

Synektik Pharma	FORMULARZ	Dokument nr: KLC F.163.U. Wersja 1 Ważna od: 17.01.2022 Zatwierdził: 
	Zatwierdzenie protokołu/ raportu z kwalifikacji urządzenia/systemu przed i po wykonaniu działań kwalifikacyjnych	Strona : 1 Strony : 1
		Zastępuje: Wersję - Ważną od: dd.mm.rrr Ważną do: dd.mm.rrr

Nazwa urządzenia/ systemu	HLC Agilent Infinity 1260
Nr inwentaryzacyjny	KLC0001-2., KLC0001-3., KLC0001-4., KLC0001-8.
Nr protokołu/ raportu	KLC AP9.2.60.02.13

ZATWIERDZENIE PROTOKOŁU PRZED WYKONANIEM KWALIFIKACJI

<i>Przed rozpoczęciem działań kwalifikacyjnych testy zaproponowane przez wykonawcę kwalifikacji zostały zaakceptowane. Dokumentacja kwalifikacyjna sporządzona na wzorach wykonawcy prac kwalifikacyjnych.</i>	
Uwagi:	
Data zatwierdzenia protokołu:	08.08.2024
Podpis osoby zatwierdzającej protokół:	

ZATWIERDZENIE PROTOKOŁU/RAPORTU PO WYKONANIU KWALIFIKACJI

<i>Po wykonaniu działań kwalifikacyjnych wyniki z przeprowadzonych testów zostały zaakceptowane. Urządzenie/ system został dopuszczony do stosowania zgodnie z jego przeznaczeniem.</i>	
Uwagi:	
Data zatwierdzenia protokołu/raportu:	09.08.2024
Podpis osoby zatwierdzającej protokół/raport:	

Opracował: 



Agilent CrossLab Compliance

Qualification Type:	LC-OQ
System ID:	KLC0004
EQP Name:	AgilentRecommended
EQP Revision:	LC.02.61
EQP Publish Date:	April 2023
Date:	August 9, 2024 1:45:42 PM
Report Type:	Report with Certificate
Org. Name:	Synektik Pharma Sp. z o.o.
Org. Location:	Artwinskiego 3, 25-734 Kielce

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Test Summary

Purpose

This section includes the Overall Qualification Status and details for each test that meets at least one of the following criteria: (1) was not scheduled; (2) was scheduled but not run; (3) was processed more than once; (4) passed recommended limits only when dual limits were selected; (5) required deviation(s) or comment(s); (6) required integration event change(s). Tests that pass and do not meet any criteria above are not included.

For a complete list of scheduled tests, see the table of contents. For supporting documentation, refer to the Attachments section.

NOTE: A Pass for the Overall Qualification Status indicates that all scheduled tests were run and passed; R, I, D, and C are blank if not applicable for that specific test.

R: runs

I: integration event changes

D: number of deviations submitted

C: number of comments submitted

Status: NS (not scheduled); NR (scheduled but not run); NC (unlocked but not completed)

Details

Test	Status			
	R	I	D	C
Injection Carry Over : Injectors 1, G1328C - G1314F, UV or UV-Vis	Pass			
	1	4		
Response Linearity : Detectors 1, G1314F, UV or UV-Vis	Pass			
	1	2		
Overall Qualification Status				
Pass				

Service Details

Purpose

This section includes local contact and delivery details for this service.

General Details

Service Order No./Request:	INC-2411979
EQP Name:	AgilentRecommended
EQP Revision:	LC.02.61
Report Type:	Report with Certificate

Organization Details

Name:	Synektik Pharma Sp. z o.o.
Location:	Artwinskiego 3, 25-734 Kielce

Local Contact Details

Name:	Monika Baran
Job Title:	Kierownik KJ
Qualification Location:	Laboratorium KJ

Operator Details

Name:	Sebastian Nowak
Job Title:	FSE

Data Acquisition Details

Acquisition Software Name:	OpenLAB CDS
Acquisition Software Revision:	2.4
Customer Data System (CDS):	Lc: OpenLAB CDS

Instrument Details

Purpose

This section describes the as found system configuration.

Details

System

System ID	KLC0004
Manufacturer	Agilent Technologies
System Scale	Analytical
Flow Data Input	Manual Data
Temperature Data Input	Manual Data or Other Data Logging
Typical System Pressure	UHPLC (> 400 bar)

Pumps 1

Manufacturer	Agilent Technologies
Name	1260
Model Number	G1311B
Scale	Analytical
Gradient Capability	Quaternary
Gradient Valve	Installed
Inlet Valve Type	PIV
Installed Options	Seal Wash
Serial Number	DEAB702535
Firmware Revision	A.06.33
Internal Degasser	Installed

Injectors 1

Manufacturer	Agilent Technologies
Name	1260
Model Number	G1328C
Maximum Injection Volume	20 ul
Serial Number	DEABG00847

Detectors 1

Manufacturer	Agilent Technologies
Detector Type	UV or UV-Vis
Name	1260
Model Number	G1314F
UV Detector Detail	Variable wavelength
Flow Cell	Standard
Serial Number	DEABB01463
Firmware Revision	B.07.28

Detectors 2

Manufacturer	Agilent Technologies
Detector Type	RID
Name	1260
Model Number	G1362A
Flow Cell	Standard
Serial Number	DEAA601257
Firmware Revision	A.06.32

Calculation Formulas

Purpose

This section includes calculation formulas for all available tests. Depending upon which tests are scheduled, all or some apply to your qualification.

Absolute Accuracy $ (X_{av} - X_{set}) $	X_{av} = Mean value X_{set} = Setpoint
% Absolute Accuracy $\frac{ (X_{av} - X_{set}) }{X_{set}} \times 100$	X_{av} = Mean value X_{set} = Setpoint
Accuracy $(X_{av} - X_{set})$	X_{av} = Mean value X_{set} = Setpoint
Average (mean of n observations) $\frac{1}{n} \sum_{i=1}^n X_i$	X_i = Value, i^{th} observation n = Total number of observations
Average Area (Corrected) $X \times \frac{C_{nom}}{C_{assay}} \times \frac{10}{Z} \times A$	X = Average area (counts) C_{nom} = Nominal concentration C_{assay} = Assay concentration Z = Path length (mm) A = Attenuation (units/mV)
% Carry Over (Analytical non-UV-Vis; prep UV-Vis) $\frac{(X_{post} - X_{pre})}{(X_s - X_{pre})} \times 100$	X_{post} = Response of blank injection after final standard injection X_{pre} = Response of blank injection before final standard injection X_s = Response of final standard injection
% Carry Over (Analytical UV-Vis) $\frac{X_b}{X_s} \times 100$	X_b = Response of blank injection X_s = Response of final standard injection

Coefficient of Determination r^2 r = Correlation**% Composition (at point i)**

$$\frac{(X_i - X_{min})}{(X_{max} - X_{min})} \times 100$$

 X_i = Signal at point i X_{min} = Mean signal where value represents 0.0% X_{max} = Mean signal where value represents 100.0%**% Composition Noise**

$$\frac{Noise_{step}}{(H_{100\%} - H_{0\%})} \times 100$$

 $Noise_{step}$ = Step noise $H_{100\%}$ = Height at the 100% step $H_{0\%}$ = Height at the 0% step**% Composition Drift**

$$\frac{Drift_{step} \times (T_{stop} - T_{start})}{H_{100\%} - H_{0\%}} \times 100$$

 $Drift_{step}$ = Step drift T_{stop} = Step stop time T_{start} = Step start time $H_{100\%}$ = Height at the 100% step $H_{0\%}$ = Height at the 0% step**Correlation (r)**

$$\frac{1}{\sqrt{\Delta_X \Delta_Y}} \times \left(n \sum_{i=1}^n X_i Y_i - \sum_{i=1}^n X_i \sum_{i=1}^n Y_i \right)$$

 n = Number of data points X_i = X value i^{th} point Y_i = Y value of i^{th} point

$$\Delta_X = n \sum_{i=1}^n X_i^2 - \left(\sum_{i=1}^n X_i \right)^2$$

$$\Delta_Y = n \sum_{i=1}^n Y_i^2 - \left(\sum_{i=1}^n Y_i \right)^2$$

Delay Volume

$$(X - Y) \times Z$$

 X = Calculated start of composition step Y = Set start of composition step Z = Flow rate**Dwell Volume**

$$(T_x - T_0) \times Z$$

 T_0 = Set time of changing gradient mix T_x = Time to reach x% of composition Z = Flow rate**Drift (slope of the regression)**

$$\frac{1}{\Delta_X} \left(n \sum_{i=1}^n X_i Y_i - \sum_{i=1}^n X_i \sum_{i=1}^n Y_i \right)$$

$$\Delta_X = n \sum_{i=1}^n X_i^2 - \left(\sum_{i=1}^n X_i \right)^2$$

 n = Number of data points X_i = Time, i^{th} observation Y_i = Response, i^{th} observation**Noise (ASTM)**

$$\frac{\sum_{m=1}^n X_{PtoPm}}{n}$$

 X_{PtoPm} = Peak to peak noise in segment m n = Number of segments**Noise (Peak to Peak)**

$$(Y_{\max k} - Y_{\text{drift } k}) - (Y_{\min l} - Y_{\text{drift } l})$$

 $Y_{\max k}$ = Response of noise peak k with maximum positive displacement from drift line $Y_{\text{drift } k}$ = Response of drift line for peak k $Y_{\min l}$ = Response of noise peak l with maximum negative displacement from drift line $Y_{\text{drift } l}$ = Response of drift line for peak l **Noise (Six Sigma)**

$$6 \times SD$$

 SD = Standard deviation

Peak to Peak Ratio

$$\frac{\left(A_x \times \frac{C_{\text{nominal } x}}{C_{\text{assay } x}}\right)}{\left(A_1 \times \frac{C_{\text{nominal } 1}}{C_{\text{assay } 1}}\right)}$$

 A_x = Area of peak 2, 3, or 5 $C_{\text{nominal } x}$ = Nominal concentration of standard X $C_{\text{assay } x}$ = Assay concentration of standard X $C_{\text{nominal } 1}$ = Nominal concentration of standard 1 $C_{\text{assay } 1}$ = Assay concentration of standard 1**Relative Standard Deviation (%RSD)**

$$\frac{SD}{X_{av}} \times 100$$

 SD = Standard deviation X_{av} = Mean value of observations**Response Factor**

$$\frac{Y}{X}$$

 X = Amount Y = Response**Stability**

$$|(Y_{\text{max}} - Y_{\text{min}})|$$

 Y_{max} = Maximum value Y_{min} = Minimum value**Standard Deviation (SD)**

$$\sqrt{\frac{1}{(n-1)} \sum_{i=1}^n (X_i - X_{av})^2}$$

 X_i = Value, i^{th} observation X_{av} = Mean value of n observations n = Total number of observations**Parts Per Million (ppm)**

$$\frac{(M_r - M_t)}{M_t} \times 1,000,000$$

 M_r = Reported mass M_t = Theoretical mass

NOTE: For many tests performed by the Automated Compliance Engine multi-step calculations are employed to reduce the raw data to a report ready form. These calculations retain the full precision of each intermediate result as the algorithm progresses through the required reduction. Where intermediated or metadata is displayed, these results must be rounded or truncated to provide the proper display values. Attempting to calculate the final value based on these display modified intermediates can result in a small difference in the final result. These intermediates, where presented, are simply used to show algorithmic progress through the calculation and not intended to act as a means of algorithmic validation. Beginning with LC.01.91, results are rounded to use the same number of decimal places as defined in the limit, which must be less than or equal to the resolution provided by the measuring equipment.

Protocol Details

Purpose

This section lists the revisions for all test units used in this report. For complete test-specific and high-level change details, refer to the Revision History document.

Test Revision	Test
LC.02.55	CDS Logon Verification - LC
LC.02.61	Gradient Composition
LC.02.60	Injection Carry Over
LC.02.60	Injection Precision
LC.02.60	Noise and Drift
LC.02.52	Pump Flow Accuracy
LC.02.52	Pump Flow Precision
LC.02.60	Response Linearity
LC.02.60	Scouting Run
LC.02.60	Signal To Noise
LC.02.60	Wavelength Accuracy

CDS Logon Verification - LC

Purpose

This test provides evidence of the logon used to collect qualification data.

Logon:

oqadmin

Results

Criteria	Observed Result	Expected Result	Status
Was the capture done?	Yes	Yes	Pass

Status:

Pass

Runs: 1

Test Evidence

Image Details:

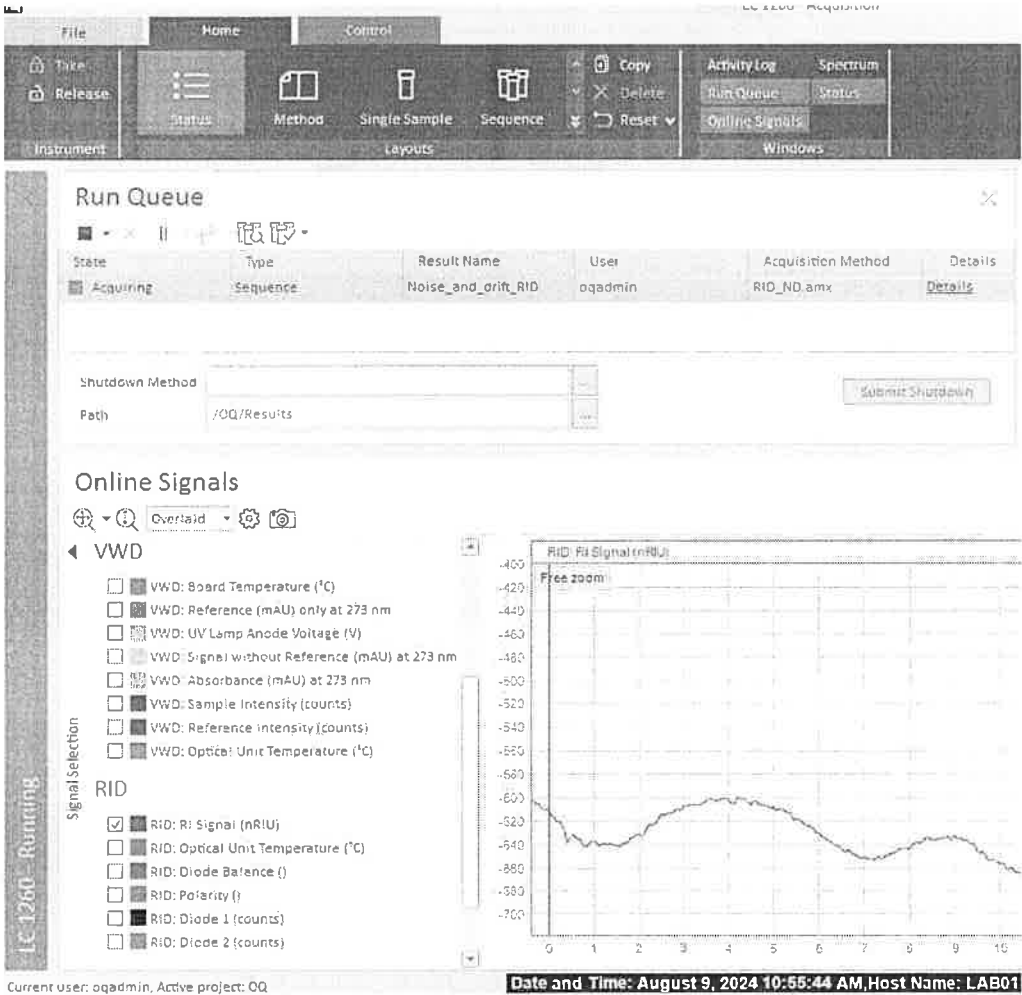
CDS Logon

Date and Time:

August 9, 2024 10:55:44 AM

Host Name:

LAB01



Overall CDS Logon Verification - LC Test Status

Pass

Pump Flow Accuracy

Purpose

This test uses a calibrated digital flowmeter to determine the accuracy of solvent flow rate. Flow accuracy is calculated as the absolute % difference of the mean of the six flow readings and the setpoint.

