ThermoFisher
SCIENTIFIC

Title: OQ Chromeleon Trace GC Series

Number: ULS-RPG-QM-4265 Revision: 028

Qualification #: 50559

Effective Date: 22 Jul 2024

CHANGE SUMMARY

(Only changes within the last 18 months are listed below in detail.)

Revision Number	Effective Date	Description of Changes
028	See Cover Sheet	• Added RPG Reports 3 Support. • Added Section 2 CDS data integrity and GxP responsibility. • Section 6.2 & 10.1: Removed part numbers for Test Mix vials. • Section 6.3 and 10.2: Added alternative to micropipette. • Section 8.1: Added instructions for using RPG Reports 2 and 3. • Section 11.3: Added instructions for reporting data in RPG Reports 2 and 3. • Sections 12-16: Updated sections to match latest RPG qualification document template.

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OQ CHROMELEON TRACE GC SERIES

1 INTRODUCTION

Documented evidence must be provided to demonstrate the integrity of data collected and validate the results obtained on laboratory instrumentation.

Many laboratories achieve this by formal quality systems, which are generally implemented in accordance with one or more of the following recognized quality standards and other quality guidelines:

- Good Laboratory Practice (GLP)
- Current Good Manufacturing Practice (cGMP)
- ISO guidelines
- USP / EP

These standards and guidelines are written in broad terms, to make them as widely applicable as possible. All stipulate general requirements specifying instruments must be fit for purpose, properly maintained, and calibrated to national or international standards. This procedure used for Thermo Fisher Scientific Operational Qualification is adapted to these standards.

This procedure is intended to guide trained and certified individuals through Operational Qualification of Thermo Scientific products.

2 CDS DATA INTEGRITY AND GXP RESPONSIBILITY

The Instrument Testing is undertaken in the customer environment; this will utilize the customer CDS software package. Implementation of user management and data auditing may have been applied to the system and is the responsibility of the system owner. An appropriate user account may be required and all actions in the CDS can be recorded by the CDS depending on the audit settings applied. It is the responsibility of the Thermo Fisher Scientific representative to ensure that all data collected is identified using appropriate naming, saved location, and recorded in the RPG Reports UI or other provided checklist. A discussion with the customer and their quality department may be necessary to ensure that any data is named, stored, and handled appropriately.

All work carried out should comply to GxP Good Documentation Practice as followed by Thermo Fisher Scientific and the customer organization.

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3 OPERATIONAL QUALIFICATION SCOPE

A hardware operational qualification (OQ) is documented verification that a system operates according to written and preapproved limits throughout all specified operating ranges.

Performing an OQ is recommended at any of the following occasions:

- After initial installation of the instrument
- When a new module is added to an existing instrument
- Following a firmware update
- Moving instruments to a new location
- After replacing a non-consumable hardware component that has a serial number

OQ documents the following items:

- **Qualification Service Representative Information**
- **Customer Information**
- **System Information**: Instrumentation, computer and software information as installed.
- **OQ Limits**: List of manufacturer-recommended limits for ensuring that the system is operating as expected.
- **Operational Tests and Results**: Testing of important functions to verify that the system operates as intended by the manufacturer and as required by the user. This is a group of selected, important parameters for testing according to the intended use of the system.

This procedure supports the following Thermo Scientific hardware/software configurations:

- **GC: Trace GC Series** (Trace 1300, Trace 1310, Trace 1600, and Trace 1610)
  - **Inlets:** SSL, PTV, SSL-Backflush, SSL-He Saver, PTV-Backflush
  - **Detectors:** FID, TCD, NPD, ECD, FPD, PDD
- **Autosampler:** AI/AS Series (AI/AS1310 and AI/AS1610), TriPlus 100LS, TriPlus RSH series (TriPlus RSH, TriPlus RSH SMART Advanced, TriPlus RSH SMART Standard), TriPlus 300, and TriPlus 500
  - **Injection Modes**: Liquid, Headspace, SPME/SPME Arrow, ITEX
- **Controlling Software:** Chromeleon 7.2.3 or later version
- **RPG Reports:** 2.x or 3.4.x or later with GCMS Systems license

  NOTE: Some model combinations cannot be supported by, or require a specific version of, the software. Please refer to the Software Release Notes document to verify what equipment is supported.

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4 RECOMMENDED DOCUMENTS

Use this document along with the gas chromatograph operator manual, Installation Procedure, and individual component operator/service manuals.

5 GAS REQUIREMENTS

- GC System
  - Helium carrier gas (minimum 99.999% purity)
- FID/NPD detectors
  - Nitrogen detector gas (minimum 99.999% purity)
  - Hydrogen gas (minimum 99.999% purity)
  - Air (minimum 99.999% purity)
- ECD detectors
  - Nitrogen detector gas (minimum 99.999% purity)
- PDD detector
  - Helium gas (minimum 99.9999% purity)
- FPD
  - Hydrogen gas (minimum 99.999% purity)
  - Air (minimum 99.999% purity)
- TCD detector
  - Helium detector gas (minimum 99.999% purity)

6 RECOMMENDED MATERIALS

6.1 GC Common Materials (Manual or Liquid Sampler)

- TR-5 7-m x 0.32-mm ID x 0.25-µm Test Column (P/N 260E113P)

  NOTE: Column for stand-alone GC Only
- Thermometer (for example, P/N 29010781)
- 40 AWG K-type thermocouple probe (for example, Fisher Catalog P/N NC0248495, 5 pack)
- Thermo Scientific GFM Pro Flowmeter (for example, P/N 66002010)
- Column Flow Measurement Adapter (P/N 24507000)
- 2-mL screw cap autosampler vials, caps and septa (P/N 24014019)
- Disposable transfer pipettes
- Suitable blanking solvent: (e.g., iso-octane for TCD/ECD, n-hexane for FID/NPD)

6.2 Materials for GC Detectors

- Detector Flow Measurement Adapter (P/N 34709348)

  Needed for FID detectors
- Detector Flow Measurement Adapter (P/N 34709610)

Needed for NPD detectors

- Detector Flow Measurement Adapter (P/N/ 34709630)

  Needed for FPD detectors.

- FID/PDD Qualification
  - FID Test Mix (P/N 33819020)
  - FID/TCD Linearity Test Mix (P/N 33819026), each kit contains 1 ampule each of the following concentrations: 200 µg/mL, 100 µg/mL, 20 µg/mL, 1 µg/mL
- TCD Qualification
  - TCD Test Mix (P/N 33819016)

  FID/TCD Linearity Test Mix (P/N 33819026), each kit contains 1 ampule each of the following concentrations: 200 µg/mL, 100 µg/mL, 20 µg/mL, 1 µg/mL
- NPD Qualification
  - NPD Test Mix (P/N 33819006)
  - NPD Linearity Test Mix (P/N 33819030), each kit contains 1 ampule each of the following concentrations: 2000 ppb, 1000 ppb, 500 ppb, 100 ppb
- ECD Qualification
  - ECD Test Mix (P/N 33819011)
  - ECD Linearity Test Mix (P/N 33819029), each kit contains 1 ampule each of the following concentrations: 60 ppb, 30 ppb, 10 ppb
- FPD Qualification
  - FPD Test Mix (33819006)
  - FPD Linearity Test Mix (33819030), each kit contains 1 ampule each of the following concentrations: 2000 ppb, 1000 ppb, 500 ppb, 100 ppb

6.3 Additional Materials for Headspace Samplers

- 20-mL sample vial with silicon-Teflon septa
- Column:
  - TriPlus 300: TR-5 7-m x 0.32-mm ID x 0.25-µm Test Column (P/N 260E113P)
  - TriPlus 500 and RSH: TR-5MS 15-m x 0.32-mm ID x 1.00-µm Test Column (P/N 260F285P)

    Note: Column for stand-alone GC Only.
- Test Mix:
  - TriPlus 300: Uses Detector Test Mix
  - TriPlus 500 and RSH: TriPlus Headspace Test Mix (P/N 33819024)
    - Optional for TriPlus 500 with FID (Supelco E-040-10X1.2ML)
- 5 µL disposable micropipettes (P/N 36520056) or 5 µL syringe (TriPlus 500 Only)

6.4 Additional Materials for SPME Samplers

- TR-5MS 15-m x 0.32-mm ID x 1.00-µm Test Column (P/N 260F285P)
- TriPlus Headspace Test Mix (P/N 33819024)

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6.5 Additional Materials for ITEX Samplers

- TR-5 7-m x 0.32-mm ID x 0.25-µm Test Column (P/N 260E113P)
- TriPlus Headspace Test Mix (P/N 33819024)
- 5 µL disposable micropipettes (P/N 36520056)

7 OQ TEST SUMMARY

7.1 Oven Tests

Oven Temperature Accuracy			
The Oven Temperature Accuracy Test verifies the functionality of the GC column oven. When the column oven is set to a certain temperature, the measured temperature should be within the set limits.			
How Test is Performed			
A test probe is placed inside the oven near the internal thermocouple. The oven temperature is set to the test point. The oven is allowed to stabilize, and the temperature is measured with an external thermometer. The measured value on the thermometer is compared to the displayed temperature value on the GC front panel. This process is repeated for all test points.			
Module	**Test Name**	**Test Point**	**OQ Limits**
Trace GC Series Oven	Oven Temperature Accuracy	40 °C	± 1 °C
		120 °C	± 2 °C

Oven Temperature Ramp Repeatability			
The Oven Temperature Ramp Repeatability test demonstrates the holistic repeatability of GC conditions (temperature and gas flow) during analysis by injecting the same sample multiple times and evaluating the relative standard deviation of the retention times. Variations in the gas flow and oven temperature deviations affect primarily the repeatability of the retention time.			
How Test is Performed			
This test is a subset of the Sampler Repeatability test. The carrier gas flow and oven temperature ramp are specified in the method. The relative standard deviation of the retention times of the six injections indicates repeatability of the system temperature ramp.			
Module	**Test Name**	**Test Point**	**OQ Limits**
Trace GC Series Oven	Oven Temperature Ramp Repeatability	Retention Time of 6 Repeatability Injections	≤ 1.0% RSD

