.3.1.
Test Procedure	Verify the presence of and record the software and firmware versions installed on the GeneChip™ Scanner 3000 System. Enter "Not applicable" for any software that is not installed.
Acceptance Criteria	The software and firmware are installed and recorded.
Actual Results	Computer operating system version: _____ Operating system service pack version: _____ ○ Affymetrix™ GeneChip™ Operating Software (GCOS) ○ GeneChip™ Instrument Control (IC) Software ○ GeneChip™ Command Console™ (GCC) Software ○ () _____ Service tools software version: _____
	GeneChip™ Scanner 3000 firmware: _____ GeneChip™ AutoLoader firmware: _____ GeneChip™ Hybridization Oven 645is firmware: _____
	○ Pass ○ Fail ○ Exception

Test No.	4.3.2.
Test Procedure	Verify that all operating system and software versions installed on the system are compatible.
Acceptance Criteria	All versions of the operating system and software are compatible according to the *GeneChip™ Scanner 3000 System Software Compatibility and User Documents Reference* (Pub. No. MAN0017185).
Actual Results	○ Pass ○ Fail ○ Exception
Optional Comments	If there are no comments, enter "Not applicable" below. _____

4.4. GeneChip™ Scanner 3000 Operation Qualification

Test No.	4.4.1.
Test Procedure	Identify the Thorlabs optical power meter and detector used for the LPM conversion factor test and verify that the calibrations are valid.
Acceptance Criteria	The Thorlabs optical power meter and detector are identified and the calibrations are valid. **Note:** If an expiration date is not printed on the calibration certificate, the calibration expiration date is 12 months from the calibration date recorded on the calibration certificate.
Actual Results	**Note:** Record the serial numbers of the optical power meter and detector, not the serial numbers of the calibration certificates. Detector serial number: Detector calibration date: Detector calibration expiration date: Meter serial number: Meter calibration date: Meter calibration expiration date: ○ Pass ○ Fail ○ Exception *Include copies of the Thorlabs optical power meter and detector calibration certificates with this completed IQ and OQ Services Protocol.*

Test No.	4.4.2.
Test Procedure	Display the LPM conversion factor and verify that it meets the specification below.
Acceptance Criteria	The test passes if the LPM conversion factor is 0.0012 - 0.0068 mW/AD.
Actual Results	LPM conversion factor ○ Pass ○ Fail ○ Exception *Include a screenshot of the LPM conversion factor screen with this completed IQ and OQ Services Protocol.*

Test No.	4.4.3.
Test Procedure	Verify that the focus collection depth of the instrument meets the specifications below for both the left and right sides, and verify that spot size specifications are met.
Acceptance Criteria	The test passes if the instrument meets the specifications below for both the left and right sides, and the Chart FCD and Fluor Doc Curves window displays the message **Waveform appears to be correctly formed**. • Width: > 300 • Peak: 18,000 - 35,000
Actual Results	Parameter / Left side result / Right side result Width Peak ○ Pass ○ Fail ○ Exception *Include a screenshot of the Chart FCD and Fluor Doc Curves window with this completed IQ and OQ Services Protocol.*
Acceptance Criteria	Two out of four spot size measurements must be > 2.8 and < 4.2.
Actual Results	Measurement / Actual results 1 2 3 4 ○ Pass ○ Fail ○ Exception *Include a copy of the text file containing the results with this completed IQ and OQ Services Protocol.*

4.4. GeneChip™ Scanner 3000 Operation Qualification *[continued]*

Test No.	4.4.4.
Test Procedure	Verify that the fluorescence depth of collection of the instrument meets the specifications below for the 2.5 µm, 3.45 µs channel. If the scanner is a 7G Plus, also confirm that the 2.5 µm, 5.0 µs channel meets this specification.
Acceptance Criteria	The test passes if the instrument meets the specifications below for each channel: • *2.5 µm, 3.45 µs channel only.* Peak location: > -25 • Peak width: 15.000 - 50.000 at 95% point
Actual Results	Parameter — 2.5 µm, 3.45 µs channel — 2.5 µm, 5.0 µs channel[1] Peak location — _____ — Not applicable Peak width — _____ — _____ [1] If the scanner is not a 7G Plus, enter "Not applicable" in this column.
	○ Pass ○ Fail ○ Exception *Include a copy of the text file containing the results with this completed IQ and OQ Services Protocol.*

[1] If the scanner is not a 7G Plus, enter "Not applicable" in this column.