Configuration Details

Model/Serial No.: G1311B DEAB702535

Setpoint Pump Flow Rate: 0.500 mL/min

Conditions

Channel: A

Measurements

Flow

1.	0.500 mL/min	3.	0.500 mL/min	5.	0.500 mL/min
2.	0.500	4.	0.501	6.	0.500

Results

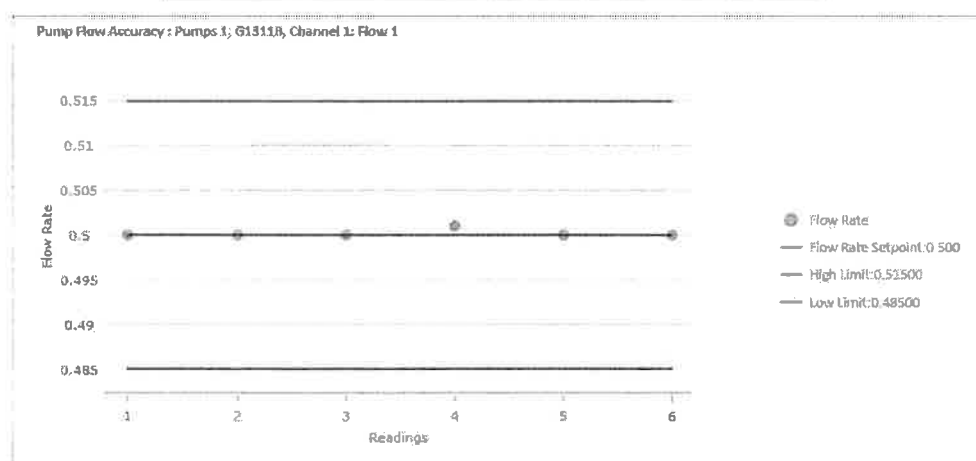
Average: 0.50017 mL/min

Accuracy (as % error): 0.03 %

Agilent Recommended: <= 3.00

Setpoint Status: Pass

Runs: 1



Setpoint Pump Flow Rate: 5.000 mL/min

Conditions

Channel: A

Measurements

Flow

1.	5.004	mL/min	3.	4.992	mL/min	5.	4.998	mL/min
2.	5.007		4.	5.012		6.	5.006	

Results

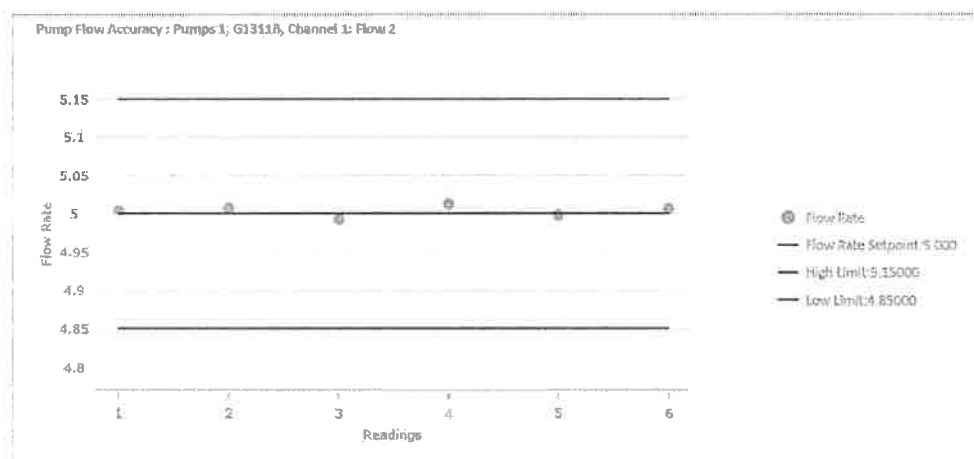
Average: 5.00317 mL/min

Accuracy (as % error): 0.06 %

Agilent Recommended: ≤ 3.00

Setpoint Status: Pass

Runs: 1

**Overall Pump Flow Accuracy Test Status**

Pass

Pump Flow Precision

Purpose

This test uses a calibrated digital flowmeter to determine the precision of solvent flow rate. Flow precision is calculated as the %RSD of the six flow readings.

Configuration Details

Model/Serial No.:

G1311B

DEAB702535

Setpoint

Pump Flow Rate:

0.500

mL/min

Conditions

Channel:

A

Measurements

Flow

1. 0.500 mL/min

3. 0.500 mL/min

5. 0.500 mL/min

2. 0.500

4. 0.501

6. 0.500

Results

Average:

0.50017

mL/min

STD Deviation:

0.00041

Precision RSD:

0.08

%

Agilent Recommended:

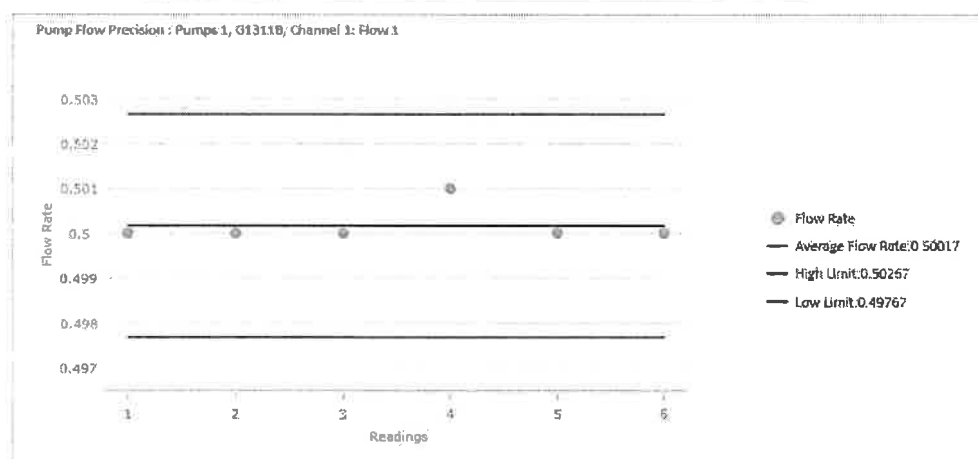
<=

0.50

Setpoint Status:

Pass

Runs: 1



Date:

August 9, 2024 1:45:42 PM

System ID:

KLC0004

Setpoint Pump Flow Rate: 5.000 mL/min

Conditions

Channel: A

Measurements

Flow

1.	5.004	mL/min	3.	4.992	mL/min	5.	4.998	mL/min
2.	5.007		4.	5.012		6.	5.006	

Results

Average: 5.00317 mL/min

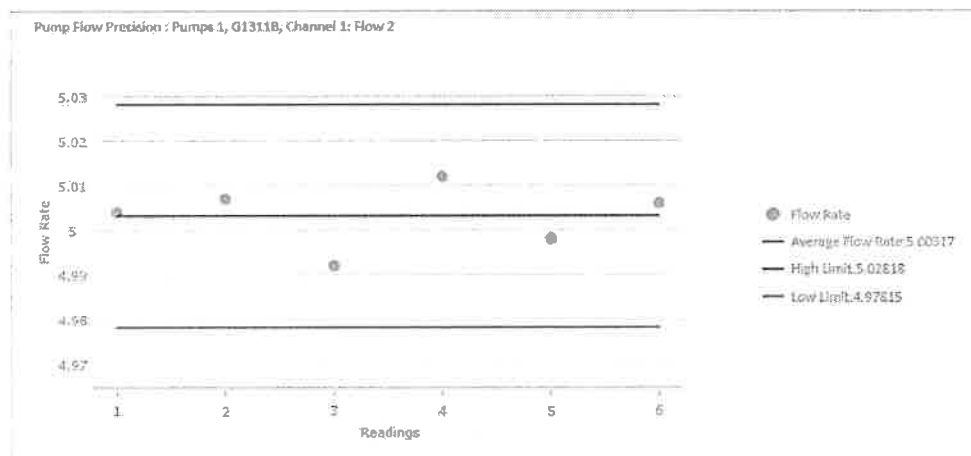
STD Deviation: 0.00711

Precision RSD: 0.14 %

Agilent Recommended: ≤ 0.50

Setpoint Status: Pass

Runs: 1

**Overall Pump Flow Precision Test Status**

Pass

Scouting Run

Purpose

Before beginning chemical qualification tests, this test is used to determine the chromatogram for presence of expected peaks, sufficient signal height for sample and tracer (if applicable), and sufficient run time.

Sequence

Line 1: Evaluation standard, 1 injection

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: UV or UV-Vis

Model/Serial No.: G1328C DEABG00847

Model/Serial No.: G1314F DEABB01463

Setpoint

Measurements

Evaluated compound:

Caffeine

Run time for standard injection test(s):

2.0 min

Standard peak retention time:

0.8 min

Injection volume for Response Linearity:

20.0 µL

Run time for Gradient Composition:

26.0 min

Column compartment temperature:

40.0 °C

Setpoint Status: Completed

Runs: 1

Data Audit Log

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024\VWD.olax

Analyzed Data Path: SDS://SessionData/OQ/Tests/LcScout_0_0/LcScout_0_0_1/PreviousRun/Run1

Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Integration Parameters :

Type of Integration : Injection

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.01

Initial Area Reject: 0

Initial Height Reject: 10

Timed Event Table :

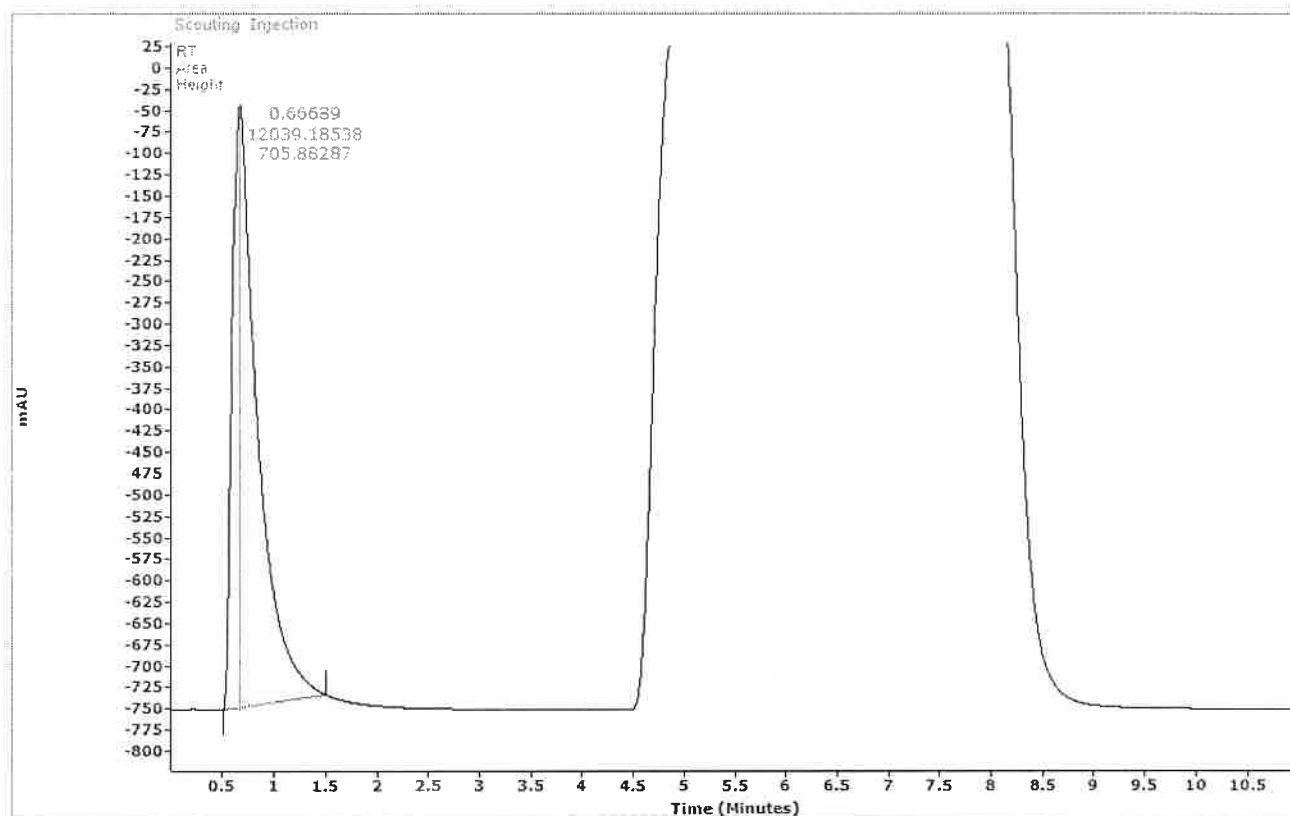
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.15
Integration	OFF	1.5

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/OQVWD.rslt/VWD_scouting.amx

Data file analyzed for this test: Scouting001.dx

Acquisition Date: Thursday, August 8, 2024 12:15:34 PM



Scouting Run area and height values are not used in any ACE calculations or to determine any test result. Therefore, for Scouting Run chromatograms only, area and height values are not converted to units used by the CDS.

Overall Scouting Run Status

Completed

(Completed is expressed as Pass in the Test Summary section.)

Wavelength Accuracy

Purpose

This test uses a traceable standard to determine accuracy, which is calculated as the absolute difference between the measured and defined wavelengths.

Configuration Details

Detector Type: UV or UV-Vis

Model/Serial No.: G1314F DEABB01463

Setpoint Wavelengths: 205 245 273 nm

Conditions

Pump Flow Rate: 1 mL/min

Run Time: 2 min

Injection Volume on Column: 20 µL

Column Compartment Temp: 40.0 °C

Sample: Caffeine Std kit, 5190-0488

Evaluated Compound: Caffeine

Wavelength Timetable:* Start/End: Detection WL -4 nm/+4; increments: 1 nm

Scan:** Start/End: Detection WL -15 nm/+17; increments: 1 nm

* For detectors with programmable change capability only; ** for detectors with no wavelength change capability only

Configuration

Evaluation Standard Concentration: 24.8 µg/mL (from Certificate of Analysis)

Signal Type: Standard

Measurements

DU is detector-specific display units: pA, mAU, and so on.

Wavelength 1:	205	nm
201.00	328.771	DU
202.00	345.572	
203.00	358.185	
204.00	364.061	
205.00	366.874	
206.00	364.952	
207.00	360.629	
208.00	350.886	
209.00	337.345	

Results

Actual Max : 205.00 nm

Accuracy (error in nm): 0 nm

Agilent Recommended: ≤ 2

Status: Pass

Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Wavelength 2:	245	nm
241.00	42.669	DU
242.00	41.023	
243.00	39.585	
244.00	38.599	
245.00	38.055	
246.00	38.067	
247.00	38.819	
248.00	40.264	
249.00	41.701	

Actual : nmAccuracy (error in nm): nmAgilent Recommended: Status:

Wavelength 3:	273	nm
269.00	118.863	DU
270.00	120.950	
271.00	122.614	
272.00	123.345	
273.00	123.542	
274.00	122.741	
275.00	121.179	
276.00	119.302	
277.00	115.833	

Actual : nmAccuracy (error in nm): nmAgilent Recommended: Status: Setpoint Status: Runs:

Data Audit Log

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024

Analyzed Data Path: SDS://SessionData/OQ/Tests/LcWI_0_0/LcWI_0_0_1/PreviousRun/Run1

Original file name:

File as analyzed:

SpectralScan_DEABB01463_09-08-2024_10-14-37.csv

wavelength_accuracy001.acedata

Overall Wavelength Accuracy Test Status

Noise and Drift

Purpose

This test determines the noise and drift of the detector signal. Noise is calculated as the average peak-to-peak noise in a number of signal segments, and drift is calculated as the slope of the linear regression for the signal.