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7.2 Inlet Tests

Inlet Flow			
The Inlet Flow Tests test the Septum Purge and Split Vent Flow for each installed GC inlet. The independently measured flow rates must be within a specified range of the expected flow rates.			
How Test is Performed			
With a test column installed, a flow meter is plumbed to the column flow measuring adapter. The carrier gas is configured for constant flow mode and the inlet is configured for splitless injection. The split gas flow is set to the appropriate set point (vacuum compensation is set to OFF). Split gas flow rate is measured and compared to the expected flow rate value. The carrier gas is then configured for constant pressure mode at the appropriate set point. Septum purge flow rate is then measured and compared to the expected flow rate value.			
Module	**Test Name**	**Test Point**	**OQ Limits**
Trace GC Series Inlet	Split Vent Flow	60.0 mL/min	± 5.0 mL/min
	Septum Purge Flow	5.0 mL/min	± 2.0 mL/min

Inlet Temperature			
The Inlet Temperature Test verifies the functionality of the inlet heater and readback from the heating sensor. When the inlet is set to a certain temperature, the measured temperature should be within the set limits.			
How Test is Performed			
A test probe is inserted into the inlet. The inlet temperature is set to the test point and allowed to stabilize. The temperature is then measured with an external thermometer. The measured value on the thermometer is compared to the displayed temperature value on the GC front panel or controlling software.			
Module	**Test Name**	**Test Point**	**OQ Limits**
Trace GC Series SSL Inlet	Inlet Temperature	100 °C	± 5 °C
Trace GC Series PTV Inlet			± 3 °C

Inlet Leak			
The Inlet Leak Test verifies the inlet holds a minimum pressure and is not leaking gas.			
How Test is Performed			
With the split valve and the septum purge valve in the off position and gas supply pressure at least 70 kPa above the inlet pressure set point, the system pressure should not decrease more than the set limits over a three-minute interval.			
Module	**Test Name**	**Test Point**	**OQ Limits**
Trace GC Series SSL Inlet	Inlet Leak	200.0 kPa (30.0 psi)	± 10.0 kPa (1.5 psi) over 3-minute interval
Trace GC Series PTV Inlet			

7.3 GC Detector Tests

GC Detector Temperature			
The GC Detector Temperature Test verifies the functionality of the detector heater. When the detector is set to a certain temperature, the displayed temperature should be within the set limits.			
How Test is Performed			
The detector temperature is set to the test point and allowed to stabilize. The displayed value on the GC front panel or controlling software is compared to the expected temperature value.			
Module	**Test Name**	**Test Point**	**OQ Limits**
Trace GC Series Detector	Detector Temperature	120 °C	± 2 °C

GC Detector Flows			
The GC Detector Flow Tests verify the functionality of the detector digital flows module. The measured flow rates must be within a specified range of the expected flow rates.			
How Test is Performed			
A flow meter is connected to the detector. The appropriate gas flow is set to the test point and allowed to stabilize. The measured value on the flow meter is compared to the displayed flow value on the GC front panel or controlling software. The test is performed for Air, Hydrogen, Reference and Makeup gases (as applicable to detector model) at both a high and low flow set point.			
Module	**Test Name**	**Test Point**	**OQ Limits (mL/min)**
Trace GC Series FID Detector	Detector Flow	H_2 Flow	Low: 30.0 ± 2.0 High: 60.0 ± 4.0
		Air Flow	Low: 90.0 ± 6.0 High: 350.0 ± 12.0
		Makeup Flow	Low: 13.0 ± 2.0 High: 45.0 ± 2.0
Trace GC Series TCD Detector		Reference Flow	Low: N/A High: 5.0 ± 1.0
Trace GC Series ECD Detector		Makeup Flow	Low: 13.0 ± 2.0 High: 45.0 ± 2.0
Trace GC Series NPD Detector		H_2 Flow	Low: N/A High: 5.0 ± 0.5
		Air Flow	Low: 90.0 ± 6.0 High: 300.0 ± 12.0
		Makeup Flow	Low: 13.0 ± 2.0 High: 45.0 ± 2.0
Trace GC Series FPD Detector		H_2 Flow	Low: 30.0 ± 2.0 High: 100.0 ± 4.0
		Air Flow	Low: 90.0 ± 6.0 High: 300.0 ± 12.0
Trace GC Series PDD Detector		Not Tested	

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GC Detector Noise, Drift, Wander			
The GC Detector Noise, Drift, Wander Tests verify the stability of the detector. ASTM definitions are used for Noise and Drift, while Wander follows what the ASTM defines as "Other Noise".			
How Test is Performed			
With Helium carrier gas and specified detector gas, at least thirty minutes of baseline signal is collected and the noise, drift over time, and additional noise (wander) are calculated. The measured values are compared to expected values for each of the three specified limits.			
Module	**Test Name**	**Test Point**	**OQ Limits**
Trace GC Series FID Detector (Nitrogen make-up)*	Detector Noise	Noise	≤ 100 fA (0.10 pA)
	Detector Drift	Drift	≤ 2500 fA/h (2.50 pA/h)
	Detector Wander	Wander	≤ 100 fA (0.10 pA)
Trace GC Series TCD Detector (Helium make-up)*	Detector Noise	Noise	≤ 12 µV
	Detector Drift	Drift	≤ 200 µV/hr
	Detector Wander	Wander	≤ 50 µV
Trace GC Series NPD Detector (Nitrogen make-up)*	Detector Noise	Noise	≤ 50 fA (0.05 pA)
	Detector Drift	Drift	≤ 200 fA/hr (0.20 pA/hr)
	Detector Wander	Wander	≤ 80 fA (0.08 pA)
Trace GC Series ECD Detector (Nitrogen make-up)*	Detector Noise	Noise	≤ 5 Hz
	Detector Drift	Drift	≤ 100 Hz/hr
	Detector Wander	Wander	≤ 20 Hz
Trace GC Series FPD Detector	Detector Noise	Noise	≤ 950 pA (*FPD-S 394 nm filter*) ≤ 1900 pA (*FPD-Ph 526 nm filter*)
	Detector Drift	Drift	≤ 1000 pA/hr
	Detector Wander	Not Tested	
Trace GC Series PDD Detector (Nitrogen make-up)*	Detector Noise	Noise	≤ 10 pA
	Detector Drift	Drift	≤ 100 pA/hr
	Detector Wander	Not Tested	
*Noise, Drift and Wander limits are based on the use of the listed makeup gas. These limits cannot be guaranteed if no gas or a different make-up gas is used. **NOTE: The Noise, Drift, Wander Test is run only once per installed detector.**			

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GC Detector Linearity			
The GC Detector Linearity verifies that the accuracy of the GC Detector. This test requires a Liquid Autosampler, and is not supported with manual injections.			
How Test is Performed			
A detector-specific test mix solution is injected (**0.5 µL for ECD**, and **1 µL for all the other detectors**) six times (three different concentrations for two injections). The peak area data are then collected, and the coefficient of determination is calculated. The calculated coefficient of determination is compared to the specified limits.			
Module	**Test Name**	**Test Point / Standard**	**OQ Limits**
Trace GC Series FID Detector	Detector Linearity	r^2 of Hexadecane peak area for injection series	≥ 0.999
Trace GC Series TCD Detector			
Trace GC Series PDD Detector			
Trace GC Series NPD Detector		r^2 of Azobenzene / Methyl Parathion peak area for injection series	≥ 0.995
Trace GC Series ECD Detector		r^2 of Lindane peak area for injection series	
Trace GC Series FPD Detector (526 nm filter only)		r^2 of Methyl Parathion peak area for injection series	≥ 0.998

7.4 Autosampler Tests

Repeatability with GC Detector			
The repeatability test demonstrates that system injections are precise and consistent over a series. The relative standard deviation (% RSD) of sample peak area characterizes the repeatability of the injection volume.			
How Test is Performed			
A standard is injected multiple times (minimum six injections) at 1.0 µL for liquid samplers and 1.0 mL for Headspace or SPME samplers and data are collected. The relative standard deviation (% RSD) of the peak areas is calculated. The % RSD is then compared to the set limits.			
Module	**Test Name**	**Test Point / Standard**	**OQ Limits**
AI/AS Series	Repeatability for Liquid Injections	Area of six Standard Injections	≤ 2.0% RSD
TriPlus Series	Repeatability for Headspace Injections		≤ 5.0% RSD
	Repeatability for SPME and ITEX Injections		≤ 6.0% RSD

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Syringe Linearity			
The syringe linearity test verifies that the autosampler uniformly delivers a sample when injecting the same compound at various volumes. **NOTE: Syringe linearity can only be performed with a GC Detector and with AS or HS injections.** **NOTE: Syringe linearity is not performed on the TriPlus 300 or TriPlus 500 sampler because of the fixed loop configuration.**			
How Test is Performed			
A single standard s injected at 0.5 µL, 1.0 µL and 2.0µL volumes for liquid injections or at 0.5 mL, 1.0 mL and 2.0 mL for headspace injections. The peak area data are then collected, and the coefficient of determination is calculated. The calculated coefficient of determination value is compared to the specified limits.			
Module	**Test Name**	**Test Point / Standard**	**OQ Limits**
AI/AS Series	Syringe Linearity for Liquid Injections	r^2 for the three Standard Injections	≥ 0.990
TriPlus RSH Series	Syringe Linearity for HS Injections		

HS/ITEX Syringe Temperature			
The HS/ITEX Syringe Temperature Test verifies the HS/ITEX syringe heater temperature control. When the HS or ITEX syringe temperature is set to a certain temperature, the measured temperature should be within the set limits. **NOTE: Syringe Temperature is not applicable to the TriPlus 300 or TriPlus 500 sampler.**			
How Test is Performed			
The syringe plunger is removed and a temperature probe (attached to thermometer) is inserted into the syringe barrel. Syringe temperature is set to appropriate setpoint, and allowed to stabilize. The measured temperature value from thermometer is then compared to set temperature value. **NOTE: A septum can be used to keep the probe in position in the middle of the syringe length.**			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus RSH Series	HS/ITEX Syringe Temperature	45 °C	± 8 °C
		90 °C	± 8 °C

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HS Syringe Gas Flush Check			
The HS Syringe Gas Flush Check verifies the flushing gas flow on the HS syringe is working properly. **NOTE: Syringe Gas Flush is not applicable to the TriPlus 300 or TriPlus 500 sampler.**			
How Test is Performed			
A flowmeter is connected to end of the syringe needle. The syringe purge is turned on and allowed to stabilize. The flow measured from the meter is then recorded. In the case that the flow exceeds the flowmeters capacity, the maximum value read by the flowmeter is recorded.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus RSH Series	HS Syringe Gas Flush Check	Gas Flush Flow	≥ 5 mL/min