4.4. GeneChip™ Scanner 3000 Operation Qualification *[continued]*

Test No.	4.4.5.
Test Procedure	Perform the linearity check to verify that the X linearity specifications in each channel, and galvo rotation specifications.
Acceptance Criteria	The X linearity must be < 2.5 pixels in each of the five channels (2.5 µm, 1.5 µm, 1.09 µm, 0.7 µm, 0.5 µm).
Actual Results	Channel — Actual results 2.5 µm 1.5 µm 1.09 µm 0.7 µm 0.5 µm
	○ Pass ○ Fail ○ Exception *Include a copy of the text file containing the results with this completed IQ and OQ Services Protocol.*
Acceptance Criteria	The galvo rotation must be < 0.250.
Actual Results	Galvo rotation
	○ Pass ○ Fail ○ Exception *Include a copy of the text file containing the results with this completed IQ and OQ Services Protocol.*

Test No.	4.4.6.
Test Procedure	Verify that the arc radius of the instrument passes in each channel. **Note:** If the scanner is a 7G Plus, do not select the 2.5 µm, 5.0 µs channel. It is not a valid selection for the arc radius check.
Acceptance Criteria	The test passes if the file displayed when the test completes indicate that the arc radius is within specifications for each channel.
Actual Results	Channel — Actual results 2.5 µm 1.5 µm 1.09 µm 0.7 µm 0.5 µm ○ Pass ○ Fail ○ Exception *Include a copy of the text file containing the results with this completed IQ and OQ Services Protocol.*

Test No.	4.4.7.
Test Procedure	Identify the gain calibration checkerboard chip used for the gain calibration tests.
Acceptance Criteria	The gain calibration checkerboard chip is identified and recorded.
Actual Results	Part number: Lot number: Expiration date: ○ Pass ○ Fail ○ Exception

4.4. GeneChip™ Scanner 3000 Operation Qualification *[continued]*

Test No.	4.4.8.
Test Procedure	Verify that the gain calibration of the instrument passes in the 2.5 µm and 1.5 µm channels. If the scanner is a 7G Plus, also confirm that the additional 2.5 µm, 5.0 µs channel meets this specification.
Acceptance Criteria	The test passes if the file displayed when the test completes indicate that the gain calibration meets the appropriate specification below for the 2.5 µm and 1.5 µm channels: ● 4 color optics: 600 - 900 ● 2 color optics: 480 - 720 If the scanner is a 7G Plus, the test passes if the file displayed when the test completes indicate that the gain calibration for Filters 3 - 6 all pass.
Actual Results	Channel — Actual results 2.5 µm 1.5 µm Filter 3 ○ Pass ○ Fail ○ Not applicable Filter 4 ○ Pass ○ Fail ○ Not applicable Filter 5 ○ Pass ○ Fail ○ Not applicable Filter 6 ○ Pass ○ Fail ○ Not applicable ○ Pass ○ Fail ○ Exception *Include a copy of the text file containing the results with this completed IQ and OQ Services Protocol.*

Test No.	4.4.9.
Test Procedure	Verify that the instrument passes the 400 format autofocus test.
Acceptance Criteria	The test passes if the Scanner column in the Active Worklist contains a dashed line (---).
Actual Results	○ Pass ○ Fail ○ Exception *Include a screenshot of the Scanner window containing the results with this completed IQ and OQ Services Protocol.*
Optional Comments	If there are no comments, enter "Not applicable" below.

4.5. GeneChip™ AutoLoader Operation Qualification

Test No.	4.5.1.
Test Procedure	Verify that the GeneChip™ AutoLoader door lock is operational. If the Customer does not have the GeneChip™ AutoLoader, select "Not applicable" in the Actual Results section below.
Acceptance Criteria	The test passes if the door is locked in the closed position when the door lock is engaged, and if the door can be opened when the door lock is disengaged.
Actual Results	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	4.5.2.
Test Procedure	Perform a chip loading test to verify the home offset of the GeneChip™ AutoLoader carousel. If the Customer does not have the GeneChip™ AutoLoader, enter and select "Not applicable" in the Actual Results section below.
Acceptance Criteria	The test passes if the chip is successfully loaded into the scanner and unloaded back into the carousel, the transfer is smooth, and it completes successfully on the first attempt.
Actual Results	Home offset
	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	4.5.3.
Test Procedure	Verify that the sensor center is within 50 counts of the home offset of the GeneChip™ AutoLoader carousel. If the Customer does not have the GeneChip™ AutoLoader, enter and select "Not applicable" in the Actual Results section below.
Acceptance Criteria	The test passes if the sensor center is within 50 counts of the home offset.
Actual Results	Sensor center
	○ Pass ○ Fail ○ Exception ○ Not applicable