Sequence

Line 1: Blank run, 1 injection

Configuration Details

Detector Type: UV or UV-Vis

Model/Serial No.: G1314F DEABB01463

Setpoint Detection Wavelength: 254 nm

Conditions

Y-Axis Unit: mAU
Run Time: 24.0 minutes
Injection Volume on Column: 0.0 µL
Pump Flow Rate: 1.0 mL/min
Column Compartment Temp: 40.0 °C
Sample: Mobile phase blank
Noise Evaluation Start Time: 3.0 minutes
Noise Evaluation Duration: 20.0 minutes

Results

	ASTM Noise	Drift
	mAU	mAU/hour
	0.007	0.260
Agilent Recommended:	<= 0.040	<= 0.500
Status:	Pass	Pass

After data is processed, test-specification limits on this form are rescaled for the CDS used to collect data.

Setpoint Status: Pass

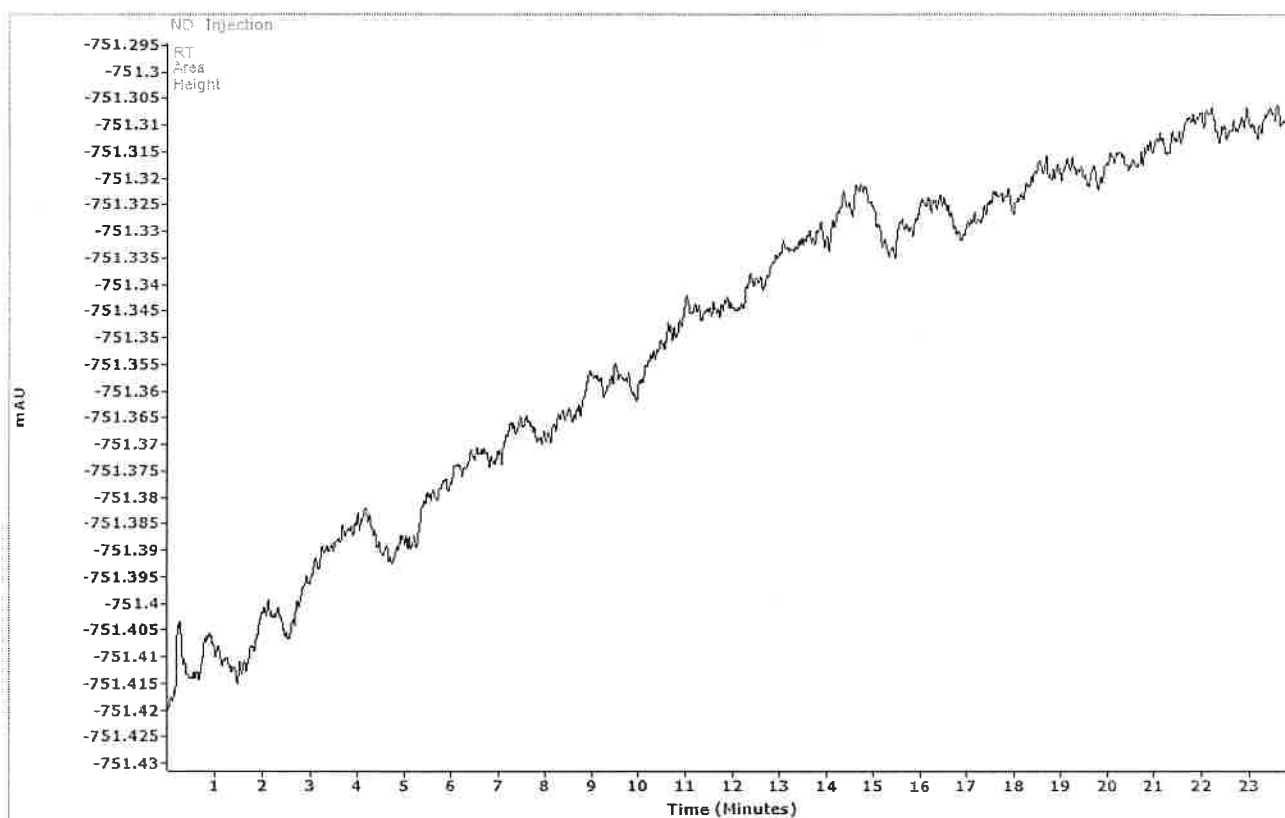
Runs: 1

Data Audit Log

Host name: LAB01
Original Data Path: C:\Users\User\Desktop\OQ LC\2024\ND.olax
Analyzed Data Path: SDS://SessionData/OQ/Tests/LcNd_0_0/LcNd_0_0_1/PreviousRun/Run1

Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/ND.rsl/VWD_ND.amx
Data file analyzed for this test: ND001.dx
Acquisition Date: Thursday, August 8, 2024 1:34:43 PM
Noise Type: ASTM
Noise Value: 0.007
Noise start time: 3.0
Noise duration: 20.0
Drift Value: 0.260

**Overall Noise and Drift Test Status**

Pass

Injection Precision

Purpose

This test uses a traceable standard to determine injection precision. The mean, standard deviation, and % RSD of six standard injections are calculated.

Sequence

Line 1: Mobile phase blank, 1 injection
Line 2: Evaluation standard, 1 injection
Line 3: Evaluation standard, 1 injection
Line 4: Evaluation standard, 1 injection
Line 5: Evaluation standard, 1 injection

Line 6: Evaluation standard, 1 injection
Line 7: Evaluation standard, 1 injection
Line 8: Mobile phase blank, 1 injection (only if carry over is run immediately after precision; not for SamplePrep)

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: UV or UV-Vis

Model/Serial No.: G1328C

DEABG00847

Model/Serial No.: G1314F

DEABB01463

Setpoint Injection Volume on Column: From EQP / Actual μL
(The injection volume from the EQP is adjusted for this delivery.)

Conditions

Y-Axis Unit:

mAU

Run Time:

2.0

min

Pump Flow Rate:

1.0

mL/min

Column Compartment Temp:

40.0

$^{\circ}\text{C}$

Detection Wavelength:

273

nm

Configuration

Sample:

Caffeine Std kit, 5190-0488

Evaluated Compound:

Caffeine

Evaluation Standard Concentration:

24.8

$\mu\text{g/mL}$

(from Certificate of Analysis)

Measurements

Area

1555.503

mAU*s

1559.828

1554.185

1536.767

1551.146

1545.639

Height

96.32278

mAU

96.13472

96.24439

95.31333

96.00722

95.89210

Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

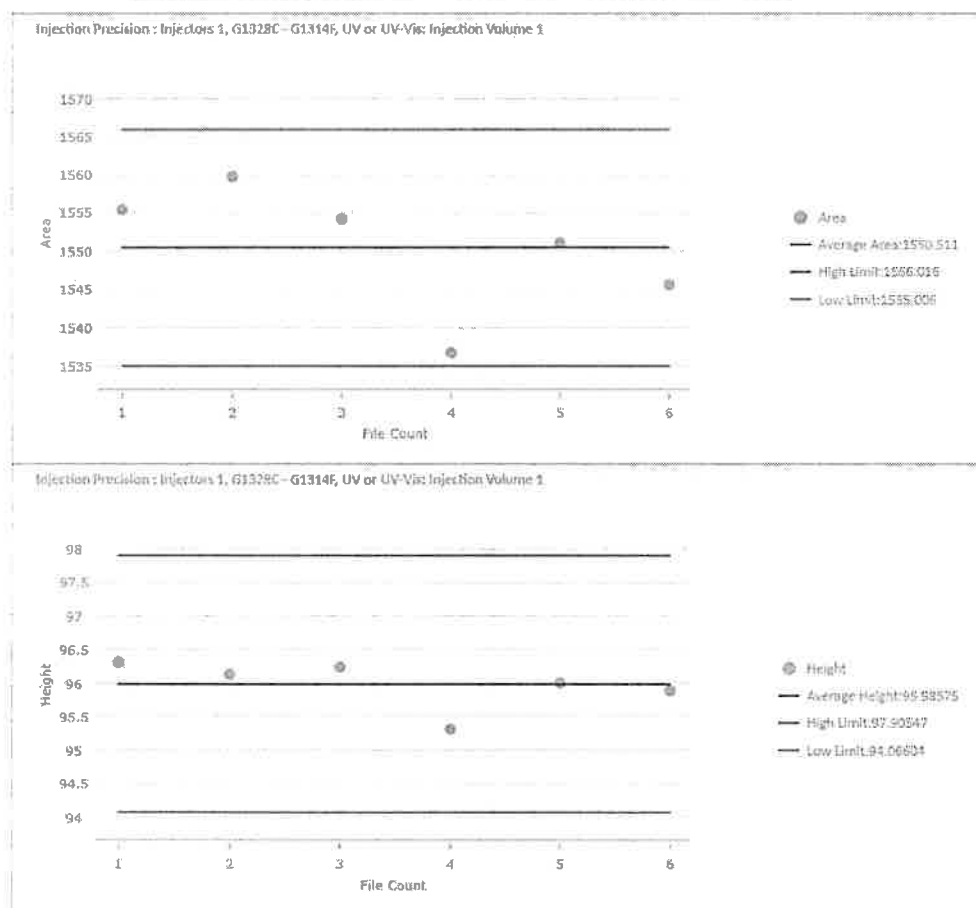
Results

	Area		Height	
Average:	1550.511	mAU*s	95.98575	mAU
STD Deviation:	8.22510	mAU*s	0.36443	mAU
RSD:	0.53	%	0.38	%
Agilent Recommended:	<= 1.00		<= 2.00	
Status:	Pass		Pass	

Setpoint Status:

Pass

Runs: 1



Data Audit Log

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024\IP.olax

Analyzed Data Path: SDS://SessionData/OQ/Tests/Lclp_0_0/Lclp_0_0_1/PreviousRun/Run1

Integration Parameters :

Type of Integration : Injection

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 50

Timed Event Table :

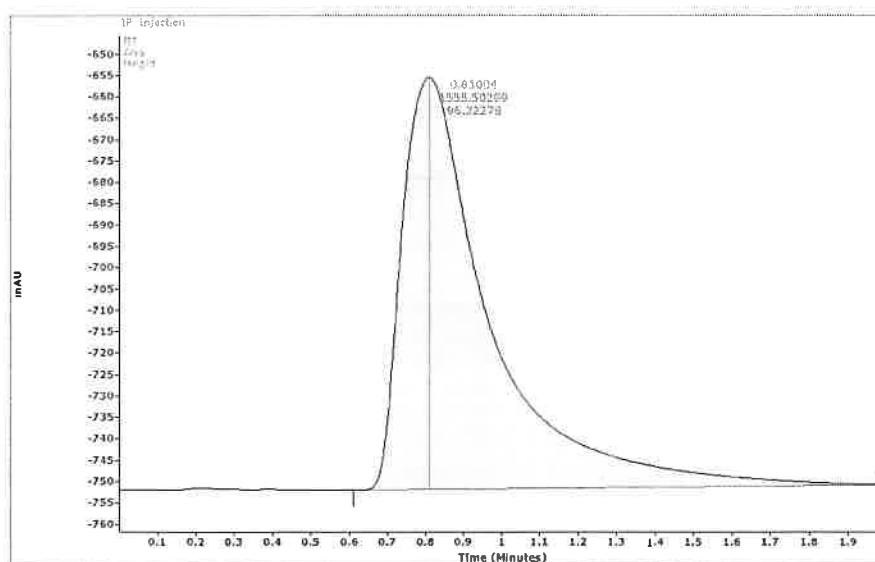
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.2

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/IP_VWD.rsl/VWD_IP.amx

Data file analyzed for this test: IP001-r001.dx

Acquisition Date: Friday, August 9, 2024 9:09:34 AM



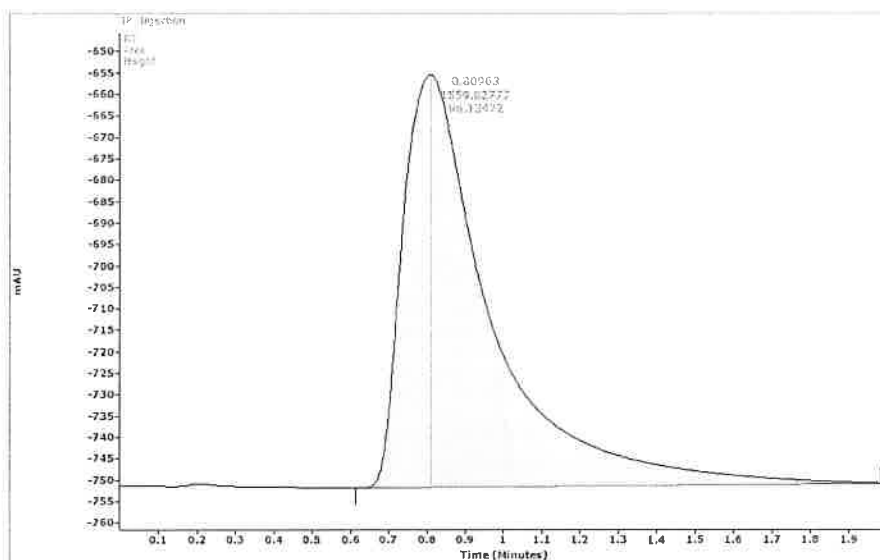
Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/IP_VWD.rsl/VWD_IP.amx

Data file analyzed for this test: IP001-r002.dx

Acquisition Date: Friday, August 9, 2024 9:11:48 AM

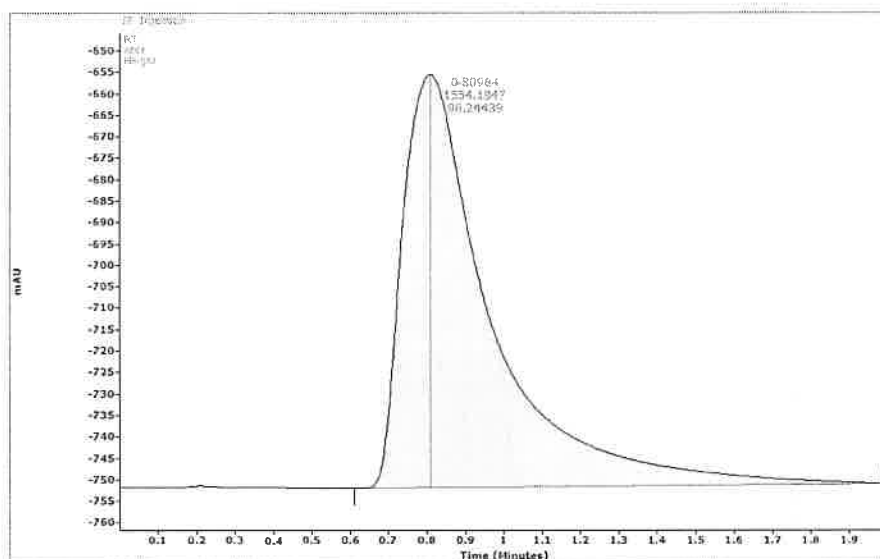


Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/IP_VWD.rsl/VWD_IP.amx

Data file analyzed for this test: IP001-r003.dx

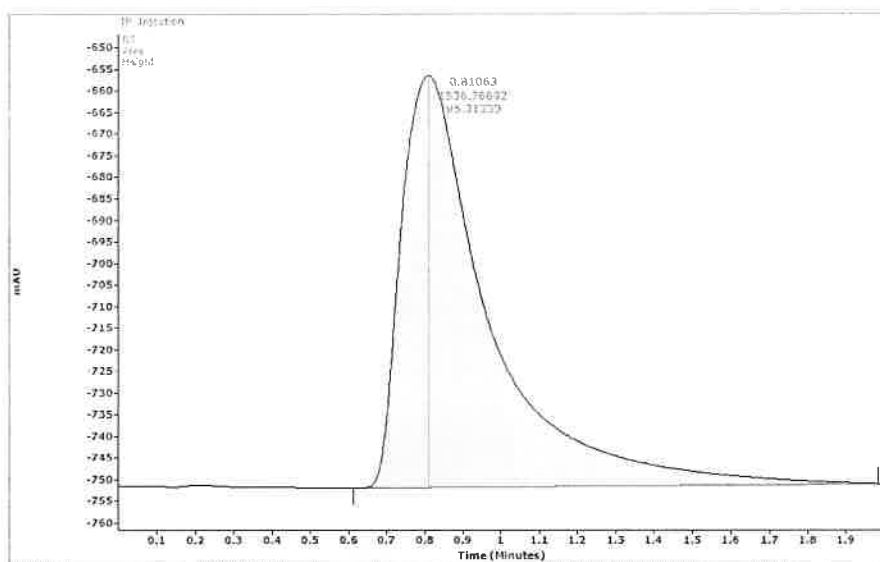
Acquisition Date: Friday, August 9, 2024 9:14:21 AM