SPME Fiber Conditioning Station Temperature			
The Fiber Conditioning Station Temperature Test verifies the temperature conditioning unit used for SPME fibers. When the fiber conditioning station is set to a certain temperature, the measured temperature should be within the set limits.			
How Test is Performed			
The fiber conditioning station temperature is set to the appropriate set point. A test probe (attached to a thermometer) is placed into the hole in the top of the station. The temperature is allowed to stabilize. The measured temperature value from the thermometer is then compared to the set temperature value.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus RSH Series	SPME Fiber Conditioning Station Temperature	100 °C (automatic & manual channels)	± 5 °C
		200 °C (automatic & manual channels)	± 5 °C

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SPME Fiber Conditioning Station Gas Flush Check			
The Fiber Conditioning Station Gas Flush check verifies the flushing gas flow of the fiber incubation oven is working properly.			
How Test is Performed			
The fiber conditioning station gas flush flow is opened. The solenoid valve is opened, and a flow meter is attached to the channel outlet. The flow is observed and recorded. This is done on both the manual and automatic channels.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus RSH Series	SPME Fiber Conditioning Station Gas Flush Check	Flushing Gas Flow (automatic & manual channels)	≥ 5 mL/min

Heatex Temperature			
The Heatex Temperature Test verifies the Heatex stirrer temperature control used for SPME Arrow injections. When the Heatex is set to a certain temperature, the measured temperature should be within the set limits.			
How Test is Performed			
The Heatex temperature is set to the appropriate set point. A test probe attached to a thermometer is placed into an empty vial and inserted into the Heatex. The temperature is allowed to stabilize. The measured temperature value from the thermometer is then compared to the set temperature value.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus RSH Series w/ SPME Arrow	Heatex Temperature	45 °C	± 5 °C
		90 °C	± 5 °C

Agitator Temperature			
The Agitator Temperature Test verifies the sample agitator/incubation oven temperature control used for HS, SPME and ITEX injections. When the agitator is set to a certain temperature, the measured temperature should be within the set limits. **NOTE: Agitator Temperature is not applicable to the TriPlus 300 or TriPlus 500 sampler.**			
How Test is Performed			
The agitator temperature is set to the appropriate set point. A test probe attached to a thermometer is placed into an empty vial and inserted into the incubation oven. The temperature is allowed to stabilize. The measured temperature value from the thermometer is then compared to the set temperature value.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus RSH Series	Agitator Temperature	45 °C	± 5 °C
		90 °C	± 5 °C

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ITEX: Trap Temperature			
The ITEX Trap Temperature tests verify the syringe trap temperature control of the ITEX tool. When the trap is set to a certain temperature the readback from the data system should be within the set limits, when the trap is heated the target temperature should be reached within a certain time interval.			
How Test is Performed			
Using the Virtual Terminal, set trap temperature to 40 °C. Open instrument 3D view within the CDS and allow the trap temperature to stabilize before taking the reading. Have a timer ready for use. Using the Virtual Terminal, set trap temperature to 300 °C and start the timer. Open instrument 3D view within the CDS and measure the time required to reach 300 °C. Allow the trap temperature to stabilize before taking reading.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus RSH Series	ITEX Trap Temperature	40 °C	± 5 °C
		300 °C	< 4 mins to reach setpoint

TriPlus 500 Temperature			
The TriPlus 500 Temperature Test verifies the functionality of the sampler heaters. When the sampler module is set to a certain temperature, the displayed temperature should be within specified limits of the set temperature.			
How Test is Performed			
A temperate probe is inserted into a vial (through cap septum) and placed in the sample. Incubation oven temperature is set to appropriate setpoint, and allowed to stabilize. The measured temperature value from thermometer is then compared to set temperature value. Temperature setpoints are entered and allowed to stabilize, readbacks from the instrument are then recorded and compared to limits for loop, sample path (needle) and transfer line (If present) temperatures.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus 500	Incubation Oven Temperature	100 °C	± 4 °C
	Loop Temperature	110 °C	± 2 °C
	Sample Path Temperature		
	Transfer Line Temperature (if present)		

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TriPlus 500 Aux Gas Leak Check			
The Aux Gas Leak Test verifies the auxiliary gas circuit holds a minimum pressure and is not leaking gas.			
How Test is Performed			
With an empty closed vial in position, the automated routine pressurizes the vial to a set point of 200 kPa. After vial pressure is achieved, the automated routing closes the gas valves; the vial pressure should not decrease more than the specified limits over a two-minute interval.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus 500	Aux Gas Leak	200.0 kPa (30.0 psi)	± 10.0 kPa (1.5 psi) over a 2-minute interval

TriPlus 500 Carrier Gas Leak Check			
The Carrier Gas Leak Test verifies the carrier gas circuit holds a minimum pressure and is not leaking gas.			
How Test is Performed			
An automated routing pressurizes the system to a set point of 200 kPa. After pressure is achieved, the automated routing closes the gas valves; the system pressure should not decrease more than the specified limits over a two-minute interval.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus 500	Carrier Gas Leak	200.0 kPa (30.0 psi)	± 10.0 kPa (1.5 psi) over a 2-minute interval

TriPlus 500 Carrier Gas Flow Check (if carrier gas control is present)			
The Carrier Gas Flow check verifies that the system is able to set a certain flow level confirming the proper functionality of the carrier gas control			
How Test is Performed			
Disconnect the transfer line from the injector adapter. From the HS Manual Operations page/ Carrier Control set the system in constant flow mode with a transfer flow setpoint of 20 mL/min. Connect the flowmeter to the transfer line and measure the flow.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus 500	Carrier Gas Flow Check	20 ml/min	± 2 mL/min

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TriPlus 300 Temperature			
The TriPlus 300 Temperature Test verifies the functionality of the sampler heaters. When the sampler module is set to a certain temperature, the displayed temperature should be within specified limits of the set temperature.			
How Test is Performed			
Temperature setpoints are entered and allowed to stabilize, readbacks from the instrument are then recorded and compared to limits.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus 300	Oven Temperature	100 °C	± 4 °C
	Manifold Temperature	110 °C	± 4 °C
	Transfer Line Temperature		± 2 °C

TriPlus 300 Aux Gas Leak Check			
The Aux Gas Leak Test verifies the auxiliary gas circuit holds a minimum pressure and is not leaking gas.			
How Test is Performed			
With an empty closed vial in position, the EV3 valve and the switching valve in the off position and EV1 and the EV2 valves on, the vial pressure is set to 200 kPa. After vial pressure is achieved, the EV1 and EV3 valves are turned to off; the vial pressure should not decrease more than the specified limits over a one-minute interval.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus 300	Aux Gas Leak	200.0 kPa (30.0 psi)	± 10.0 kPa (1.5 psi) over a 1-minute interval

TriPlus 300 Carrier Gas Leak Check			
The Carrier Gas Leak Test verifies the carrier gas circuit holds a minimum pressure and is not leaking gas.			
How Test is Performed			
A manometer is connected to the end of the transfer line; the carrier gas is pressurized to 200 kPa. The carrier gas is turned off and the carrier gas is pressure should not decrease more than the specified limits over a one-minute interval.			
Module	**Test Name**	**Test Point**	**OQ Limits**
TriPlus 300	Carrier Gas Leak	200.0 kPa (30.0 psi)	± 10.0 kPa (1.5 psi) over a 1-minute interval

8 PREPARING THE SYSTEM FOR OPERATIONAL QUALIFICATION

Prior to performing the Operational Qualification, completion of an Installation Qualification and/or preventive maintenance routine is highly recommended. This should include:

- Gas Chromatograph
  - Installation Qualification (for new installations)
  - Preventive Maintenance (for existing instruments)
  - GC Detector Checkout (as applicable)
- Autosampler
  - Installation Qualification (for new installations)
  - Preventive Maintenance (for existing instruments)

8.1 Reporting User Interface

All data and chromatograms for Qualification test results will be summarized in test reports against OQ limits of tolerance. Test reports will be generated using the OQ reporting user interface (RPG Reports) to discern the outcome of each test. In most cases, the project will have already been started with the IQ.

8.1.1 RPG REPORTS 2.X:

1. Open the RPG Reports UI and start a new project (an GCM Systems license must be used for the project).
2. In **Section 1, Settings** configure the following:
   a. Qualification Type: **GC Only (or GCMS Systems if qualifying with an MS)**
   b. Qualification Control Software: **Chromeleon**
3. In **Section 1,** choose the applicable instrument models and complete the rest of the configuration fields.
4. Tests will now be visible in **Section 4: OQ**.

8.1.2 RPG REPORTS 3.X:

1. Open the RPG Reports UI and start a new project (an GCMS Systems license must be activated for the project).
2. The following **Settings** are required before you can proceed:
   a. Group: ***Select applicable TFS Group (e.g., Analytical Instrument Group)***
   b. Service: **IQOQ** or **OQ**
   c. Hardware Configuration: **GC**
   d. Control Software: **Chromeleon** ***& software version (e.g., 7.3)***
3. On the **Settings** screen, you may now specify the components of the system to be tested by moving them from the **Available Modules** to the **Selected Modules** with the arrow button.

   Note: Instrument PC, GC Oven, Inlets, Detectors, Samplers, and RSH Tools are all treated as individual Modules for testing.
4. Click the **Next** button to advance.
5. This will create a report page section for each selected module (with a numeric identifier in case more than one of the same instrument are added).

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6. The individual module details are then completed, and once **Powered On Successfully?** is completed, tests can be selected per each module.

   Note: Recommended tests will already be checked, but this can be modified, multiple copies of a test can also be added (they will receive a similar numeric identifier to allow for adding the additional tests).

7. Selected test pages will be added under the instrument module.
8. **Test Equipment and Standards** and **Protocols** may be identified at this time on the applicable report pages, and any electronic files attached.
9. The project should be saved before then proceeding with testing.

8.2 Chromeleon eWorkflows

Automated tests are run using a pre-defined Chromeleon eWorkflow file. The file contains sequence and processing templates as well as built-in reports for generating chromatograms and exportable data.