Test No.	4.5.4.
Test Procedure	Insert 48 chips with readable barcodes into the carousel, then perform a chip loading test to verify the barcode reader alignment. If the Customer does not have the GeneChip™ AutoLoader, select "Not applicable" in the Actual Results section below.
Acceptance Criteria	The test passes if a chip was picked up, the barcode was read, and the chip successfully loaded and unloaded in each of the 48 slots with no errors or retries.
Actual Results	○ Pass ○ Fail ○ Exception ○ Not applicable

4.5. GeneChip™ AutoLoader Operation Qualification *[continued]*

Test No.	4.5.5.
Test Procedure	Remove six random chips from the carousel, then click Test Inventory to verify that the correct number of chips were detected. If the Customer does not have the GeneChip™ AutoLoader, select "Not applicable" in the Actual Results section below.
Acceptance Criteria	The test passes if the all 42 remaining chips are detected.
Actual Results	○ Pass ○ Fail ○ Exception ○ Not applicable *Include a screenshot of the AutoLoader test results with this completed IQ and OQ Services Protocol.*

Test No.	4.5.6.
Test Procedure	Perform the temperature test to verify that the hot and cold temperatures are correct. If the Customer does not have the GeneChip™ AutoLoader, enter and select "Not applicable" in the Actual Results section below.
Acceptance Criteria	The test passes if the temperatures meet the specifications below: • Hot temperature: 35°C • Cold temperature: 15°C
Actual Results	Hot temperature _____ Cold temperature _____
	○ Pass ○ Fail ○ Exception ○ Not applicable *Include a screenshot of the temperature graphs with this completed IQ and OQ Services Protocol.*
Optional Comments	If there are no comments, enter "Not applicable" below.

4.6. GeneChip™ Fluidics Station 450 Operation Qualification

Test No.	4.6.1.
Test Procedure	Verify the mechanical function of each GeneChip™ Fluidics Station 450 by performing the checks below. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.

Acceptance Criteria	The test passes if the following are true:
	● The top lid cover opens and closes properly.
	● When the cartridge door of each module is engaged, the needles are aligned with the wash block and the assembly engages properly.
	● When a blank cartridge with perforated septum is inserted into each module, the cartridge door engages properly.
	● The door for each module seats properly.
	● The pump cover doors open and close properly, and the magnets properly secure the doors.
	● Each module is secure in the chassis.
	● Each module's quick disconnect fittings are properly connected:
	  ● Wash A - white
	  ● Wash B - red
	  ● Water - blue
	● The drain tubing (2x) of each module are attached to the drain tube.
	● When powered on, the LCD window displays the following on each module:
	  ● Power-on done
	  ● NOT PRIMED 25°C

Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

4.6. GeneChip™ Fluidics Station 450 Operation Qualification *[continued]*

Test No.	4.6.2.
Test Procedure	Perform a sensor test on each GeneChip™ Fluidics Station 450 and verify that it completes successfully. During the test, inspect each module for leaks at all fittings and lines. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if no errors or leaks were observed and the LCD displays the following: ● Sensor test complete ● 25°C
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

Test No.	4.6.3.
Test Procedure	Perform a valve test on each GeneChip™ Fluidics Station 450 and verify that it completes successfully. During the test, inspect each module for leaks at all fittings and lines. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if no errors or leaks were observed and the LCD displays the following: ● Valve exercising done ● 25°C
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

Test No.	4.6.4.
Test Procedure	Perform a temperature test on each GeneChip™ Fluidics Station 450 and verify that it completes successfully. During the test, inspect each module for leaks at all fittings and lines. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if no errors or leaks were observed and the LCD displays the following: ● Test completed ● 25°C
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

Test No.	4.6.5.
Test Procedure	Perform a pump test on each GeneChip™ Fluidics Station 450 and verify that it completes successfully. During the test, inspect each module for leaks at all fittings and lines. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if no errors or leaks were observed and the LCD displays the following: ● Pump test done ● 25°C
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