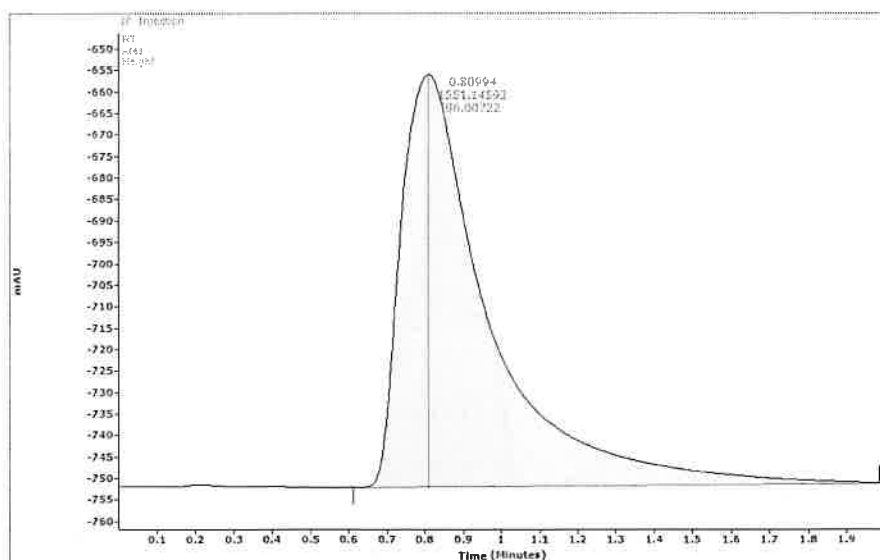
Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/IP_VWD.rsl/VWD_IP.amx
Data file analyzed for this test: IP001-r004.dx
Acquisition Date: Friday, August 9, 2024 9:16:36 AM



Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/IP_VWD.rsl/VWD_IP.amx
Data file analyzed for this test: IP001-r005.dx
Acquisition Date: Friday, August 9, 2024 9:19:07 AM



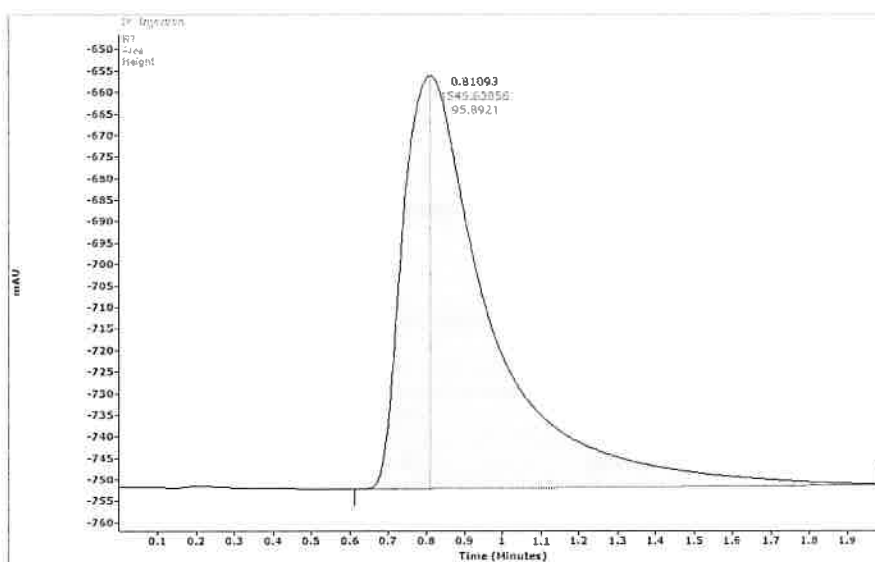
Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/IP_VWD.rsl/VWD_IP.amx

Data file analyzed for this test: IP001-r006.dx

Acquisition Date: Friday, August 9, 2024 9:21:22 AM



Overall Injection Precision Test Status

Pass

Injection Carry Over

Purpose

This test uses a traceable standard to determine injection carry over.

Sequence

Line 1: Evaluation standard, 1 injection

(Used when carry over is run standalone. If carry over follows

Line 2: Mobile phase blank, 1 injection

injection precision, see Injection Precision's sequence.)

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: UV or UV-Vis

Model/Serial No.: G1328C

DEABG00847

Model/Serial No.: G1314F

DEABB01463

Setpoint Injection Volume on Column: From EQP 10 / Actual 20 μL

(The injection volume from the EQP is adjusted for this delivery.)

Conditions

Y-Axis Unit:

mAU

Run Time:

2.0

minutes

Pump Flow Rate:

1.0

mL/min

Column Compartment Temp:

40.0

$^{\circ}\text{C}$

Detection Wavelength:

273

nm

Configuration

Sample:

Caffeine Std kit, 5190-0488

Evaluated Compound:

Caffeine

Evaluation Standard Concentration:

24.8

$\mu\text{g/mL}$

(Certificate of Analysis)

Measurements

	Area		Height
Standard Peak:	1553.776	mAU*s	97.30533 mAU
Carry Over:	0.96821	mAU*s	0.06342 mAU
Standard Peak Retention Time:	0.80447	minutes	
Carry Over Retention Time:	0.84592	minutes	

Results

Carry Over:	0.06	%	0.07	%
Agilent Recommended:	<=	0.10	<=	0.20
Status:	Pass		Pass	

If 0% carry over is reported, a peak of interest was not found or was below detectable limits.

Setpoint Status:

Pass

Runs: 1

Data Audit Log

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024\CO.olax

Analyzed Data Path: SDS://SessionData/OQ/Tests/LcCo_0_0/LcCo_0_0_1/PreviousRun/Run1

Integration Parameters :

Type of Integration : Injection

Integration Count 4

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 50

Timed Event Table :

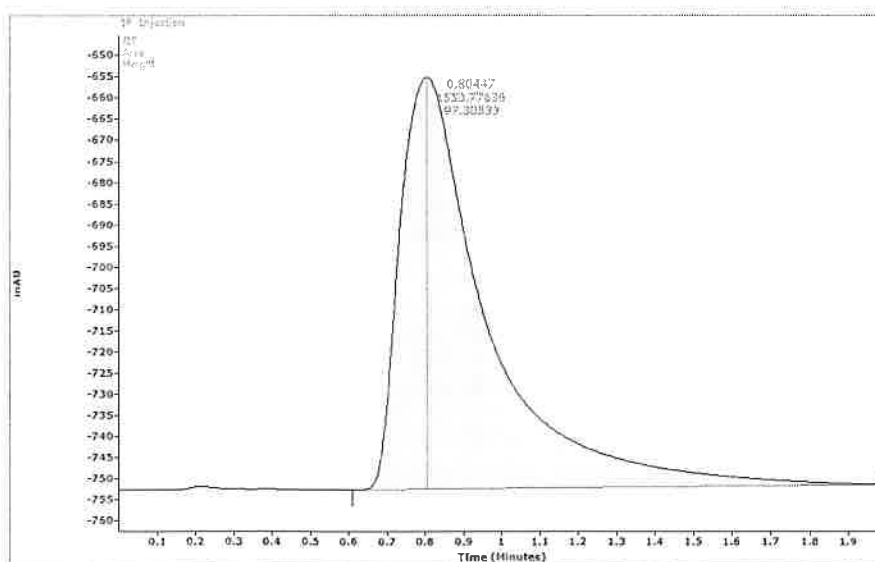
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.2

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/CO.rslt/VWD_IP.amx

Data file analyzed for this test: IP001.dx

Acquisition Date: Friday, August 9, 2024 9:36:44 AM



Integration Parameters :

Type of Integration : Carry Over

Integration Count 4

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 0.1

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 0

Timed Event Table :

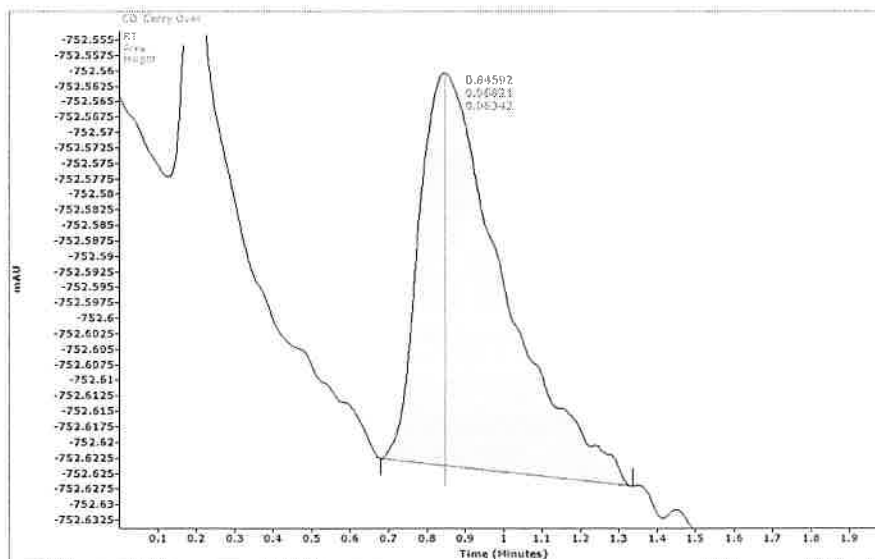
Integration Type	Value	Time
Integration	Off	0
Integration	On	0.2
Integration	Off	1.35

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/CO.rsl/VWD_IP.amx

Data file analyzed for this test: CO001.dx

Acquisition Date: Friday, August 9, 2024 9:40:12 AM

**Overall Injection Carry Over Test Status**

Pass

Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Signal to Noise

Purpose

This test uses a traceable standard (or water) to determine signal to noise.

Sequence:

Line 1: Evaluation standard, 1 injection

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: UV or UV-Vis

Model/Serial No.: G1314F DEABB01463

Setpoint

Conditions

Y-Axis Unit: mAU

Run Time: 7.0 min

Injection Volume on Column: 20 µL

Pump Flow Rate: 1.0 mL/min

Column Compartment Temp: 40.0 °C

Sample: Caffeine Std kit, 5190-0488

Detection Wavelength: 273 nm

Evaluated Compound: Caffeine

Noise Evaluation Start Time/Duration: 3.00 min / 3.00 min

Configuration

Evaluation Standard Concentration: 24.8 µg / mL (Certificate of Analysis)

Detector Path Length: 10 mm

Measurements

Noise (ASTM):	0.00206	mAU
Height:	91.30436	mAU
	46.02034	mAU

(First height is uncorrected. Second is corrected for attenuation; path length; differences between nominal and reported concentration, actual injected amount and the amount this SN limit is based on; analog data is corrected for the applied signal reduction [range/attenuation].)

Results

Signal to Noise:	22352
Agilent Recommended:	>= 3000

The limit is based on an injection of:

250	ng	of	Caffeine
-----	----	----	----------

ACE uses unrounded values in its calculations; only the final result is rounded. Therefore, for high signal-to-noise ratios (high peaks/low noise), ACE calculations may appear to differ slightly from your manual calculations using the reported height and noise.

Setpoint Status:**Pass**

Runs: 1

Data Audit Log

Host name:	LAB01
Original Data Path:	C:\Users\User\Desktop\OQ LC\2024\SN.olax
Analyzed Data Path:	SDS://SessionData/OQ/Tests/LcSn_0_0/LcSn_0_0_1/PreviousRun/Run1

Integration Parameters :

Type of Integration : Injection

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 10

Timed Event Table :

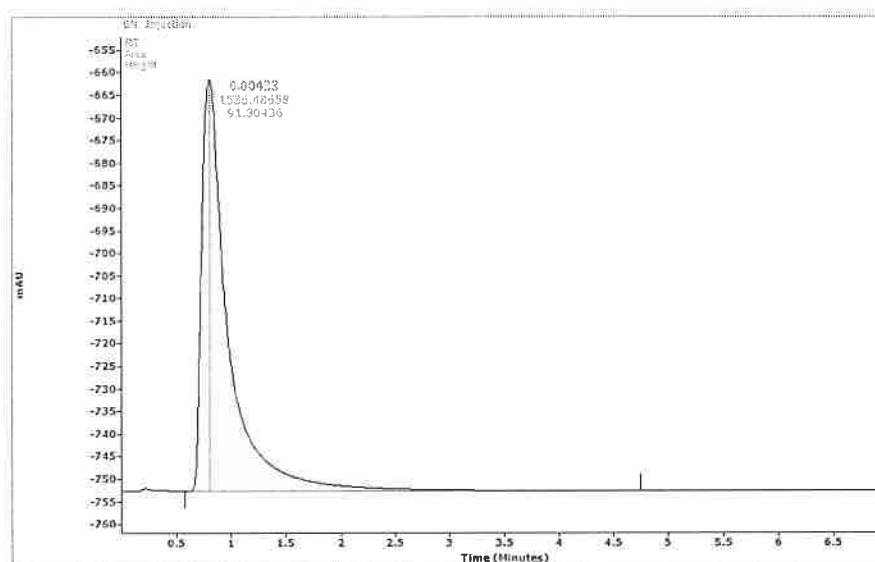
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.2

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/SN.rsl/VWD_SN.amx

Data file analyzed for this test: SN001.dx

Acquisition Date: Friday, August 9, 2024 9:47:22 AM

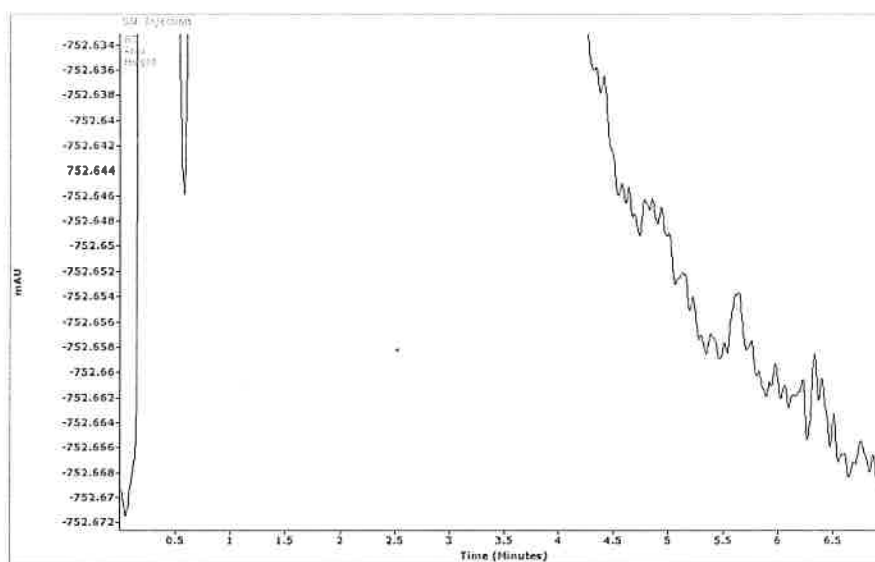


Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/SN.rsl/VWD_SN.amx

Data file analyzed for this test: SN001.dx

Acquisition Date: Friday, August 9, 2024 9:47:22 AM



Overall Signal to Noise Test Status

Pass

Response Linearity

Purpose

This test uses a traceable standard to determine response linearity. Response linearity is calculated by determining the coefficient of determination (r^2) of the peak areas versus concentration. In addition, (1) the %RSD of response factors for all five peaks is calculated and (2) optionally, the peak area ratios for two sets of responses can also be calculated.