8.3 Instrument Method Parameters

Instrument method parameters for the tests can be found in a method reference file. There is a method reference tab for standard injections as well as noise and drift tests. Recommended parameters may be modified as needed to be appropriate for the instrument configuration.

8.4 Importing the eWorkflow(s)

1. Prior to importing the eWorkflow(s), check to ensure that no workflows for GC OQ already exist in Chromeleon. If, workflows for GC OQ already exist in Chromeleon, rename or delete the outdated eWorkflow.
2. From within the RPG Reports UI, select the appropriate eWorkflow(s); i.e., **OQ for GC LS.ewfx**. This will start the import process within Chromeleon.
3. When the eWorkflow import wizard opens, choose the desired Destination data vault and click **Start**.
4. From the eWorkflow tab, select the imported workflow from the left-hand column and the instrument to be tested from the right-hand column; then click **Launch**.
5. When the **Method** window opens, click **Next**.
6. When the **Sampler Configuration** window opens, click **Finish**.
7. Browse to the appropriate location to save the sequence file and click **Finish** (if the name is already in use, Chromeleon will enumerate the sequence name).

   NOTE: Be sure not to run the sequence at this time.

8. Open the **Custom Sequence Variables** tab at the bottom of the sequence page.
9. Manually enter the Qualification Number.
10. Save and close the sequence.
11. Repeat this process for all eWorkflows listed in the RPG Reports UI.

8.5 Creating Instrument Methods

1. Create a **Standard** Instrument Method.
   a. Open the appropriate OQ sequence.
   b. Select Create and Instrument Method.
   c. Click on **Method Reference File** (Section3: FILES in the RPG Reports UI), set the instrument parameters according to the compound tab.

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d. Save this instrument method as the target compound name.

2. Create a **Noise, Drift and Wander** Instrument Method.
   a. Open the appropriate OQ sequence.
   b. Select **Create** and **Instrument Method**.
   c. Using the method reference file, set the instrument parameters according to the Detector Noise and Drift tab.
   d. Save this instrument method as **Noise and Drift**.
3. In the sequence, assign the **Noise and Drift** method to the **Noise and Drift** sample injection. Assign the **compound name** method to all other injections.
4. Create additional methods for additional detectors and/or sampler modes as needed.

9 PERFORMING THE QUALIFICATION – MANUAL TESTS

9.1 GC Oven Temperature Accuracy Test

9.1.1 TEST INSTRUCTIONS

1. Place the temperature probe in the column oven to within 1 cm of the oven sensor.
2. Close the column oven; set the **GC oven temperature** to **40.0 °C**.
3. Allow the temperature to stabilize.
4. Transcribe the temperature value from the digital temperature meter into the corresponding field of the RPG Reports UI.
5. Set the **GC oven temperature** to **120.0 °C**.
6. Allow the temperature to stabilize.
7. Transcribe the temperature value from the digital temperature meter into the corresponding field of the RPG Reports UI.

9.2 Inlet Temperature and Leak Tests

9.2.1 SSL INLET TEMPERATURE TEST INSTRUCTIONS

1. The inlet temperature may be measured through the top or bottom of the inlet.
   a. To measure through the bottom of the inlet (preferred approach), remove the capillary adapter and inlet liner, if installed.
   b. To measure through the top of inlet, remove the septa holder and inlet liner, if installed.
2. Insert the thermocouple probe (0.25 mm diameter) **from the top**, approx. **40 mm** inside the inlet.
3. To approximate the distance, a septum may be attached to the thermocouple wire to mark depth.
4. Set the appropriate **SSL inlet temperature** to **100 °C**.
5. Allow the temperature to stabilize (**wait at least 10 minutes for system thermalization)**.
6. Transcribe the temperature value from the digital temperature meter into the corresponding field of the RPG Reports UI.
7. Repeat these steps for an additional SSL inlet as necessary.

9.2.2 PTV INLET TEMPERATURE TEST INSTRUCTIONS

1. The inlet temperature may be measured through the top or bottom of the inlet.

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a. To measure through the bottom of the inlet (preferred approach), remove the capillary adapter and inlet liner, if installed.

b. To measure through the top of inlet, remove the septa holder and inlet liner, if installed.

2. Insert the thermocouple probe (0.25 mm diameter) approximately **50 mm** inside the inlet.

   a. To approximate the distance, a septum may be attached to the thermocouple wire to mark the depth.

3. Set the appropriate **PTV inlet temperature** to **100 °C**.
4. Allow the temperature to stabilize.
5. Transcribe the temperature value from the digital temperature meter into the corresponding field of the RPG Reports UI.
6. Repeat these steps for an additional PTV inlet as necessary.

9.2.3 INLET LEAK TEST INSTRUCTIONS

1. With the GC powered on, set the **initial oven temperature** to **40 °C**, keeping the door open.
2. Insert a blanking ferrule into the **M4** capillary inlet; attach the nut to the capillary inlet and tighten.
3. In the inlet, install the splitless liner.
4. Tighten the inlet adapter enough to create a seal around the liner.
5. Install a new, unused septum and seal with the septum nut.
6. Set the following for the tested inlet:
   - Inlet for constant pressure at **200 kPa (30 psi)**
   - **Splitless Mode**
   - **Split flow** to **50 mL/min**
   - **Constant septum purge** to **Yes**
7. Run **Leak Check**.
8. Transcribe the pressure value into the corresponding field of the RPG Reports UI.
9. Repeat these steps for an additional inlet as necessary.
10. Set the inlet pressure to **OFF**.

9.3 GC Detector Temperature and Flow Tests

9.3.1 DETECTOR TEMPERATURE TEST INSTRUCTIONS

1. Set the oven temperature to 40 °C.
2. Set the appropriate detector temperature to 120 °C.
3. Allow the temperature to stabilize.
4. Transcribe the temperature value from the displayed temperature into the corresponding field of the RPG Reports UI.
5. Repeat for additional detectors as necessary.

9.3.2 DETECTOR FLOW TEST INSTRUCTIONS

1. If necessary, insert a blanking ferrule into the **M4** capillary inlet nut (attach the nut to the capillary inlet and tighten)

2. Connect the gas flow meter to the measurement port on the detector.
   a. See the Trace 13xx Service Manual section: Measuring the detector gases flow for instructions on connecting flow meter to detector.
3. Energize the GC and make sure that the inlet pressure or flow is off.
4. Set the **oven temperature** to **40 °C**. On the GC display (or control software), access the appropriate detector menu. With all gases off, ensure that there is no gas flow coming out of the detector exit lines.
5. One at a time, set each gas flow to the appropriate test point noted in the following table:

Detector	Gas	Flow Set Point (mL/min)
FID	H_2 Flow	Low: 30.0 High: 60.0
	Air Flow	Low: 90.0 High: 350.0
	Makeup Flow	Low: 13.0 High: 45.0
TCD	Reference Flow	Low: N/A High: 5.0
ECD	Makeup Flow	Low: 13.0 High: 45.0
NPD	H_2 Flow	Low: N/A High: 5.0
	Air Flow	Low: 90.0 High: 300.0
	Makeup Flow	Low: 13.0 High: 45.0
FPD	H_2 Flow	Low: 30.0 High: 100.0
	Air Flow	Low: 90.0 High: 300.0
PDD	Not Tested	

6. Allow the flow to stabilize.
7. Transcribe the Measured (flow meter) and Displayed (GC front panel or control software) flow rate values into the corresponding fields of the RPG Reports UI.
8. Repeat these steps for all applicable detector gases at both High and Low set points.
9. Return each gas setting to the Low flow set point as noted in the above table.
10. Repeat these steps for additional detectors as necessary.

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9.4 Inlet Flow Tests

9.4.1 TEST INSTRUCTIONS

1. Turn on the inlet pressure and configure Inlet for:
   - **Splitless injection**
   - **Split flow** to **60.0 mL/min**
2. Configure the appropriate Carrier to:
   - **Constant flow mode**
   - **Flow to 5.0 mL/min**
3. Turn on the split and septum purge valves.
4. Attach the flow meter to split vent measuring port (front) and allow the flow to stabilize.
5. Transcribe the Split Vent Flow value into the corresponding field of the RPG Reports UI.
6. Configure the appropriate Carrier for:
   - **Constant pressure mode**
   - **Carrier gas pressure to 125 kPa (18 psi)**
7. Attach the flow meter to septum purge measuring port (back) and allow the flow to stabilize.
8. Transcribe the Septum Purge Flow value into the corresponding field of the RPG Reports UI.
9. Repeat these steps for all tests for the additional channel (if installed).
10. Remove the flow measuring adapter and return the system to its previous state.

9.5 Sample Agitator (Incubation Oven) and Heatex Temperature Test (if applicable)

9.5.1 TEST INSTRUCTIONS

1. Using the data system sampler control software, set the **Agitator (or Heatex stirrer) temperature** to **45 °C**.
2. Prepare a water sample by filling a 20-mL vial ¾-full with water.
3. Crimp the septa and cap in place.
4. Using the cutting blade, cut a cross into the septa to allow the temperature probe to pass through it.
5. Place a 20-mL water sample into the vial housing 1 of the incubation oven / Heatex.
6. Insert the thermometer probe:
   a. TriPlus
      i. Close sliding cover of the incubation oven / Heatex.
      ii. Insert the probe into the vial through the hole on top.
      iii. Push the probe to the bottom of the vial.
   b. TriPlus RSH
      i. Insert the probe into the vial with the incubation oven / Heatex cover open.
      ii. Push the probe to the bottom of the vial.

iii. Gently close the incubation oven / Heatex cover; the probe wire will be protruding from the front of the cover.

7. Allow the temperature to stabilize.
8. Connect the probe to thermometer and allow the reading to stabilize.
9. Transcribe the observed temperature value from the thermometer into the corresponding field of the RPG Reports UI.
10. Increase the **Agitator / Heatex temperature** to **90 °C**.
11. Allow the temperature to stabilize.
12. Transcribe the observed temperature value from the thermometer into the corresponding field of the RPG Reports UI.
13. Remove the temperature measuring probe from the vial.
14. Reduce the temperature to ambient temperature.