4.6. GeneChip™ Fluidics Station 450 Operation Qualification *[continued]*

Test No.	4.6.6.
Test Procedure	Perform a prime test on each GeneChip™ Fluidics Station 450 and verify that it completes successfully. During the test, inspect each module for leaks at all fittings and lines. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if no errors or leaks were observed and the LCD displays the following: ● Priming done ● READY 25°C
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

Test No.	4.6.7.
Test Procedure	Perform a wash and stain test on each GeneChip™ Fluidics Station 450 and verify that it completes successfully. During the test, inspect each module for leaks at all fittings and lines. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if no errors or leaks were observed and the LCD displays the following: ● Protocol done ● READY 25°C
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable
	○ Pass ○ Fail ○ Exception

4.6. GeneChip™ Fluidics Station 450 Operation Qualification *[continued]*

Test No.	4.6.8.
Test Procedure	Perform the final inspection shutdown on each GeneChip™ Fluidics Station 450 and verify that it completes successfully. During the test, inspect each module for leaks at all fittings and lines. If the Customer has fewer than four GeneChip™ Fluidics Station 450s, select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if no errors or leaks were observed and the LCD displays the following: ● Shutdown done ● NOT PRIMED 25°C
Actual Results	First GeneChip™ Fluidics Station 450: ○ Pass ○ Fail Second GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Third GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable Fourth GeneChip™ Fluidics Station 450: ○ Pass ○ Fail ○ Not applicable ○ Pass ○ Fail ○ Exception
Optional Comments	If there are no comments, enter "Not applicable" below.

4.7. GeneChip™ Hybridization Oven 645i Operation Qualification

Test No.	4.7.1.
Test Procedure	Verify that the door, push buttons, LED displays, and circulation fan are functioning properly on each GeneChip™ Hybridization Oven 645i. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, enter/select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if the following is true for each GeneChip™ Hybridization Oven 645i: • **Door gasket:** is seated properly • **Door latch and catch:** hold the door closed properly • **Push buttons and LED displays:** functioning properly upon power up • **Circulation fan:** is functioning properly in the rear of the oven

Actual Results

	First oven	Second oven
Door gasket:	○ Pass ○ Fail	○ Pass ○ Fail ○ Not applicable
Door latch and catch:	○ Pass ○ Fail	○ Pass ○ Fail ○ Not applicable
Push buttons and LED displays:	○ Pass ○ Fail	○ Pass ○ Fail ○ Not applicable
Circulation fan:	○ Pass ○ Fail	○ Pass ○ Fail ○ Not applicable

○ Pass ○ Fail ○ Exception

Test No.	4.7.2.
Test Procedure	Verify that the actual rotation speed of each GeneChip™ Hybridization Oven 645i carousel meets the specifications below. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, enter/select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if each GeneChip™ Hybridization Oven 645i carousel completes 30 rotations in **30 ± 2 seconds**.

Actual Results

	Actual rotation speed
First GeneChip™ Hybridization Oven 645i:	
Second GeneChip™ Hybridization Oven 645i:	

○ Pass ○ Fail ○ Exception

4.7. GeneChip™ Hybridization Oven 645i Operation Qualification *[continued]*

Test No.	4.7.3.
Test Procedure	Identify the left and right temperature data logger probes used for the temperature test and verify that the calibrations are valid.
Acceptance Criteria	The left and right temperature data logger probes are identified and the calibrations are valid. **Note:** If an expiration date is not printed on the calibration certificate, the calibration expiration date is 12 months from the calibration date recorded on the calibration certificate.
Actual Results	**Note:** Record the serial numbers of the temperature probes, not the serial numbers of the calibration certificates. Left probe serial number: Left probe calibration date: Left probe calibration expiration date: Right probe serial number: Right probe calibration date: Right probe calibration expiration date:
	○ Pass ○ Fail ○ Exception *Include copies of the left and right temperature data logger probes calibration certificates with this completed IQ and OQ Services Protocol.*