Sequence:

Line 1: Mobile phase blank, 1 injection

Line 2: Standard 1, 1 injection

Line 3: Standard 2, 1 injection

Line 4: Standard 3, 1 injection

Line 5: Standard 4, 1 injection

Line 6: Standard 5, 1 injection

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: UV or UV-Vis

Model/Serial No.:

G1314F

DEABB01463

Setpoint

Conditions

Y-Axis Unit:

mAU

Run Time:

2.0

min

Injection Volume on Column:

20.0

µL

Pump Flow Rate:

1.0

mL/min

Column Compartment Temp:

40.0

°C

Sample:

Caffeine Std kit, 5190-0488

Detection Wavelength:

273

nm

Evaluated Compound:

Caffeine

Configuration

Standard 1 Concentration (lowest):

5

Theoretical

Actual*

4.97

µg/mL

Standard 2 Concentration:

25

24.8

µg/mL

Standard 3 Concentration:

50

50.1

µg/mL

Standard 4 Concentration:

100

99.6

µg/mL

Standard 5 Concentration (highest):

200

202.7

µg/mL

* Concentrations
from Certificate of
Analysis

Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Measurements

	Area mAU*s	Height mAU	R/F* mAU*s	
Run 1:	282.1752	19.16100	56.77570	* /units, as specified in Configuration section r2 result is based on area.
Run 2:	1437.227	96.65957	57.95269	
Run 3:	2887.336	189.3787	57.63146	
Run 4:	5872.983	369.6590	58.96569	
Run 5:	12067.55	718.3255	59.53403	

Results

R/F Average:* 58.17191 mAU*s

R/F STD Deviation:* 1.09259 mAU*s

Coefficient of Determination (r2): 0.99994 R/F Precision RSD: 1.88 %

Agilent Recommended: >= 0.99900 <= 5.00

Status:

Pass

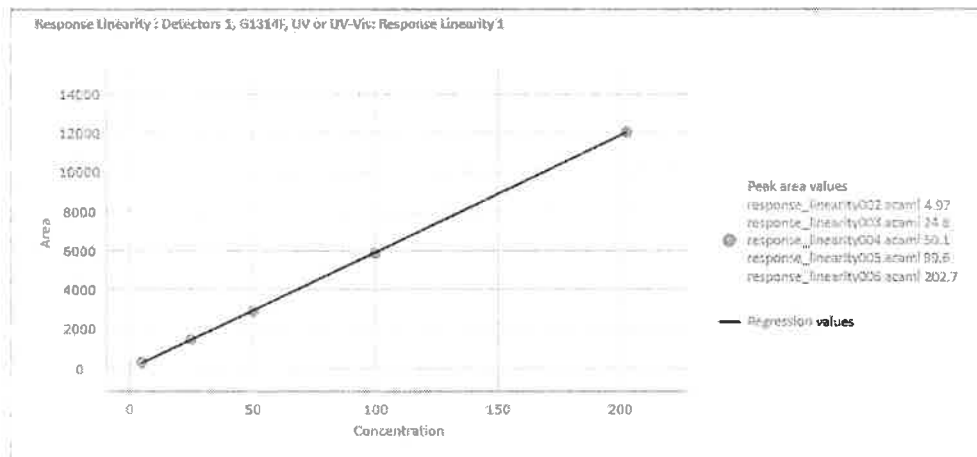
Status:

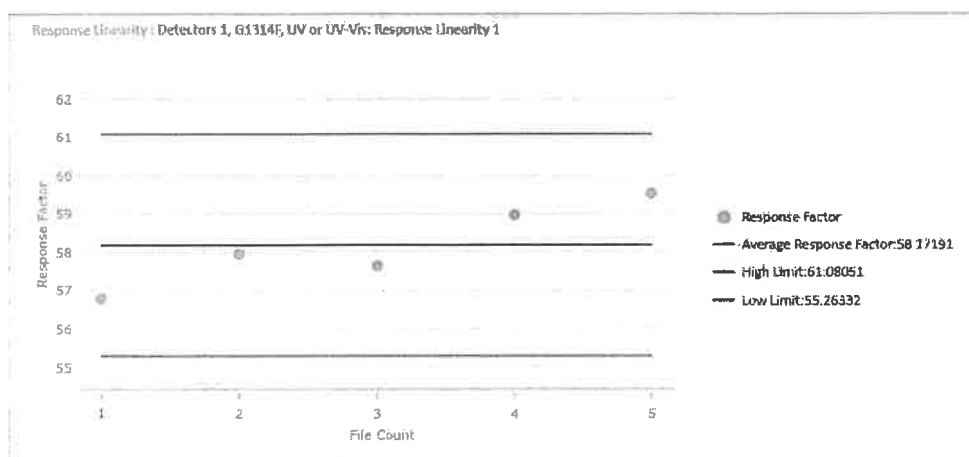
Pass

Setpoint Status:

Pass

Runs: 1



**Data Audit Log**

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024\Resp_lin.olax

Analyzed Data Path: SDS://SessionData/OQ/Tests/LcRI_0_0/LcRI_0_0_1/PreviousRun/Run1

Integration Parameters :

Type of Integration : Injection

Integration Count 2

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 6

Timed Event Table :

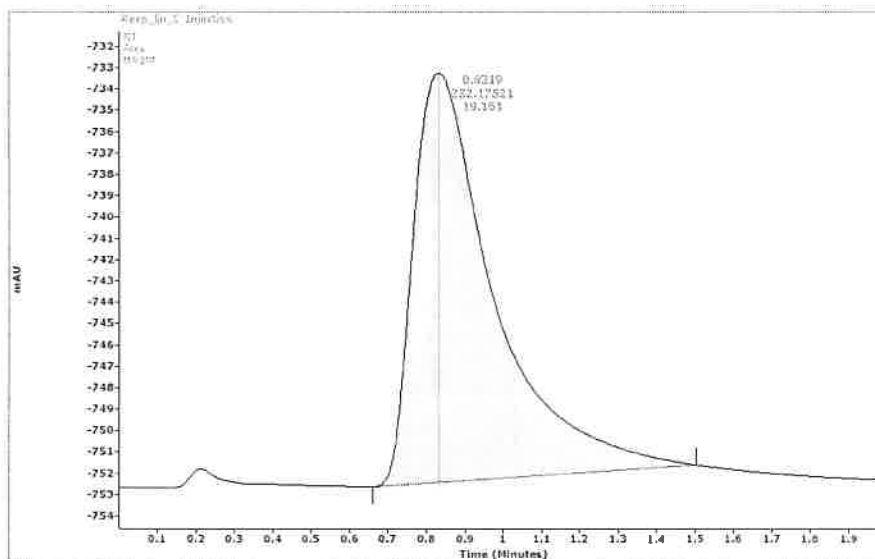
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.2
Integration	Off	1.5

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/RespLin.rsl/VWD_RL.amx

Data file analyzed for this test: Resp_lin_5001.dx

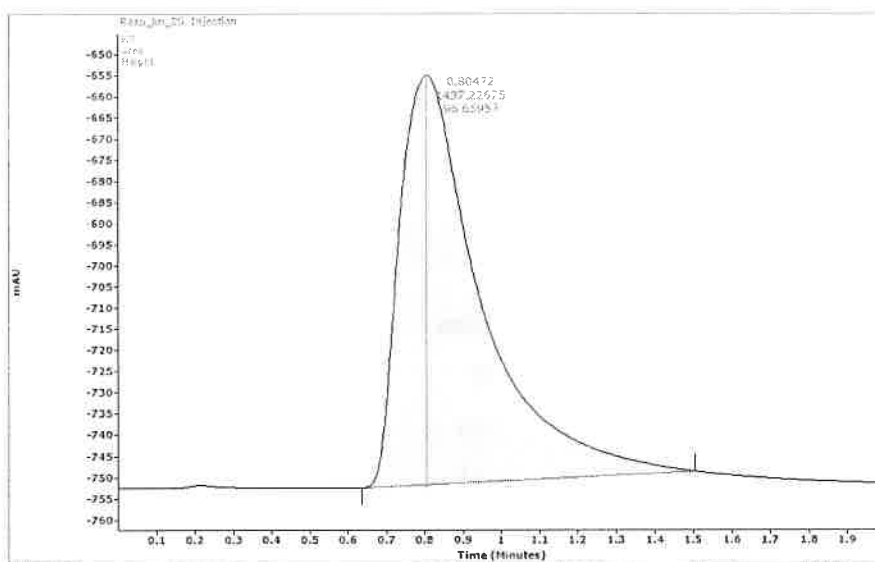
Acquisition Date: Friday, August 9, 2024 9:57:57 AM



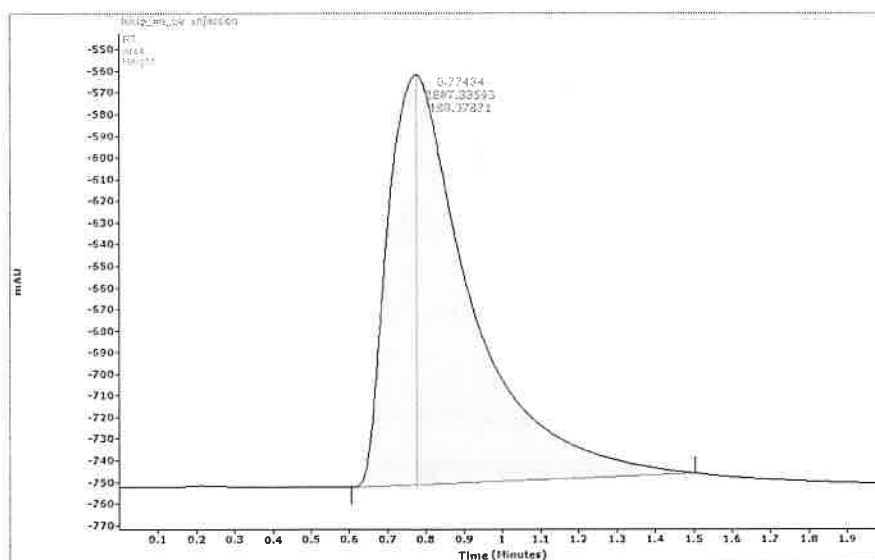
Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

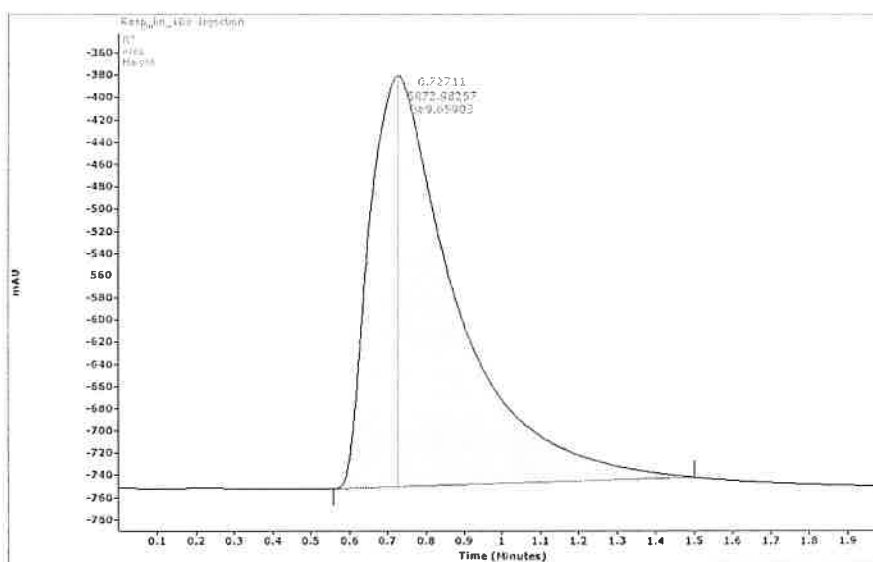
Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/RespLin.rsl/VWD_RL.amx
Data file analyzed for this test: Resp_lin_25002.dx
Acquisition Date: Friday, August 9, 2024 10:00:16 AM



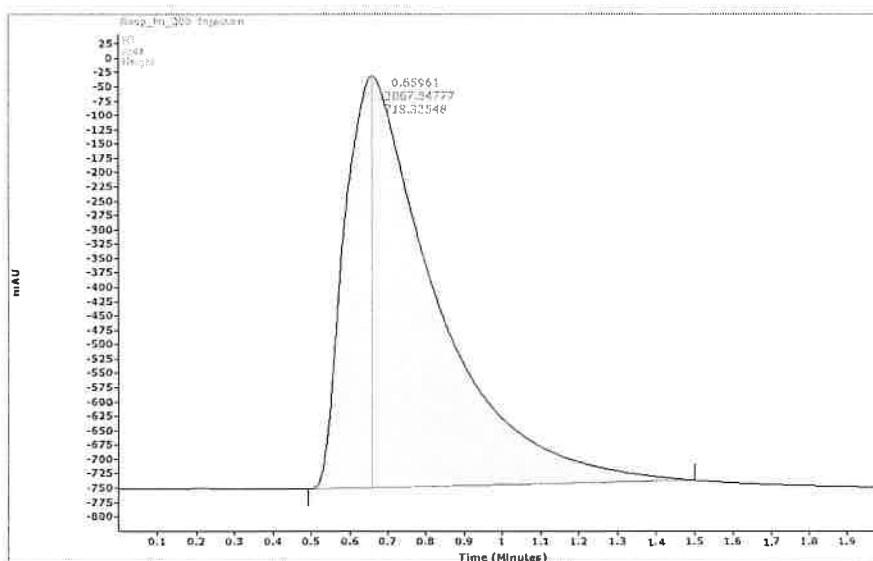
Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/RespLin.rsl/VWD_RL.amx
Data file analyzed for this test: Resp_lin_50003.dx
Acquisition Date: Friday, August 9, 2024 10:02:40 AM



Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/RespLin.rsl/VWD_RL.amx
Data file analyzed for this test: Resp_lin_100004.dx
Acquisition Date: Friday, August 9, 2024 10:04:56 AM



Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/RespLin.rsl/VWD_RL.amx
Data file analyzed for this test: Resp_lin_200005.dx
Acquisition Date: Friday, August 9, 2024 10:07:08 AM



Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Overall Response Linearity Test Status

Pass

Gradient Composition

Purpose

This test uses a tracer to determine solvent gradient composition accuracy, stability, and linearity. Accuracy (composition error) is calculated as the absolute difference between the mean found composition and the nominal step composition. Stability is determined by the noise and drift at each composition step: noise is reported as the Six Sigma value, and drift is the slope of the linear regression in each composition step. Linearity of the gradient control is measured at the start, midpoint (checking 50:50 performance), and end of a forced linear gradient and is reported as the coefficient of determination (r^2). Other values are reported for information only and require no limits: (1) delay volume; (2) measurements at 0% and 100% reference points; and (3) dwell volume of a fast 0% to 100% gradient step change, an optional evaluation.