9.6 Headspace and ITEX Syringe Temperature Test (if applicable)

9.6.1 TEST INSTRUCTIONS

1. TriPlus
   a. Remove the heated syringe assembly from the turret and disassemble it.
   b. Reassemble the heated syringe assembly without the syringe.
   c. Install the heated syringe holder into the turret assembly and secure it.
2. TriPlus RSH
   a. Remove the syringe from the HS/ITEX tool.
   b. Command the sampler to load the HS/ITEX tool.
3. Using the data system sampler control software, set the **HS/ITEX Stand-by Syringe temperature** to **45 °C**.
4. Open the **Sampler Virtual View** window and verify that the actual temperatures reach the set-point.
5. Insert probe:
   a. TriPlus
      i. Insert the temperature probe into the hole in the top of the syringe cover.
      ii. Push the temperature probe all the way to the bottom of the syringe assembly.
      iii. Apply constant pressure to the temperature probe to ensure good contact with the bottom of the heated syringe compartment.
   b. TriPlus RSH

   NOTE: A 40 AWG thermocouple probe is needed to perform this test properly.

      i. With the HS/ITEX tool attached to the sampler arm, insert the temperature probe up into the tool's syringe hole. Removal of the needle guide tip may be necessary in some cases.
      ii. Push the probe further into the tool as necessary.

   NOTE: You can use a septum to keep the probe in position in the middle of the syringe length.
6. Allow the temperature to stabilize.

7. Connect probe to thermometer and allow reading to stabilize.
8. Transcribe the observed temperature value from the thermometer into the corresponding field of the RPG Reports UI.
9. Increase the **Stand-by Syringe temperature** to **90 °C**.
10. Allow the temperature to stabilize.
11. Transcribe the observed temperature value from the thermometer into the corresponding field of the RPG Reports UI.
12. Reduce the temperature to ambient temperature.
13. Reinstall the HS/ITEX syringe into the heater syringe holder / tool.

9.7 Headspace Syringe Gas Flush Check (if applicable)

9.7.1 TEST INSTRUCTIONS

1. By using the **Syringe Flush** direct command, enable the solenoid valve to turn on the syringe purge gas source.
2. On the Pressure Regulator on the back of the autosampler, set the **pressure** as follows:
   - TriPlus = **200 kPa** (30 psi)
   - TriPlus RSH = **50 kPa** (7.25 psi)
3. Allow the system to pressurize for 10 seconds.
   a. TriPlus:
   b. Connect the flow meter to the end of the syringe needle.
4. Measure the flow out of the syringe needle.
5. TriPlus RSH:
   a. Verify that a flow is coming out of the syringe. Check via flow meter if a connection directly to the syringe needle is possible.
6. Transcribe the observed flow value from the meter into the corresponding field of the RPG Reports UI. If the flow exceeds the flowmeter capacity, you can input the maximum value read by the flowmeter into the UI.
7. Return the system to its previous configuration.

9.8 ITEX Trap Temperature Test (if applicable)

9.8.1 TEST INSTRUCTIONS

1. Using the data system sampler control software, set the **ITEX trap temperature** to **40°C**.
2. Open the **Sampler Virtual View** window and verify that the actual temperatures reach the set-point.
3. Allow the temperature to stabilize.
4. Observe the temperature readback from the data system and compare it with the setpoint.
5. Transcribe the observed readback into the corresponding field of the RPG Reports UI.
6. Have a timer ready for use. Set the **ITEX trap temperature** to **300°C** and start the timer.
7. Open the instrument 3d viewer within the data system and measure the time to reach 300°C and stabilize.
8. Record the time elapsed into the corresponding field of the RPG Reports UI.

9.9 TriPlus 500 Temperature Test (if applicable)

9.9.1 TEST INSTRUCTIONS

1. Using the control software or TriPlus 500 Maintenance Tool, set the Set the **TriPlus 500 Loop, Sample Path and Transfer Line** (if present) **Temperature** to **110 °C**.
2. Set the **TriPlus 500 Incubation Oven temperature** to **100 °C**.
3. Place the temperature sensor through the cap and septa and into a 20-mL vial. Use the septa to hold the temperature probe to the middle of the vial.
4. Using the TriPlus 500 Maintenance Tool:
   a. Ensure that the Lifter is lowered (Low).
   b. Ensure that the oven door is closed.
   c. Move the carousel to position 1.
5. Place the vial with the temperature probe in position 1 of the vial carousel, ensure that there is at least 6 inches of available length of temperature probe to be extended into the incubation oven.
6. Using the TriPlus 500 Maintenance Tool:
   a. Place the oven door into the Hold position.
   b. Raise the Loader Lifter (High).
   c. Open the oven door.
   d. Lower the Loader Lifter (Low).
   e. Place the oven door into the Hold position.
7. Allow the Incubation Oven temperature to stabilize.
8. Measure the Incubation Oven temperature and transcribe it into the corresponding field of RPG Reports UI.

   NOTE: Caution the materials removed from oven will be hot!
9. Using the TriPlus 500 Maintenance Tool extract the vial from the incubator oven.
   a. Open the oven door.
   b. Raise the Loader Lifter (High).
   c. Place the oven door into the Hold position.
   d. Lower the Loader Lifter (Low).
   e. Close the oven door.
10. Using the control software or the TriPlus 500 Maintenance Tool, verify that the **Loop temperature** has stabilized and transcribe the value into the corresponding field of RPG Reports UI.
11. Using the control software or the TriPlus 500 Maintenance Tool, verify that the **Sample Path** temperature has stabilized and transcribe the value into the corresponding field of RPG Reports UI.
12. Using the control software or the TriPlus 500 Maintenance Tool, verify that the **Transfer Line** (if present) temperature has stabilized and transcribe the value into the corresponding field of RPG Reports UI.
13. Using the control software or TriPlus 500 Maintenance Tool, set the Set the **TriPlus 500 Loop, Sample Path and Transfer Line Temperature** to **80 °C**.

9.10 TriPlus 500 Aux Gas Leak Test (if applicable)

9.10.1 TEST INSTRUCTIONS

1. Ensure that the **carrier gas pressure** from the source is set to at least **250 kPa (36 psi)**.
2. Using the control software or the TriPlus 500 Maintenance Tool perform the automated leak check using the following parameters:
   a. Leak check time (min): **2 min**
   b. Leak check pressure (kPa): **200 kPa (30 psi)**
   c. Leak check acceptance pressure drop (kPa): **10 kPa (1.5 psi)**
   d. Discharge pressure threshold (kPa): **10 kPa (1.5 psi)**
   e. Discharge timeout (min): **0.2 min**
3. Start the test.
4. At completion of the automated leak test, transcribe the results into the corresponding field of RPG Reports UI.

9.11 TriPlus 500 Carrier Gas Leak Test (if applicable)

9.11.1 TEST INSTRUCTIONS

1. Ensure that the **carrier gas pressure** from the source is set to **250 kPa (36 psi)**.
2. Plug the TriPlus 500 interface with a blind ferrule.
3. Using the control software or the or Trace 13xx front panel, perform the automated injector leak check for the back inlet using the following parameters:
   a. Leak check time/Duration (min): **2 min**
   b. Leak check pressure/Pressure Setpoint (kPa): **200 kPa (30 psi)**
   c. Leak check acceptance pressure drop/Allowed pressure drop (kPa): **10 kPa (1.5 psi)**
4. Start the test.
5. At completion of the automated leak test, transcribe the results into the corresponding field of RPG Reports UI.

9.12 TriPlus 500 Carrier Gas Flow Test (if applicable)

9.12.1 TEST INSTRUCTIONS

1. Disconnect the transfer line from the injector adapter and connect to flowmeter.
2. From the HS Manual Operations page > Carrier Control set the system in **constant flow** mode with a **transfer flow** setpoint of **20 mL/min**.
3. Allow the flow to stabilize.
4. Transcribe the reading into the corresponding field of RPG Reports UI.
5. Reconnect the transfer line to the injector adapter.

9.13 TriPlus 300 Temperature Test (if applicable)

9.13.1 TEST INSTRUCTIONS

1. Set the **TriPlus 300 oven temperature** to **100 °C** (maintenance mode "temp" tab) and select **test**.
2. Allow the temperature to stabilize.
3. Transcribe the displayed temperature (TriPlus 300 front panel or software) value into the corresponding field of the RPG Reports UI.
4. Set the **TriPlus 300 manifold temperature** to **110 °C**.
5. Allow the temperature to stabilize.
6. Transcribe the displayed temperature (TriPlus 300 front panel or software) value into the corresponding field of the RPG Reports UI.
7. Set the **TriPlus 300 transfer line temperature** to **110 °C**.
8. Allow the temperature to stabilize.
9. Transcribe the displayed temperature (TriPlus 300 front panel or software) value into the corresponding field of the RPG Reports UI.

9.14 TriPlus 300 Aux Gas Leak Test (if applicable)

9.14.1 TEST INSTRUCTIONS

1. Ensure that the **carrier gas pressure** from the source is set to at least **250 kPa (36 psi)**.
2. Turn on the supply of gas to the TriPlus 300 and allow the pressure reading to stabilize.
3. Place a clean closed vial onto the vial lifter.
4. Using the maintenance mode (Mov.), press the vial size button in the vial Inserter Lifter section and "down" to lower the vial into the system.
5. Using the clockwise arrow button, move the vial into the sampling position.
6. Select the vial size in the Vial Sampler Lifter section to lift the vial into sample position.
7. Check that valves EV1 and EV2 are ON (valve tab).
8. Check that valve EV3 and the switching valve are OFF.
9. Set the **vial pressure** to **200 kPa (30 psi)** and pressurize the system by selecting the test button.
10. Allow the vial pressure to stabilize.
11. Transcribe the displayed vial pressure (TriPlus 300 front panel or software) value into the corresponding field of the RPG Reports UI.
12. Turn valves EV1 and EV2 to OFF.
13. After a minute, transcribe the displayed vial pressure (TriPlus 300 front panel or software) value into the corresponding field of the RPG Reports UI.

9.15 TriPlus 300 Carrier Gas Leak Test (if applicable)

9.15.1 TEST INSTRUCTIONS

1. Ensure that the **carrier gas pressure** from the source is set to **200 kPa (30 psi)**.
2. Connect the Manometer to the end of the transfer line.

3. Turn on the supply of gas to the TriPlus 300 and allow the pressure reading on the manometer to stabilize.
4. Transcribe the initial displayed pressure reading displayed on the manometer into the corresponding field of the RPG Reports UI.
5. Turn off the supply of gas to the TriPlus 300.
6. After a minute, transcribe the final displayed pressure reading displayed on the manometer into the corresponding field of the RPG Reports UI.