4.7. GeneChip™ Hybridization Oven 645i Operation Qualification *[continued]*

Test No.	4.7.4.
Test Procedure	Verify that the left and right side temperatures and the temperature range of each GeneChip™ Hybridization Oven 645i meet the specifications below. If the Customer does not have a second GeneChip™ Hybridization Oven 645i, enter/select "Not applicable" as appropriate in the Actual Results section below.
Acceptance Criteria	The test passes if the left and right side temperatures at the 18th data point from when the probes went into the oven and the temperature range of each GeneChip™ Hybridization Oven 645i meet the specifications below: ● Left: 49°C - 51°C ● Right: 49°C - 51°C ● Range: < 1°C
Actual Results	Left / Right / Range First GeneChip™ Hybridization Oven 645i: ____ ____ ____ Second GeneChip™ Hybridization Oven 645i: ____ ____ ____ ○ Pass ○ Fail ○ Exception
Optional Comments	If there are no comments, enter "Not applicable" below.

4.8. Operation Qualification (OQ) completion

Test No.	4.8.1.
Test Procedure	Verify that all required OQ tests have been completed, and all exceptions have been recorded.
Acceptance Criteria	All required OQ tests have been completed, and all exceptions have been recorded.
Actual Results	All required OQ tests have been completed: ○ Yes ○ No
	All exceptions have been recorded on an exception report: ○ Yes ○ No ○ Not applicable
	FSE initials: Date:
	○ Pass ○ Fail The Customer must review the entries in the OQ tests and sign below to indicate acceptance. **Reviewed by:** Customer name: Title/Role: Signature: Date:
Optional Comments	If there are no comments, enter "Not applicable" below.

PART 5. Customer training verification

5.1. Customer training verification

Test No.	5.1.1.
Test Procedure	*New GeneChip™ Scanner 3000 System installations only.* Verify that users have received basic user training for the GeneChip™ Scanner 3000 System by Thermo Fisher Scientific or a service provider authorized by Thermo Fisher Scientific. If this is not a new GeneChip™ Scanner 3000 System installation, then select "Not applicable" in the Actual Results below.
Acceptance Criteria	Users have received basic user training for the GeneChip™ Scanner 3000 System by Thermo Fisher Scientific or a service provider authorized by Thermo Fisher Scientific.
Actual Results	○ Pass ○ Fail ○ Exception ○ Not applicable *Include any applicable training record(s) with this completed IQ and OQ Services Protocol.*
	Record the name and title/role of the users who received training during this IQ and OQ Service: Name: Title/Role: Name: Title/Role: Name: Title/Role: Name: Title/Role: Name: Title/Role:
Optional Comments	If there are no comments, enter "Not applicable" below.

PART 6. IQ and OQ Services Protocol completion

6.1. Summary of results

6.1.1. These Final Approval Signatures are confirmation that all required IQ and OQ Services Protocol activities have been successfully completed, with all required documentation completed and attached to this final report. Any required rework has been documented and completed, with successful test results documented.

6.1.2. The successful completion of this IQ and OQ Services Protocol confirms that, at the time of testing, the identified GeneChip™ Scanner 3000 System has been installed and/or is operational in accordance with Thermo Fisher Scientific Acceptance Criteria.

IQ and OQ Services Protocol Completion and Report Final Approval	
Summary of Results	All required tests in this IQ and OQ Services Protocol were completed successfully. ○ Yes ○ No
Select one:	○ **Pass**: All qualification tests were successfully completed. ○ **Pass with exception**: Some of the qualification tests were completed with Customer-accepted corrections or deviations (logged as Exceptions). ○ **Fail**: Some of the qualification tests were not successfully completed.

6.1.3. If **Pass** or **Pass with exception** is selected above, then the Field Service Engineer must either enter optional comments below or enter "Not applicable" to indicate there are no comments. If **Fail** is selected above, then the Field Service Engineer must describe the failure(s) below:

6.2. Final instructions

6.2.1. The FSE reviews the completed IQ and OQ Services Protocol to verify:

- All blanks contain an appropriate value for the test or "Not applicable" if a test does not apply, unless a procedure instructs that it is not necessary to mark a blank field with "Not applicable" for a particular test.
- For all Yes or No responses, either Yes or No is specified.
- For all Pass/Fail/Exception responses, either Pass or Fail or Exception is specified.
- All Signature/Date fields are completed.
- Training and calibration certificates indicated in tests are signed and included with the IQ and OQ Services Protocol, and they are listed in the attachment cross-reference section in this IQ and OQ Services Protocol.