Configuration Details

Detector Type: UV or UV-Vis

Pump Details:

Model/Serial No.:

Model/Serial No.:

Quaternary

G1311B

G1314F

Primary

DEAB702535

DEABB01463

Setpoint	Steps:	20.00	40.00	60.00	80.00	%
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Conditions

Composition Timetable:	Start	0.00	%	tracer
	Hold at	0.00	%	tracer
	Immediate increase to	20.00	%	tracer
	Hold at	20.00	%	tracer
	Immediate increase to	40.00	%	tracer
	Hold at	40.00	%	tracer
	Immediate increase to	60.00	%	tracer
	Hold at	60.00	%	tracer
	Immediate increase to	80.00	%	tracer
	Hold at	80.00	%	tracer
	Immediate increase to	100.00	%	tracer
	Hold at	100.00	%	tracer
	Linear decrease to	0.00	%	tracer
	End	0.00	%	tracer

Y-Axis Unit:	mAU	
Run Time:	26.0	min
Injection Volume on Column:	0.0	µL
Pump Flow Rate:	2.0	mL/min
Column Compartment Temperature:	40.0	°C
Detection Wavelength:	265	nm
Evaluated Compound:	Acetone	

Measurements

Reference Points:	0%	100%	
Start Time:	0	14.55797	minutes
Stop Time:	1.41833	16.45875	minutes
Average Height:	-908.29981	573.5392	mAU
Noise (Six Sigma):	131.0033	1.26497	mAU
Drift:	18.07554	0.28990	mAU/min

Step 1: 20.00 %

Results**Measurements**

Start Time:	2.33302	minutes
Stop Time:	4.50208	minutes
Average Height:	-598.20518	mAU
Noise (Six Sigma):	17.61335	mAU
Drift:	4.43012	mAU/min

Composition:	20.92634	%
Delay Volume:	0.81667	ml
Composition Error (%):	0.93	%
Agilent Recommended:	<= 2.00	

Status: Pass

Results

Composition Noise (%):	1.19	%
Agilent Recommended:	<= 2.00	
Status:	Pass	

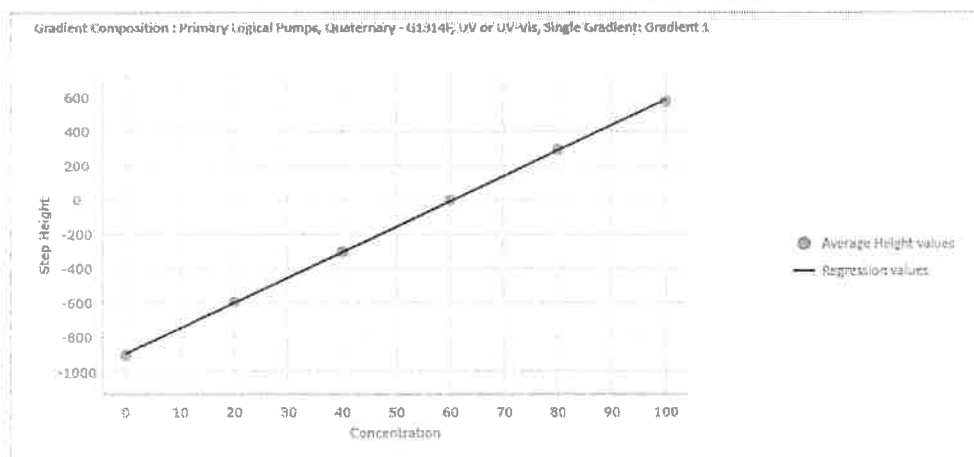
Composition Drift (%):	0.65	%
	<= 2.00	
Status:	Pass	

Step 2:	40.00	%	Results	
Measurements			Composition:	40.98032 %
Start Time:	5.36806	minutes	Composition Error (%):	0.98 %
Stop Time:	7.46542	minutes	Agilent Recommended:	<= 2.00
Average Height:	-301.03749	mAU	Status:	Pass
Noise (Six Sigma):	8.18577	mAU		
Drift:	1.96280	mAU/min		
Results				
Composition Noise (%):	0.55	%	Composition Drift (%):	0.28 %
Agilent Recommended:	<= 2.00			<= 2.00
Status:	Pass			Pass

Step 3:	60.00	%	Results	
Measurements			Composition:	61.21099 %
Start Time:	8.64645	minutes	Composition Error (%):	1.21 %
Stop Time:	10.31763	minutes	Agilent Recommended:	<= 2.00
Average Height:	-1.25156	mAU	Status:	Pass
Noise (Six Sigma):	4.82910	mAU		
Drift:	1.34585	mAU/min		
Results				
Composition Noise (%):	0.33	%	Composition Drift (%):	0.15 %
Agilent Recommended:	<= 2.00			<= 2.00
Status:	Pass			Pass

Step 4:	80.00	%	Results	
Measurements			Composition:	81.03720 %
Start Time:	11.65955	minutes	Composition Error (%):	1.04 %
Stop Time:	13.50542	minutes	Agilent Recommended:	<= 2.00
Average Height:	292.5409	mAU	Status:	Pass
Noise (Six Sigma):	16.08167	mAU		
Drift:	2.35374	mAU/min		
Results				
Composition Noise (%):	1.09	%	Composition Drift (%):	0.29 %
Agilent Recommended:	<= 2.00			<= 2.00
Status:	Pass			Pass

Gradient Linearity	Start of Gradient:	50:50 Zone:	End of Gradient:
	95.00 %	75.00 %	25.00 %
Coefficient of Determination (r ²):	0.99990	0.99996	0.99987
Agilent Recommended:	>= 0.99900	>= 0.99900	>= 0.99900
Status:	Pass	Pass	Pass
Setpoint Status:	Pass		Runs: 1

**Data Audit Log**

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024\Grad.olax

Analyzed Data Path: SDS://SessionData/OQ/Tests/LcGr_0_0/LcGr_0_0_1/PreviousRun/Run1

Date: August 9, 2024 1:45:42 PM

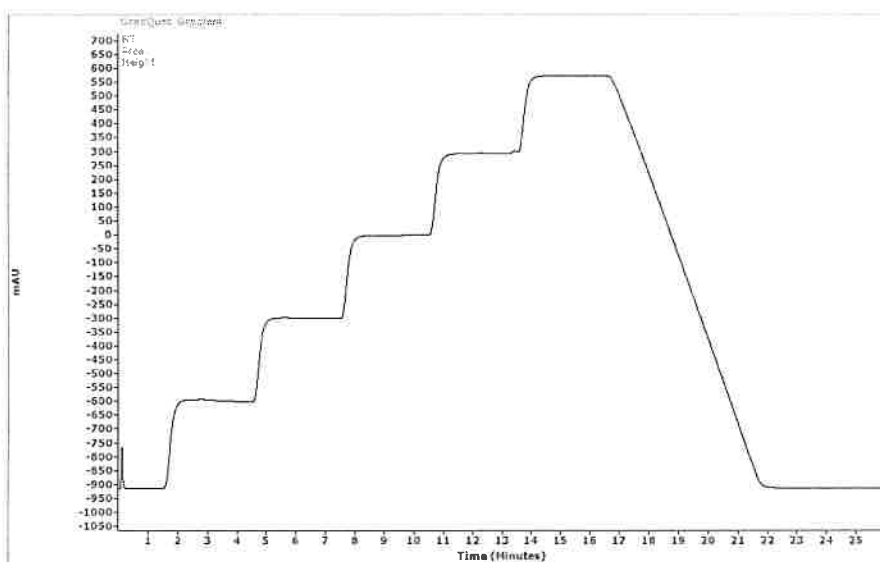
System ID: KLC0004

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/GradQuat2.rsl/GradQuat.amx

Data file analyzed for this test: GradQuat01.dx

Acquisition Date: Friday, August 9, 2024 1:11:44 PM



Integration Parameters :

Type of Integration : 1st Derivative

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 0.05

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 200

Timed Event Table :

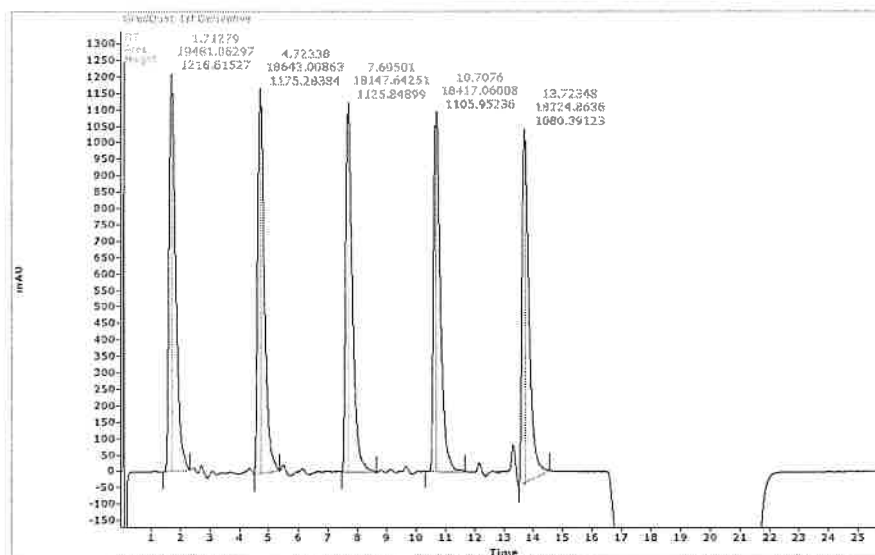
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	1.01
Integration	OFF	16

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/GradQuat2.rsl/GradQuat.amx

Data file analyzed for this test: GradQuat01.dx

Creation Time : Friday, August 9, 2024 1:41:01 PM



Integration Parameters :

Type of Integration : 2nd Derivative

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 0.2

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 200

Timed Event Table :

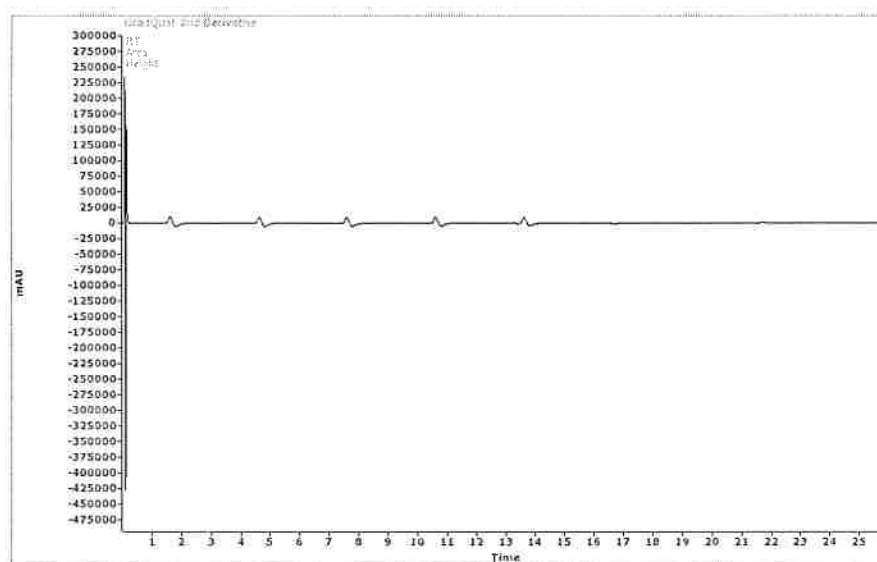
Integration Type	Value	Time
Integration	OFF	0

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/GradQuat2.rsl/GradQuat.amx

Data file analyzed for this test: GradQuat01.dx

Creation Time : Friday, August 9, 2024 1:41:01 PM

**Overall Gradient Composition Test Status**

Pass

Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Scouting Run

Purpose

Before beginning chemical qualification tests, this test is used to determine the chromatogram for presence of expected peaks, sufficient signal height for sample and tracer (if applicable), and sufficient run time.

Sequence

Line 1: Evaluation standard, 1 injection

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: RID

Model/Serial No.:

G1328C

DEABG00847

Model/Serial No.:

G1362A

DEAA601257

Setpoint

Measurements

Evaluated compound:

Glycerin

Run time for standard injection test(s):

2.0

min

Standard peak retention time:

0.4

min

Injection volume for Response Linearity:

5

µL

Column compartment temperature:

40.0

°C

Setpoint Status:

Completed

Runs: 1

Data Audit Log

Host name:

LAB01

Original Data Path:

C:\Users\User\Desktop\OQ LC\2024\Scout_RI.olax

Analyzed Data Path:

SDS://SessionData/OQ/Tests/LcScout_1_0/LcScout_1_0_1/PreviousRun/Run1

Date:

August 9, 2024 1:45:42 PM

System ID:

KLC0004

Integration Parameters :

Type of Integration : Injection

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.01

Initial Area Reject: 0

Initial Height Reject: 10

Timed Event Table :

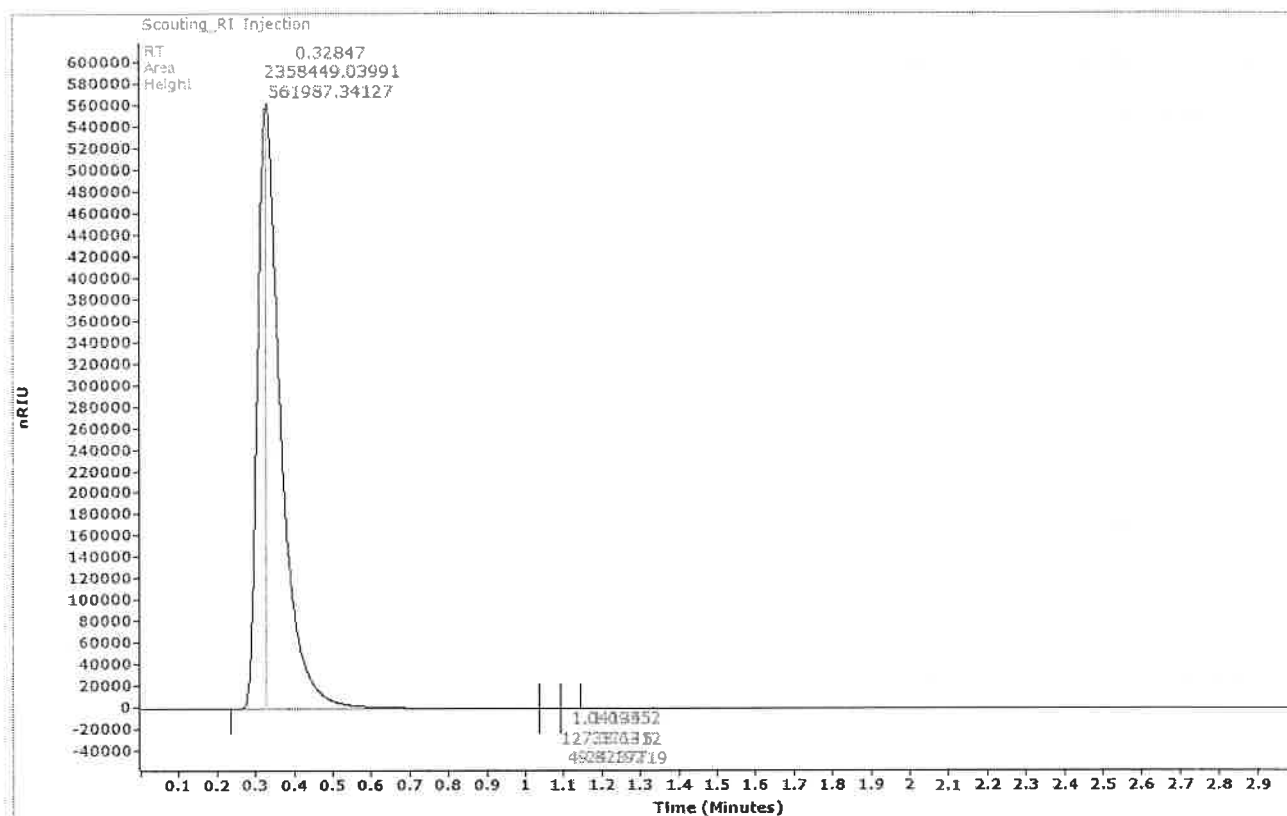
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.15
Integration	OFF	1.5

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/Scouting_RI.rsl/RID_scouting.amx

Data file analyzed for this test: Scouting_RI01.dx

Acquisition Date: Friday, August 9, 2024 11:16:03 AM



Scouting Run area and height values are not used in any ACE calculations or to determine any test result. Therefore, for Scouting Run chromatograms only, area and height values are not converted to units used by the CDS.