9.16 SPME Fiber Conditioning Station Temperature Test (if applicable)

9.16.1 TEST INSTRUCTIONS

NOTE: A 4 AWG thermocouple probe is needed to perform this test properly.

1. By using the data system sampler control software, set the fiber conditioning station stand-by temperatures to 100 °C.
2. Insert the temperature measuring probe 6 cm into the automatic conditioning channel.
3. Allow the temperature to stabilize.
4. Connect the probe to thermometer and allow the reading to stabilize.
5. Transcribe the observed temperature value from the thermometer into the corresponding field of the RPG Reports UI.
6. Repeat the test, at the same temperature, for the manual conditioning channel.
7. Increase the fiber conditioning station stand-by temperatures to 200 °C.
8. Allow the temperature to stabilize.
9. Once reading stabilizes, transcribe the observed temperature value from the thermometer into the corresponding field of the RPG Reports UI.
10. Repeat the test at the same temperature for the manual conditioning channel.
11. Remove the temperature measuring probe from the conditioning channel.
12. Reduce the stand-by temperature to ambient temperature.

9.17 SPME Fiber Conditioning Station Gas Flush Check (if applicable)

9.17.1 TEST INSTRUCTIONS FOR TRIPLUS CLASSIC

1. De-energize the sampler and remove the turret from the sampler.
2. Re-energize the sampler. (The TriPlus sampler without the turret emits an alarm signal; wait until the stop of the acoustic signal.)
3. Flushing gas test on the automatic channel:
   a. On the Pressure Regulator of the incubation oven, set the **pressure** to:
   b. TriPlus = **200 kPa** (30 psi)
   c. Verify that the fiber conditioning station gas flushing flow is closed by completely rotating the knob clockwise.
   d. Excite the solenoid valve of the fiber conditioning station scrolling a card in proximity of the fiber identification sensor to interrupt its light beam.
   e. Place the flow meter in contact on the outlet of the automatic channel.

f. Transcribe the observed flow value from the meter into the corresponding field of the RPG Reports UI.

4. Flushing gas test on the manual channel:
   a. Open the fiber conditioning station gas flushing flow by completely rotating the knob counterclockwise.
   b. Excite the solenoid valve of the incubation oven scrolling a card in proximity of the oven identification sensor to interrupt its light beam.
   c. Place the flow meter in contact on the outlet of the manual channel.
   d. Transcribe the observed flow value from the meter into the corresponding field of the RPG Reports UI.
5. Return the system to its previous configuration.

9.17.2 TEST INSTRUCTIONS FOR TRIPLUS RSH

1. Set pressure to **100 kPA** (14.5 psi).
2. Press down on the pin to activate flow.
3. Place the flow meter in contact on the outlet of the automatic channel.
4. Transcribe the observed flow value from the meter into the corresponding field of the RPG Reports UI.
5. Repeat these steps for the manual Fiber Conditioning Station option.
6. Return the system to its previous configuration.

10 PERFORMING THE QUALIFICATION – AUTOMATED TESTS

10.1 Sample Preparation – Liquid Samples

10.1.1 FID SAMPLE PREPARATION

1. Add 1.0 mL of a suitable solvent blank to an autosampler vial and label it as **Blank**.
2. Transfer the contents of the 1-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
3. Transfer the contents of the 20-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
4. Transfer the contents of the 100-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
5. Situate the vials into the sampler tray positions listed below.

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Hexane or suitable blanking solvent	Blank
1 µg/mL	2	Hexadecane	FID Linearity Repeatability Syringe Linearity
20 µg/mL	3		
100 µg/mL	4		

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10.1.2 TCD SAMPLE PREPARATION

1. Add 1.0 mL of a suitable solvent blank to an autosampler vial and label it **Blank**.
2. Transfer the contents of the 20-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
3. Transfer the contents of the 100-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
4. Transfer the contents of the 200-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
5. Situate the vials into the sampler tray positions listed below.

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Hexane or suitable blanking solvent	Blank
20 µg/mL	2	Hexadecane	TCD Linearity Repeatability Syringe Linearity
100 µg/mL	3		
200 µg/mL	4		

10.1.3 NPD SAMPLE PREPARATION

1. Add 1.0 mL of a suitable solvent blank to an autosampler vial and label it **Blank**.
2. Transfer the contents of the 100-ng/mL azobenzene / methyl parathion from the test kit into a 2.0-mL screw top vial or similar vessel.
3. Transfer the contents of the 500-ng/mL azobenzene / methyl parathion from the test kit into a 2.0-mL screw top vial or similar vessel.
4. Transfer the contents of the 1000-ng/mL azobenzene / methyl parathion from the test kit into a 2.0-mL screw top vial or similar vessel.
5. Situate the vials into the sampler tray positions listed below.

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	iso-Octane or suitable blanking solvent	Blank
100 ng/mL	2	Azobenzene / Methyl Parathion	NPD Linearity Repeatability Syringe Linearity
500 ng/mL	3		
1000 ng/mL	4		

10.1.4 ECD SAMPLE PREPARATION

1. Add 1.0 mL of a suitable solvent blank to an autosampler vial and label it **Blank**.
2. Transfer the contents of the 10-ng/mL lindane from the test kit into a 2.0-mL screw top vial or similar vessel.
3. Transfer the contents of the 30-ng/mL lindane from the test kit into a 2.0-mL screw top vial or similar vessel.
4. Transfer the contents of the 60-ng/mL lindane from the test kit into a 2.0-mL screw top vial or similar vessel.
5. Situate the vials into the sampler tray positions listed below.

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	iso-Octane or suitable blanking solvent	Blank
10 ng/mL	2	Lindane	ECD Linearity Repeatability Syringe Linearity
30 ng/mL	3		
60 ng/mL	4		

10.1.5 FPD SAMPLE PREPARATION

1. Add 1.0 mL of a suitable solvent blank to an autosampler vial and label it **Blank**.
2. Transfer the contents of the 100-ng/mL azobenzene / methyl parathion from the test kit into a 2.0-mL screw top vial or similar vessel.
3. Transfer the contents of the 500-ng/mL azobenzene / methyl parathion from the test kit into a 2.0-mL screw top vial or similar vessel.
4. Transfer the contents of the 1000-ng/mL azobenzene / methyl parathion from the test kit into a 2.0-mL screw top vial or similar vessel.
5. Situate the vials into the sampler tray positions listed below.

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	iso-Octane or suitable blanking solvent	Blank
100 ng/mL	2	Methyl Parathion	FPD Linearity Repeatability Syringe Linearity
500 ng/mL	3		
1000 ng/mL	4		

10.1.6 PDD SAMPLE PREPARATION

1. Add 1.0 mL of a suitable solvent blank to an autosampler vial and label it as **Blank**.
2. Transfer the contents of the 1-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
3. Transfer the contents of the 20-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.
4. Transfer the contents of the 100-µg/mL hexadecane from the test kit into a 2.0-mL screw top vial or similar vessel.

5. Situate the vials into the sampler tray positions listed below.

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Hexane or suitable blanking solvent	Blank
1 µg/mL	2	Hexadecane	PDD Linearity Repeatability Syringe Linearity
20 µg/mL	3		
100 µg/mL	4		

10.2 Sample Preparation – Headspace Samples

10.2.1 SAMPLE PREPARATION

10.2.1.1 TriPlus 300

1. Prepare eight 20-mL sample vials.
2. The two blank vials are empty capped and placed in position
3. From the chart below identify the proper test mix:

Detector Used	Test Mix	Peak of Interest
FID	FID Test Mix (P/N 33819020)	Hexadecane
TCD	TCD Test Mix (P/N 33819016)	Hexadecane
NPD	NPD Test Mix (P/N 33819006)	Parathion Methyl
ECD	ECD Test Mix (P/N 33819011)	Lindane
FPD	FPD Test Mix (33819006)	Parathion Methyl
PDD	FID Test Mix (P/N 33819020)	Hexadecane

4. Draw 20 µL of test detector specific test mix into the syringe barrel followed by a small air gap (ensure that the syringe needle is empty).
5. Insert the syringe needle into the first 20-mL empty vial.
6. Inject the test mix into the vial, but make sure that the end of the needle touches the internal wall of the vial; cap each vial after preparation.
7. Repeat these steps 3-5 for all vials.

8. Install the eight prepared vials into the sampler tray positions listed below:

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Empty	NDW*
Blank	2	Empty	Blank
(Peak of Interest)	3	(Peak of Interest)	Repeatability
(Peak of Interest)	4		
(Peak of Interest)	5		
(Peak of Interest)	6		
(Peak of Interest)	7		
(Peak of Interest)	8		

***Only used if no LS present.**

10.2.1.2 TriPlus 500 Headspace Samplers

1. Prepare eight 20-mL sample vials.
2. From the chart below identify the proper peak of interest in the Test Mix:

Detector Used	Test Mix	Peak of Interest
FID[1]	TriPlus Headspace Test Mix (P/N 33819024)	Ethanol
TCD		Ethanol
NPD		Nitrobenzene
ECD		1-3 Dichlorobenzene
FPD		Tert-butyl sulfide
PDD		Ethanol

3. The two blank vials are empty capped and placed in position.
4. Using a 5 µL disposable micropipette (PN 36520056), dip to pipette into the TriPlus Headspace Test Mix (P/N 33819024), allow the micropipette to fill completely.

   Note: The samples can also be prepared by using a suitable micro syringe to transfer the 5 µL of the standard.
5. Place the entire micropipette filled with TriPlus Headspace Test Mix into the first 20-mL empty vial and cap the vial.
6. Repeat these steps 3-5 for all vials.