6.2. Final instructions *[continued]*

6.2.2. If this service is completed using the electronic form, then the FSE must:

- Obtain the Customer's signature in Section 4.3.2. System Owner or designee final approval.
- If applicable, obtain any additional signer signatures in Section 4.3.3. (Optional) Additional signer(s) final approval.
- Sign in Section 4.3.1. FSE final approval.
- Scan any non-electronic supporting documentation.
- Email the completed, signed, and locked IQ and OQ Services Protocol, any exception reports, and all supporting documentation to the Customer.

6.2.3. If this service is completed using a printed document instead of using the electronic form, then the FSE must:

- Obtain the Customer's signature in Section 4.3.2. System Owner or designee final approval.
- If applicable, obtain any additional signer signatures in Section 4.3.3. (Optional) Additional signer(s) final approval.
- Sign in Section 4.3.1. FSE final approval.
- Provide the completed, signed IQ and OQ Services Protocol with any exception reports and all supporting documentation to the Customer.

6.3. Final approval signatures

6.3.1. FSE final approval

Print FSE name:		Initials:	
Title/Role:			
Signature:			
Date:			

6.3. Final approval signatures *[continued]*

6.3.2. System Owner or designee final approval

Print System Owner or designee name:		Initials:
Title/Role:		
Signature:		
Date:		

6.3.3. (Optional) Additional signer(s) final approval

(Optional) Print additional signer name:		Initials:
Title/Role:		
Signature:		
Date:		

(Optional) Print additional signer name:		Initials:
Title/Role:		
Signature:		
Date:		

PART 7. Add-on service cross-reference

7.1. Add-on service cross-reference

The Customer purchased the add-on service to test one or more additional GeneChip™ Fluidics Station 450(s) connected to this workstation: ○ Yes ○ No

If **Yes**, then record the serial number for each additional instrument below. Up to four additional GeneChip™ Fluidics Station 450(s) may be tested, for a total of eight GeneChip™ Fluidics Station 450s connected to a single workstation.

First additional GeneChip™ Fluidics Station 450:	
Second additional GeneChip™ Fluidics Station 450:	
Third additional GeneChip™ Fluidics Station 450:	
Fourth additional GeneChip™ Fluidics Station 450:	

Include the corresponding completed IQ and OQ Services Protocol Supplement for Additional GeneChip™ Fluidics Station 450 Qualification (Pub. No. MAN0017107) for each additional instrument tested.

PART 8. Exception reports

8.1. Exception report cross-reference

List exception reports with cross-references, and include all exception reports and supporting documentation with this completed IQ and OQ Services Protocol. **It is not necessary to mark blank rows with "Not applicable."**

Exception report no.	Protocol test no.	Resolution date			Description

PART 9. Supporting documentation

9.1. Attachment cross-reference

List all attachments with cross-references, and include all attachments with this completed IQ and OQ Services Protocol. **It is not necessary to mark blank rows with "Not applicable."**

Attachment no.	Protocol test no.	# of attachment pages	Description

9.1. Attachment cross-reference *[continued]*

Attachment no.	Protocol test no.	# of attachment pages	Description

Check document | Lock document

Affymetrix Inc. | 3450 Central Expressway | Santa Clara, California 95051 USA

Revision history: Pub. No. MAN0017103

Revision	Date	Description
B.0	23 March 2023	Autoloader now ships attached with instrument (Rhea project). Changed 645 oven to 645i oven; added new site prep guide; deleted Test 4.2.1 Power On (was for Dx only); changed AGCC to GCDC software; deleted field to capture 645 firmware; moved spot sizes test (OQ 4.4.3) to after OQ 4.4.1 (FCD section); deleted lot number in OQ Test 4.4.5; changed Acceptance Criteria in OQ 4.4.7 (to green check wording); in IQ, moved Tests 4.4.8 and 4.4.9 to after 4.4.2. Changed Newport meter to Thorlabs power meter and detector. Minor wording and format changes.
A.0	07 September 2017	New document: updated branding, boilerplate content, and protocol template. Supersedes Pub. No.FM554 Rev. 3.
FM554 Rev. 3	09 May 2014	Added revision history and document table. Updated document title, header and footer branding logos, page formatting, and Section 4.4 with relevant test procedures. Added references to "operational qualification".
FM554 Rev. 2	07 May 2012	Added revision information to the header and footer.
FM554 Rev. 1	31 May 2011	Initial release.

The information in this guide is subject to change without notice.