[1] *Supelco E-040-10X1.2ML standard and alternative method can be used in place of PN 33819024 for FID detectors.*

7. Install the eight prepared vials into the sampler tray positions listed below:

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Empty	NDW*
Blank	2	Empty	Blank
Test Mix	3	(Peak of Interest)	Repeatability
Test Mix	4		
Test Mix	5		
Test Mix	6		
Test Mix	7		
Test Mix	8		

***Only used if no LS present.**

10.2.1.3 TriPlus 500 Headspace Samplers (Alternative method for FID detectors only) using Supelco E-040-10X1.2ML standard

1. Prepare eight 20-mL sample vials.
2. The two blank vials are empty capped and placed in position.
3. Draw 1 mL of the Supelco E-040-10X1.2ML standard into the syringe barrel followed by a small air gap (ensure that the syringe needle is empty).
4. Insert the syringe into the first 20-mL empty vial.
5. Inject the test mix into the vial, but make sure that the end of the needle touches the internal wall of the vial; cap each vial after preparation.
6. Repeat these steps 3-5 for all vials.
7. Install the eight prepared vials into the sampler tray positions listed below:

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Empty	NDW*
Blank	2	Empty	Blank
Test Mix	3	(Peak of Interest)	Repeatability
Test Mix	4		
Test Mix	5		
Test Mix	6		
Test Mix	7		
Test Mix	8		

***Only used if no LS present.**

10.2.1.4 TriPlus RSH and Other Headspace Samplers

1. Prepare eleven 20-mL sample vials.
2. From the chart below identify the proper peak of interest in the Test Mix:

Detector Used	Test Mix	Peak of Interest
FID	TriPlus Headspace Test Mix (P/N 33819024)	Ethanol
TCD		Ethanol
NPD		Nitrobenzene
ECD		1-3 Dichlorobenzene
FPD		Tert-butyl sulfide
PDD		Ethanol

3. The two blank vials are empty capped and placed in position
4. Draw 2 µL of TriPlus Headspace Test Mix (P/N 33819024) into the syringe barrel followed by a small air gap (ensure that the syringe needle is empty).
5. Insert the syringe needle into the first 20-mL empty vial.
6. Inject the test mix into the vial, but make sure that the end of the needle touches the internal wall of the vial; cap each vial after preparation.
7. Repeat these steps 3-5 for all vials.
8. Install the eleven prepared vials into the sampler tray positions listed below:

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Empty	NDW*
Blank	2	Empty	Blank
Test Mix	3	(Peak of Interest)	Repeatability Syringe Linearity
Test Mix	4		
Test Mix	5		
Test Mix	6		
Test Mix	7		
Test Mix	8		
Test Mix	9		
Test Mix	10		
Test Mix	11		

***Only used if no LS present.**

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10.3 Sample Preparation – SPME

10.3.1 SAMPLE PREPARATION

1. Prepare eight 20-mL sample vials.
2. From the chart below identify the proper peak of interest in the Test Mix:

Detector Used	Test Mix	Peak of Interest
FID	TriPlus Headspace Test Mix (P/N 33819024)	Ethanol
TCD		Ethanol
NPD		Nitrobenzene
ECD		1-3 Dichlorobenzene
FPD		Tert-butyl sulfide
PDD		Ethanol

3. The two blank vials are empty capped and placed in position
4. Draw 2 µL of TriPlus Headspace Test Mix (P/N 33819024) into the syringe barrel followed by a small air gap (ensure that the syringe needle is empty).
5. Insert the syringe needle into the first 20-mL empty vial.
6. Inject the test mix into the vial, but make sure that the end of the needle touches the internal wall of the vial; cap each vial after preparation.
7. Repeat these steps 3-5 for all vials.
8. Install the eight prepared vials into the sampler tray positions listed below:

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Empty	NDW*
Blank	2	Empty	Blank
Test Mix	3	(Peak of Interest)	Repeatability
Test Mix	4		
Test Mix	5		
Test Mix	6		
Test Mix	7		
Test Mix	8		

***Only used if no other sampler is present.**

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10.4 Sample Preparation – ITEX

10.4.1 SAMPLE PREPARATION

1. Prepare eight 20-mL sample vials, six standards and two blanks.
2. From the chart below identify the proper peak of interest in the Test Mix:

Detector Used	Test Mix	Peak of Interest
FID	TriPlus Headspace Test Mix (P/N 33819024)	1,3 - Dichlorobenzene

3. Cap the blanks and place it in position 1 in the autosampler tray.
4. Use a 5-µL disposable micropipette (PN 36520056): dip the pipette tip into the test solution and allow the micropipette to fill completely.
5. Place the entire micropipette filled with the test solution into an empty vial and cap the vial.
6. Repeat steps 4-5 for all remaining vials.
7. Place the vials containing the test solutions in positions 2-7 of the autosampler tray.

Vial Label	Recommended Autosampler Position	Sample	Test
Blank	1	Empty	NDW*
Blank	2	Empty	Blank
Test Mix	3	1,3 - DCB	Repeatability
Test Mix	4		
Test Mix	5		
Test Mix	6		
Test Mix	7		
Test Mix	8		

***Only used if no other sampler is present.**

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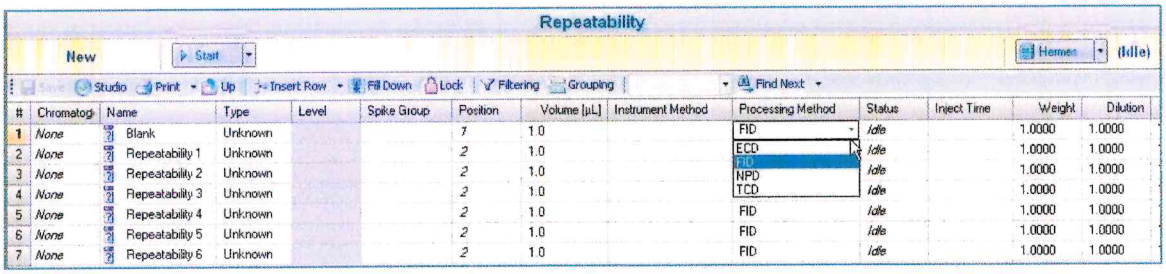
10.5 Running the Automated Tests

10.5.1 LIQUID SAMPLERS

10.5.1.1 Preparing the System

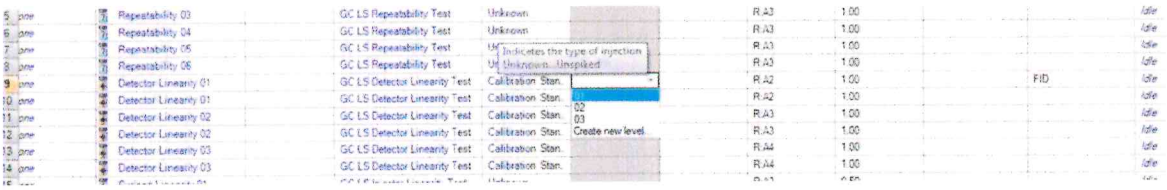
1. Install the **TR-5** test column for splitless injection as described in the Trace GC Series Standard Operating Procedures.
2. Perform a column evaluation and verify that it completes successfully.
3. Turn the detector flame on (if applicable).
4. Increase the **oven temperature** to **230 °C**.
5. Allow the column to bake out for 30 minutes.
6. After bakeout, set the **oven temperature** to **50 °C** and set the **initial time** to **40 min** (Ramp Off).
7. Ensure that all blank samples and standards are loaded into the sampler tray at the appropriate position as specified in the sequence.
8. In the **Processing Method** column of the displayed sequence, choose the appropriate processing method from the given list for all samples.

   NOTE: The processing method should be selected for every sample in the sequence, regardless of test.



#	Chromatogr	Name	Type	Level	Spike Group	Position	Volume [µL]	Instrument Method	Processing Method	Status	Inject Time	Weight	Dilution
1	None	Blank	Unknown			1	1.0		FID	Idle		1.0000	1.0000
2	None	Repeatability 1	Unknown			2	1.0		ECD	Idle		1.0000	1.0000
3	None	Repeatability 2	Unknown			2	1.0		FID	Idle		1.0000	1.0000
4	None	Repeatability 3	Unknown			2	1.0		NPD	Idle		1.0000	1.0000
5	None	Repeatability 4	Unknown			2	1.0		TCD	Idle		1.0000	1.0000
6	None	Repeatability 5	Unknown			2	1.0		FID	Idle		1.0000	1.0000
7	None	Repeatability 6	Unknown			2	1.0		FID	Idle		1.0000	1.0000

9. In the **Instrument Method** column of the displayed sequence, choose the appropriate instrument method for each injection.
10. Verify that the vial position, type and injection volume information is correct for each injection and save the sequence.
11. For Detector Linearity samples, verify that the type is set to **Calibration Standard** and be sure to select the appropriate levels (01-03) as defined in the applicable, detector-specific, processing method.



10.5.1.2 Running the Sequences

1. Select the appropriate sequence and add it to the instrument queue.
2. Open the **Instrument View** window and display the **Queue** tab. As soon as the queue has started, Chromeleon will run the sequence.
3. When acquisition has completed, double-click on the samples to view the data in the Chromeleon Studio.
4. If necessary, edit the integration parameters in the processing method to optimize for peak detection on the following components:

Detector Used	Peak of Interest
FID	Hexadecane
TCD	Hexadecane
NPD	Parathion Methyl
ECD	Lindane
FPD	Parathion Methyl
PDD	Hexadecane

5. Repeat these steps for any additional liquid samplers, if installed.

10.5.2 HEADSPACE / SPME / ITEX SAMPLERS

10.5.2.1 Preparing the System

1. Install the **TR-5** headspace test column (TriPlus 300/500 and ITEX) or **TR-5MS** (other HS and SPME samplers) as described in the Trace GC Series Standard Operating Procedures; perform an evaluation, and bake out for 30 minutes at **230 °C**.
2. In the **Processing Method** column of the displayed sequence, verify that an appropriate processing method has been specified.

   NOTE: The processing method should be selected for every sample in the sequence, regardless of test.
3. In the **Instrument Method** column of the displayed sequence, choose the appropriate instrument method for each injection.
4. Verify that the vial position, type and injection volume information is correct for each injection and save the sequence.
5. For Detector Linearity samples, verify that the type is set to **Calibration Standard** and be sure to select the appropriate levels (01-03) as defined in the applicable, detector-specific, processing method.

10.5.2.2 Running the Sequences

1. Select the appropriate sequence and add it to the instrument queue.
2. Open the **Instrument View** window and display the **Queue** tab. As soon as the queue has started, Chromeleon will run the sequence.
3. When acquisition has completed, double-click on the samples to view the data in the Chromeleon Studio.
4. If necessary, edit the integration parameters in the processing method to optimize for peak detection for the peak of interest.

5. Repeat these steps for any additional samplers, if installed.

11 EVALUATING THE TEST SEQUENCES

11.1 Review

1. Review each chromatogram to ensure that the standard peak has been properly identified and integrated. Processing parameters may need to be updated to ensure proper standard integration.
2. Some reports may need editing. To edit any report, open the report, remove the protection (if any), make the appropriate edits or record entries, and then save the report to incorporate customer specific information.
3. If any samples were re-run for any reason and should not be used in the final OQ analysis, they must be marked with an X in the **Do Not Use** column of the sample sequence. This may occur if a test needed to be re-run. The **Do Not Use** column of the sequence can be displayed by moving the **Do Not Use** column to the visible sequence columns. By placing an X in the **Do Not Use** column, the data will not be exported to the RPG Reports UI for analysis of the final OQ results.

11.2 Exporting the Data

11.2.1 EXPORTING THE NOISE DRIFT WANDER DATA

1. Open the Noise and Drift sample chromatogram in the **Chromeleon Console**.
2. In the chromatogram window, right-click and select **Export Chromatogram (Text format)**.
3. Select the destination file location and select the option for **Raw Data**, and select **OK**.

11.2.2 EXPORTING THE STANDARD INJECTION DATA

1. Open the OQ sequence view.
2. Select the sequence in the **Data** column.
3. Right-click and select **Export**.
4. Use the following export settings:
   a. Use report template: **smaRT Export**
   b. With selected channel: **(Specific Detector)**
   c. Parent Folder: **Select OQ data folder**
   d. Export Formats and Filenames: **Text format (Results)(*.txt)**
5. Click **OK**.

11.3 Importing the Data into RPG Reports

11.3.1 RPG REPORTS 2.X

Noise Drift And Wander Tests:

1. In section 4 of the RPG Reports UI, click the **Noise Drift and Wander** section.
2. Complete any necessary system/detector information fields.
3. Using the export file created from the **Noise Drift and Wander** test, load the XY data and set the column filters for **Time** and **Detector Signal** (*typically columns A and C*).
4. **Apply** the filter and wait for the values to be confirmed in the lower left-hand portion of the Data Filter screen, before clicking **Continue**.
5. Click the **Evaluate** button to evaluate the results.

Standard Injection Tests:

1. In section 4 of the RPG Reports UI, click the **Repeatability** section.
2. Complete any necessary system/detector information fields.
3. Using the smaRT export file created, load the peak data, and set the filters for **Sample Name, Injection Volume, Retention Time,** and **Peak Area**.

   The **Data Filter Column Designator** should be set to the **smaRT** column with the **Filter Criteria** using **R** (in order to filter just the Repeatability samples).
4. **Apply** the filter and wait for the values to be confirmed in the lower left-hand portion of the Data Filter screen, before clicking **Continue**.
5. Repeat the process for the remaining Standard Injection Tests (as applicable): **Detector Linearity, and Syringe Linearity**.

11.3.2 RPG REPORTS 3.X

Noise Drift And Wander Tests:

1. In the RPG Reports project, select the test **Noise Drift and Wander** report page.
2. For **Test Configuration** select the configuration (**e.g., Default**) to populate the limits.
3. For **Data Entry Mode** select **Import** as the data will be imported from the export file created earlier.
4. Click the **Import Test Data** button and browse to the Noise and Drift qualification data file that was exported from the CDS for the test (typically .txt file format).
5. Complete **Time** and **Signal** filter settings for the imported Data (*typically columns A and C*), ensuring to set a Conversion factor if raw detector units are different from the defined limits (Default conversion is 1).

   The **Data Filter Column Designator** should be set to column **A** with the default **Filter Criteria** (numeric).

   Note: Filters must be applied ensure the proper data is used from the file. The Reset button can be used to change the filter.
6. **Apply** the filter and confirm the data is properly adjusted, then click **Continue**.
7. Select **Run Test** to process the results.
8. Add comments, as necessary.

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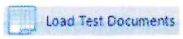
Standard Injection Tests:

1. Open the **Repeatability** report page.
2. For **Test Configuration** select the configuration (**based on injection type**) to populate the limits.
3. For **Data Entry Mode** select **Import** as the data will be imported from the export file created earlier.
4. Click the **Import Test Data** button and browse to the smaRT export file created earlier (typically .txt file format).
5. Complete the **Sample Name, Injection Volume, Retention Time,** and **Peak Area** filter settings for the imported Data.

   The **Data Filter Column Designator** should be set to the **smaRT** column with the **Filter Criteria** using **R** (in order to filter just the Repeatability samples).

   Note: Filters must be applied ensure the proper data is used from the file. The Reset button can be used to change the filter.
6. **Apply** the filter and confirm the data is properly adjusted, then click **Continue**.
7. Select **Run Test** to process the results.
8. Add comments, as necessary.
9. Repeat the process for the remaining Standard Injection Tests (as applicable): **Detector Linearity, and Syringe Linearity**.

   If an imported test fails, a report for that individual test should be created for the qualification packet, and a note made to the Exceptions and Comments. After remediation, additional data may be imported into RPG Reports.
10. If the test is fully reported in Chromeleon, for **Data Entry Mode** select **Results Only** as there is no Data to import. The Empower report is then attached to the test Page using the the **Load Test Documents** button. 

11. .Save the RPG Reports Projects before closing.

12 EXCEPTIONS AND COMMENTS

If an exception is made during the qualification, the exception must be recorded in the appropriate **Comments** section of the Qualification Checklist or RPG Reports UI.

12.1 What to do if a Test Fails

If at any point the instrument results do not pass within the specified limits, the instrument must be serviced and repaired. It is necessary to notify the customer that the system has failed a test and discuss the next steps, as the customer may have internal documentation to be completed detailing the repair. The appropriate hardware or service guide for the instrument may need to be referenced to return the instrument to operation. Once the repair has been completed, all applicable tests we need to be carried out. The failing and passing data or result report must be kept as part of the Qualification record.

All actions for failures and repairs should be recorded on the Comments section of the Qualification Checklist or in the RPG Reports UI.

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13 QUALIFICATION REVIEW

The Service Representative must review all data and results and confirm whether each Qualification Test, and the overall qualification, has **Passed** or **Failed**. These results must be documented on generated Operational Qualification Reports or Checklists.

The Service Representative must indicate on the **OQ Review and Completion** and/or **Service Review and Completion** section of the RPG Reports UI that the Overall Operational Qualification is complete.

14 PRINTING AND SAVING QUALIFICATION DATA

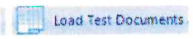
Ensure that all supporting data, chromatograms, and reports have been printed from the CDS. Ensure that all qualification test reports have been printed. If reporting is electronic, ensure all materials have been generated in a suitable file format (e.g., PDF).

Save to a storage device or other specified media or location all qualification related data and files that may have been created during the qualification process; this is an optional convenience for the customer.

14.1 Generating the Qualification Report in RPG Reports 2

1. Evaluate and review all applicable reports in the RPG Reports UI (Section 5: FINISH).
2. In the **Print/Publish** screen, move and arrange the desired reports from the **Available** list-box to the **Selected** list-box; click **Create PDF**.
3. Be sure to attach all CDS Reports to the Qualification Packet.

14.2 Generating the Qualification Report in RPG Reports 3

1. Attach the certificates in the **Test Equipment and Standards** section. PDF copies can be attached directly to the appropriate sections in the RPG Reports UI.
   a. FSE Certificate
   b. Tool Certificates
   c. Reagents Certificates
2. Procedures can be attached using the **Protocols** section (Note: this can drastically increase the size of the final report).
3. External CDS Reports should be attached to the applicable test page using the **Load Test Documents** button. 

4. Ensure the pages required are all selected, and that the content and order of the pages is correct.
5. The PDF Viewer button in the tool bar will allow you to see the final PDF report.
6. Select the number of signatures and signoff preference for the report:
   a. Use Digital Signature (allows to attach a digital signature to the final PDF through Acrobat, signatures can be applied to electronic report after it is Submitted)
   b. Use Pad Signature (allows to sign the report in the RPG Reports application using a signature pad, this must be done before Submitting the Report)
   c. Manual Signature (spaces for handwritten signatures will be added to the final report, this requires printing)
7. Select **Finalize Report** to complete the report and remove the watermark (**Open Report** option will allow you to go back and make changes).

   You may then go to **File > Print** and either print the report to paper or save to PDF for electronic distribution.

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15 BUILDING THE QUALIFICATION PACKAGE

1. Place all documentation in the appropriate section of the printed qualification binder/folder (paper documentation) or organize accordingly in the appropriate electronic storage location (electronic eBinder documentation).

   NOTE: Alternative / customer-oriented document storage is allowed.

2. Documentation required as follows (as applicable):
   - Hardware Installation Qualification Procedure
   - Software Installation Qualification Procedure
   - Hardware / Software Installation Qualification Reports/Checklists
   - Hardware Installation Qualification Data System Generated Test Reports
   - Hardware / Software Operational Qualification Procedure
   - Hardware / Software Operational Qualification Reports/Checklists
   - Hardware Operational Qualification Data System Generated Test Reports
   - Qualification Service Representative's Training Certificates
   - Test Equipment Certificates and Chemical standards Certificate(s) of Analysis
   - Any Additional Supplementary Documentation (e.g., Deviation Memo)
3. Complete the information on the qualification stickers, seal, and place a sticker on each of the following:
   - Qualification binder spine or folder (if paper is used, for component serial number, write Qual Package).
   - Each main system component that was qualified.
4. Complete the information on the qualification stickers, seal, and place a sticker on each of the following:
   - Qualification binder spine or folder (if paper is used, for component serial number, write Qual Packet).
   - Each main system component that was qualified.

16 QUALIFICATION COMPLETION AND REVIEW WITH CUSTOMER

The Service Representative must sign and date the qualification results (electronically or pen and ink). It is important that all qualification attachments have been properly labeled, initialed, and dated (as applicable).

It is critical the final Qualification Package be reviewed with the customer as the final step in completing the Qualification. The customer can perform any reviewer signoffs at this time. This will help educate the customer on the work performed, allow any questions to be answered, and help prevent return visits.

After qualification, ensure the system is left in an appropriate state for the customer. This includes setting applicable modules into a standby (or off) status, removing any test columns, replacing any solvents, and disposing of any standard vials accordingly.

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