Overall Scouting Run Status

Completed

(Completed is expressed as Pass in the Test Summary section.)

Noise and Drift

Purpose

This test determines the noise and drift of the detector signal. Noise is calculated as the average peak-to-peak noise in a number of signal segments, and drift is calculated as the slope of the linear regression for the signal.

Sequence

Line 1: Blank run, 1 injection

Configuration Details

Detector Type: RID

Model/Serial No.: G1362A

DEAA601257

Setpoint

Conditions

Y-Axis Unit:

nRIU

Run Time:

24.0

minutes

Injection Volume on Column:

0.0

µL

Pump Flow Rate:

1.0

mL/min

Column Compartment Temp:

40.0

°C

Sample:

Mobile phase blank

Noise Evaluation Start Time:

3.0

minutes

Noise Evaluation Duration:

20.0

minutes

Results

ASTM Noise

nRIU

5.144

Drift

nRIU/hour

332.643

Agilent Recommended:

<= 10.000

<= 400.000

Status:

Pass

Pass

After data is processed, test-specification limits on this form are rescaled for the CDS used to collect data.

Setpoint Status:

Pass

Runs: 1

Data Audit Log

Host name:

LAB01

Original Data Path:

C:\Users\User\Desktop\OQ LC\2024\ND_RI.olax

Analyzed Data Path:

SDS://SessionData/OQ/Tests/LcNd_1_0/LcNd_1_0_1/PreviousRun/Run1

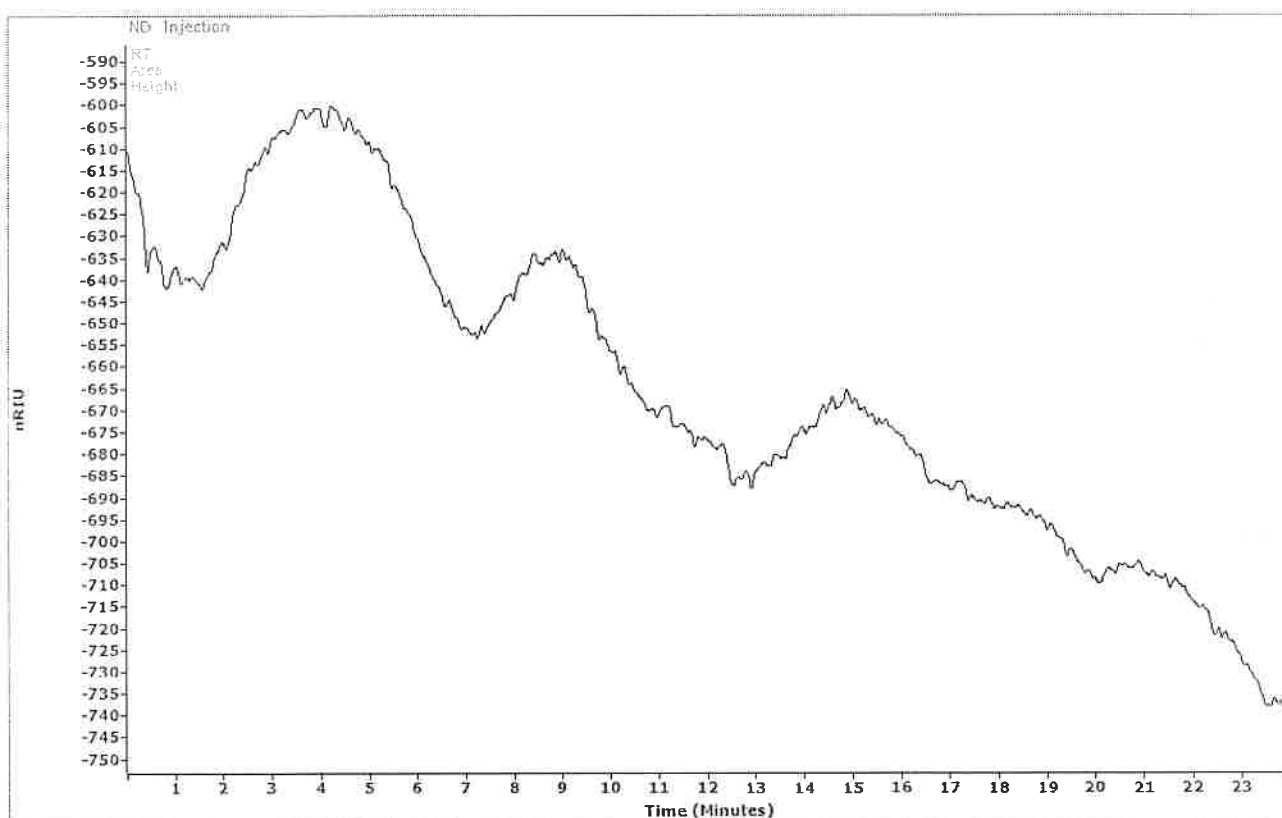
Date:

August 9, 2024 1:45:42 PM

System ID:

KLC0004

Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/Noise_and_drift_RID.rs!t/RID_ND.amx
Data file analyzed for this test: ND02.dx
Acquisition Date: Friday, August 9, 2024 10:40:00 AM
Noise Type: ASTM
Noise Value: 5.144
Noise start time: 3.0
Noise duration: 20.0
Drift Value: 332.643



Overall Noise and Drift Test Status

Pass

Signal to Noise

Purpose

This test uses a traceable standard (or water) to determine signal to noise.

Sequence:

Line 1: Evaluation standard, 1 injection

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: RID

Model/Serial No.: G1362A DEAA601257

Setpoint

Conditions

Y-Axis Unit:	nRIU
Run Time:	7.0 min
Injection Volume on Column:	5 µL
Pump Flow Rate:	1.0 mL/min
Column Compartment Temp:	40.0 °C
Sample:	RID Std kit, 5064-8220
Detection Wavelength:	Not Applicable nm
Evaluated Compound:	Glycerin
Noise Evaluation Start Time/Duration:	3.00 min / 3.00 min

Configuration

Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Measurements

Noise (ASTM):	3.57340	nRIU
Height:	519180.0	nRIU
	104044.1	nRIU

(First height is uncorrected. Second height is corrected for attenuation as needed and for differences between nominal and reported concentration, actual injected amount and the amount this SN limit is based on.)

Results

Signal to Noise:	29116
Agilent Recommended:	>= 2000

The limit is based on an injection of:

50 µg of Glycerin

ACE uses unrounded values in its calculations; only the final result is rounded. Therefore, for high signal-to-noise ratios (high peaks/low noise), ACE calculations may appear to differ slightly from your manual calculations using the reported height and noise.

Setpoint Status:**Pass**

Runs: 1

Data Audit Log

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024\SN_RI.olax

Analyzed Data Path: SDS://SessionData/OQ/Tests/LcSn_1_0/LcSn_1_0_1/PreviousRun/Run1

Integration Parameters :

Type of Integration : Injection

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 20000

Timed Event Table :

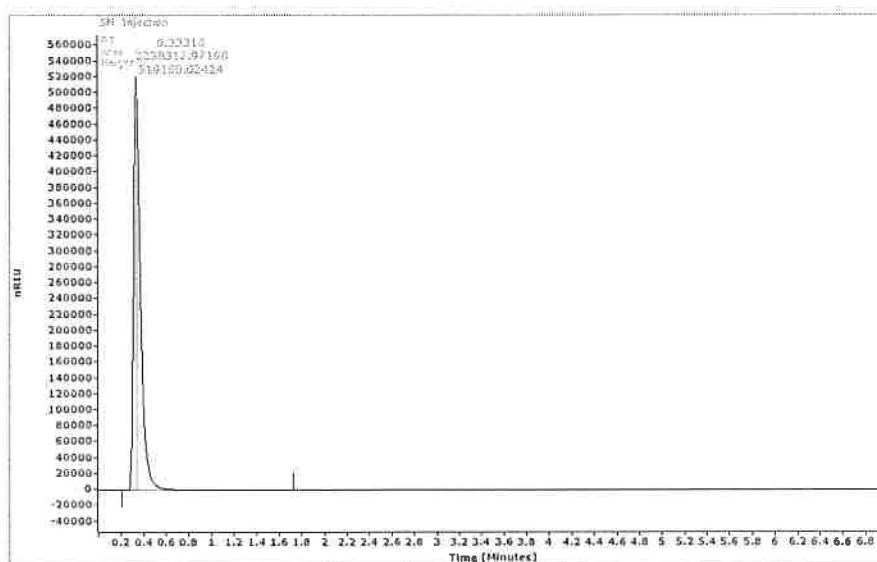
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.2

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/SigNoise_RI.rsl/RID_SN.amx

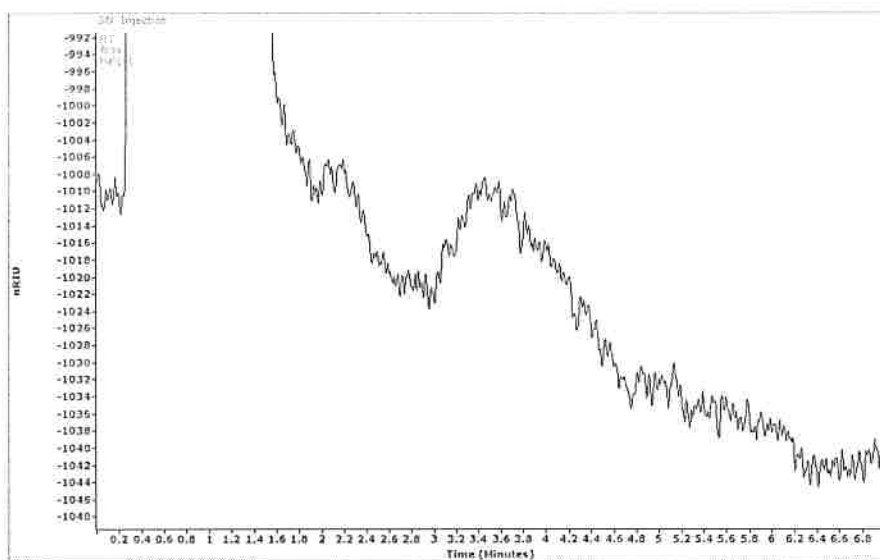
Data file analyzed for this test: SN08.dx

Acquisition Date: Friday, August 9, 2024 11:40:34 AM



Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Acquisition operator: oqadmin
 Acquisition method: /OQ/Results/OQ2024/SigNoise_RI.rsl/RID_SN.amx
 Data file analyzed for this test: SN08.dx
 Acquisition Date: Friday, August 9, 2024 11:40:34 AM



Overall Signal to Noise Test Status

Pass

Response Linearity

Purpose

This test uses a traceable standard to determine response linearity. Response linearity is calculated by determining the coefficient of determination (r^2) of the peak areas versus concentration. In addition, (1) the %RSD of response factors for all five peaks is calculated and (2) optionally, the peak area ratios for two sets of responses can also be calculated.

Sequence:

Line 1: Mobile phase blank, 1 injection

Line 2: Standard 1, 1 injection

Line 3: Standard 2, 1 injection

Line 4: Standard 3, 1 injection

Line 5: Standard 4, 1 injection

Line 6: Standard 5, 1 injection

Configuration Details

Injector and detector model and serial numbers below may be the same for mainframe systems.

Detector Type: RID

Model/Serial No.: G1362A DEAA601257

Setpoint

Conditions

Y-Axis Unit:

nRIU

Run Time:

2.0

min

Injection Volume on Column:

5

µL

Pump Flow Rate:

1.0

mL/min

Column Compartment Temp:

40.0

°C

Sample:

RID Std kit, 5064-8220

Detection Wavelength:

Not Applicable

nm

Evaluated Compound:

Glycerin

Configuration

Standard 1 Concentration (lowest):

5

Theoretical

Actual*

5.0

mg/mL

Standard 2 Concentration:

10

10.1

mg/mL

Standard 3 Concentration:

15

15.1

mg/mL

Standard 4 Concentration:

25

25.1

mg/mL

Standard 5 Concentration (highest):

50

49.9

mg/mL

* Concentrations
from Certificate of
Analysis

Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Measurements

	Area nRIU*s	Height nRIU	R/F* nRIU*s	
Run 1:	232278.4	55672.15	46455.67	* /units, as specified in Configuration section r2 result is based on area.
Run 2:	479936.4	115253.9	47518.46	
Run 3:	729670.5	175633.4	48322.55	
Run 4:	1176120	281669.2	46857.39	
Run 5:	2372315	564669.9	47541.38	

Results

R/F Average:* 47339.09 nRIU*s

R/F STD Deviation:* 716.3709 nRIU*s

Coefficient of Determination (r2): 0.99985 R/F Precision RSD: 1.51 %

Agilent Recommended: >= 0.99500 <= 10.00

Status:

Pass

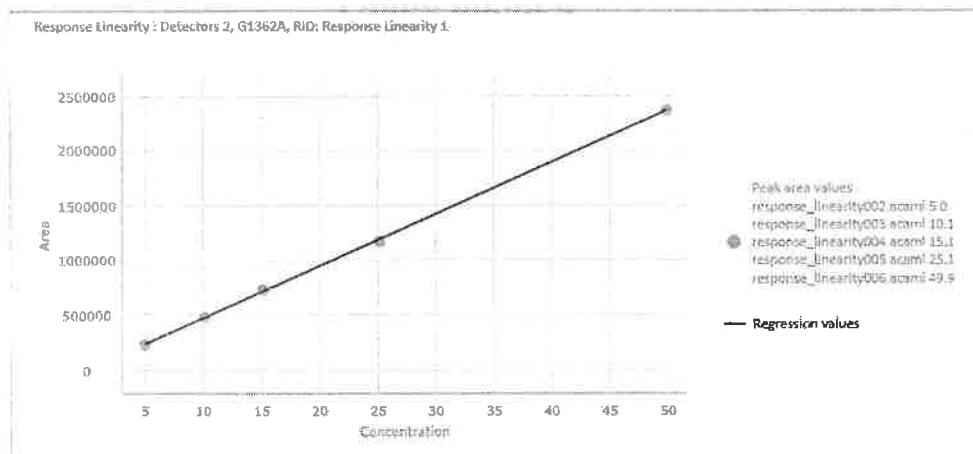
Status:

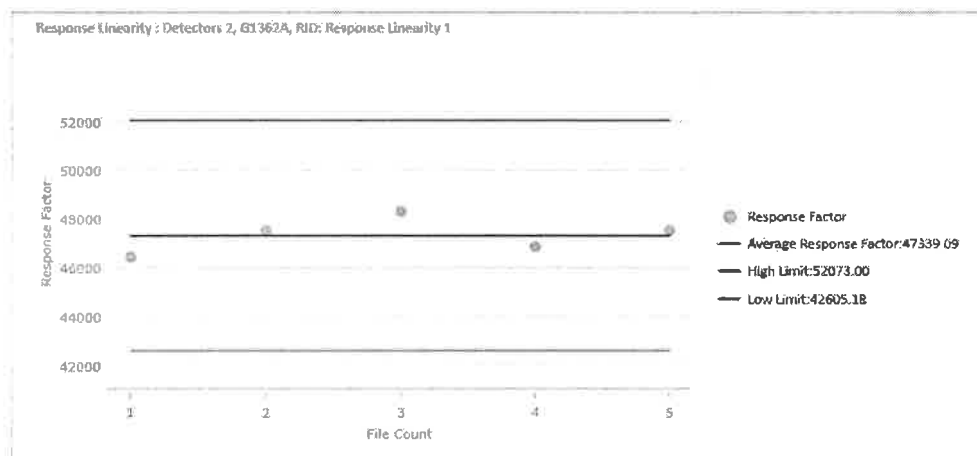
Pass

Setpoint Status:

Pass

Runs: 1



**Data Audit Log**

Host name: LAB01

Original Data Path: C:\Users\User\Desktop\OQ LC\2024\RespLin_RI.olx

Analyzed Data Path: SDS://SessionData/OQ/Tests/LcRI_1_0/LcRI_1_0_1/PreviousRun/Run1

Integration Parameters :

Type of Integration : Injection

Integration Count 0

Optional Values :

Baseline Correction Mode: Advanced

Initial Slope Sensitivity: 10

Initial Peak Width: 0.1

Initial Area Reject: 0

Initial Height Reject: 5000

Timed Event Table :

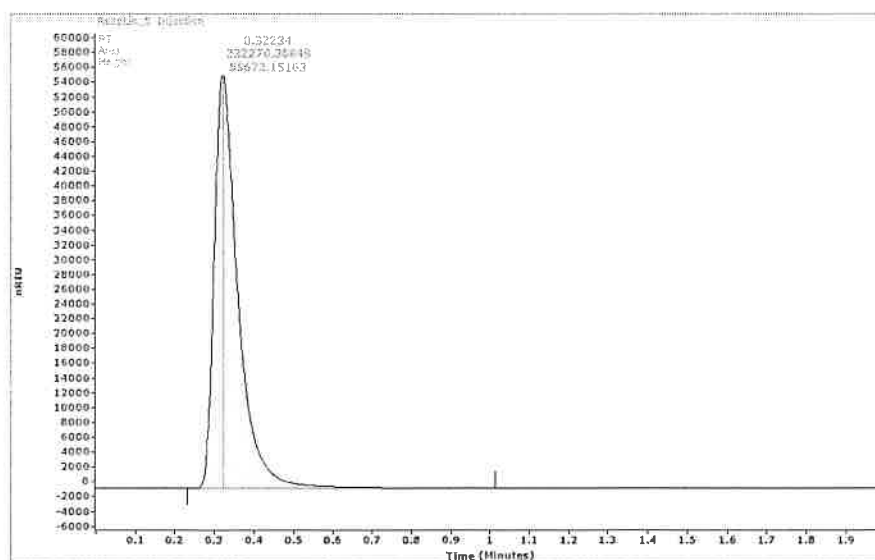
Integration Type	Value	Time
Integration	OFF	0
Integration	ON	0.2

Acquisition operator: oqadmin

Acquisition method: /OQ/Results/OQ2024/Resp_lin_RL.rsl/RID_RL.amx

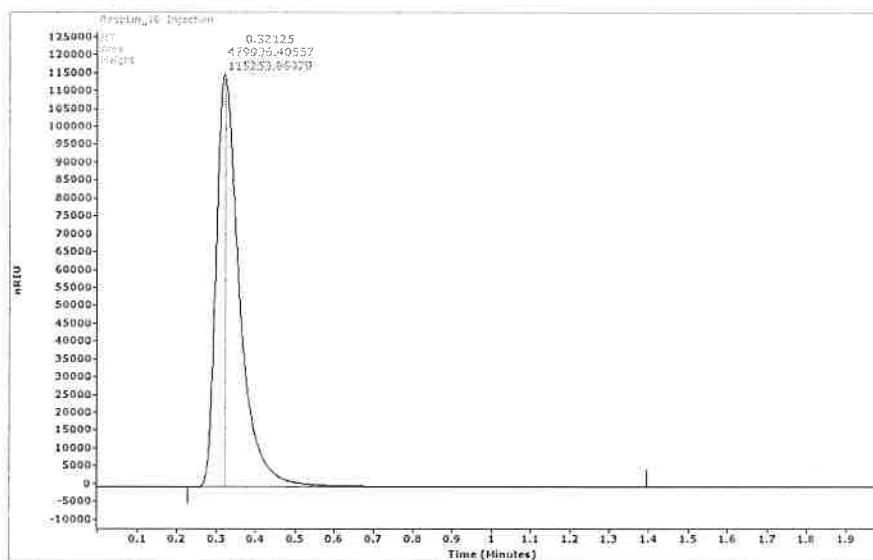
Data file analyzed for this test: RespLin_503.dx

Acquisition Date: Friday, August 9, 2024 11:23:48 AM

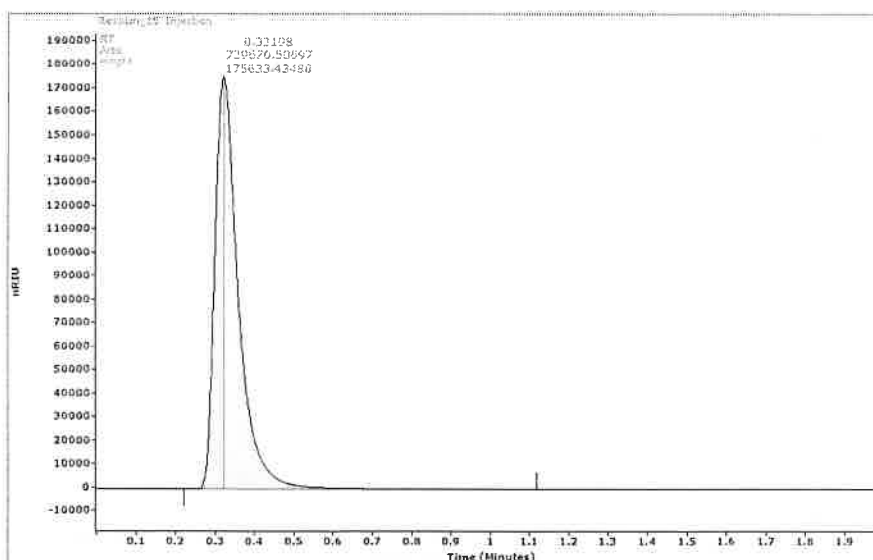


Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

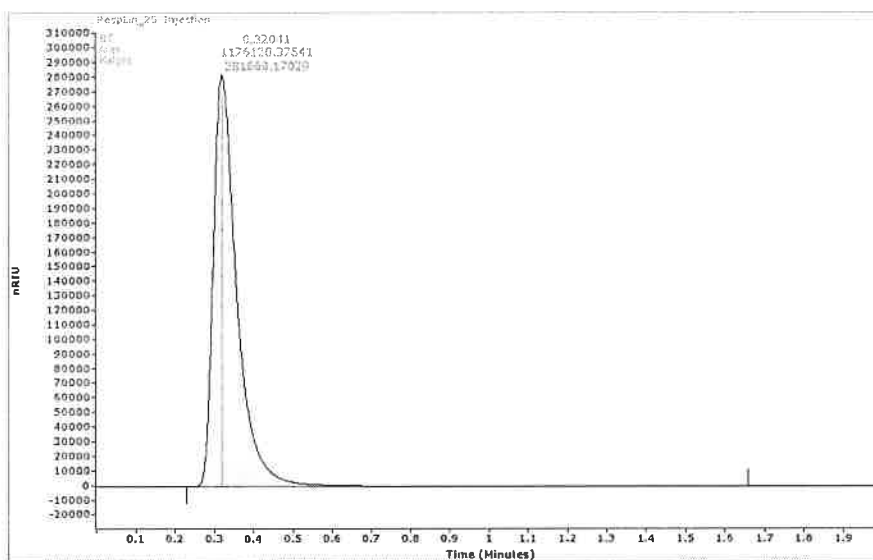
Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/Resp_lin_RI.rsl/RID_RL.amx
Data file analyzed for this test: RespLin_1004.dx
Acquisition Date: Friday, August 9, 2024 11:26:23 AM



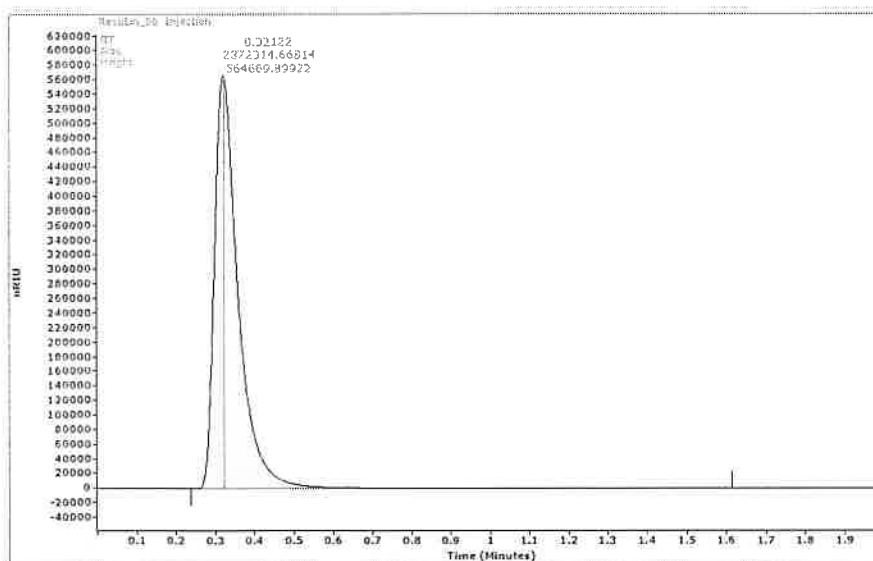
Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/Resp_lin_RI.rsl/RID_RL.amx
Data file analyzed for this test: RespLin_1505.dx
Acquisition Date: Friday, August 9, 2024 11:29:02 AM



Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/Resp_lin_RI.rsl/RID_RL.amx
Data file analyzed for this test: RespLin_2506.dx
Acquisition Date: Friday, August 9, 2024 11:31:16 AM



Acquisition operator: oqadmin
Acquisition method: /OQ/Results/OQ2024/Resp_lin_RI.rsl/RID_RL.amx
Data file analyzed for this test: RespLin_5007.dx
Acquisition Date: Friday, August 9, 2024 11:33:38 AM



Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Overall Response Linearity Test Status

Pass

Declaration of Change Control

This document is under change control. Revision history is maintained and printed on each document. Access to the master documents is limited to process owners. Documents receive periodic review and cannot be assigned an evergreen status. The qualification performed according to this document refers only to the hardware/software configuration in place at the time of the qualification. Agilent Technologies recommends that instrument configuration change management procedures be in place in order to maintain the validation process. Any changes to the analytical or computer hardware or software must be clearly specified. A change management system provides a means for determining the degree of requalification required according to the extent of the changes made. All details of the changes must be thoroughly recorded and documented, together with details of completed tests and their results. Note: Hardware/software configuration management is the customer's responsibility.

Attachments

Training requirements note: The delivery engineer attaches an ACE technique-specific training certificate to the Equipment Qualification Report (EQR). Obtaining ACE technique-specific certification includes pre-requisite trainings for Data Integrity, General Compliance topics (GMP, GLP, ALCOA, etc.), instrument hardware and software components, and the ACE technique itself. The one certificate encompasses all pre-requisite trainings as documented in the Agilent Learning Management System called Success Factors.

Location	Category	Document Name	Page
EQR	General	ACE Self Qualification Certificate	72
EQR	General	Operator's training certificate and qualifications	73
EQR	General	Operator's training certificate and qualifications	74
EQR	General	Operator's training certificate and qualifications	75
EQR	Tool	Certificate of Calibration Liquid Flowmeter	76
EQR	Tool	Certificate of Calibration Thermometer and Probe	77
EQR	Material	Certificate of Analysis Caffeine Standard	79
EQR	Material	Certificate of Analysis Glycerin Standard	81
EQR	Material	Water	82
EQR	Material	Acetone	82

General

Document Name: ACE Self Qualification Certificate



Agilent Technologies

Agilent Compliance Engine Self Qualification

Date: July 3, 2023 10:12:55 PM

Drive Serial #: 0EED745C

Platform Revision:

ACE 3.12.57

Individual self-qualification reports for each specific technique installed are also available upon request. They provide additional details on the general report from the concise summary and are structured by the actual algorithms challenged during the process. There is not a one-to-one relationship between algorithms and OQ program tests because some algorithms are used by several tests and across multiple similar hardware components of the qualified systems.

Technique Type	Tests Completed	Result
Atomic Absorption	7	Conforms
Capillary Electrophoresis	10	Conforms
Dissolution	6	Conforms
Emission Spectroscopy	3	Conforms
Gas Chromatography - GCMS	17	Conforms
Gas Chromatography	29	Conforms
Gel Permeation Chromatography	9	Conforms
ICP-MS	6	Conforms
Infrared Spectroscopy	7	Conforms
Liquid Chromatography	17	Conforms
Liquid Chromatography - LCMS	8	Conforms
Microfluidics	18	Conforms
Sample Preparation - Gas Chromatography	9	Conforms
Sample Preparation - Liquid Chromatography	8	Conforms
Supercritical Fluid Chromatography	15	Conforms
Software	6	Conforms
UV-Vis Spectrophotometer	13	Conforms

Overall Qualification Status

Conforms

Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

General

Document Name: Operator's training certificate and qualifications



Certificate of Completion

Learner Name: Sebastian Nowak

Title Of Course: AN-CE-SS-II-033-A: ACE Training Certificates: EQR requirements

Completion Date: July 9, 2021

Certified By Company: Learning at Agilent

All Service and Support training certificates have the following specific limitations.

A certificate for Service and Support training is only valid while employed by Agilent Technologies or while working as an Agilent-authorized service provider, through which the service employee has ongoing access to Agilent's: Safety Alerts, Service Notices, internal technical updates, update training, current documentation, technical support, current parts, and parts updates. Completion of training alone, without being employed by Agilent Technologies, does not qualify an individual to safely install, service or maintain Agilent products.

General

Document Name:

Operator's training certificate and qualifications



Certificate of Completion

Learner Name:

Sebastian Nowak

Title Of Course:

AN-CE-LC-3-031-A: General Agilent LC Service Training

Completion Date:

March 29, 2019

Certified By Company:

Learning at Agilent

All Service and Support training certificates have the following specific limitations.

A certificate for Service and Support training is only valid while employed by Agilent Technologies or while working as an Agilent-authorized service provider, through which the service employee has ongoing access to Agilent's: Safety Alerts, Service Notes, internal technical updates, update training, current documentation, technical support, current parts, and parts updates. Completion of training alone, without being employed by Agilent Technologies, does not qualify an individual to safely install, service or maintain Agilent products.

General

Document Name: Operator's training certificate and qualifications



Certificate of Completion

Learner Name: Sebastian Nowak

Title Of Course: AN-FSE-NDS-I-305-A: OpenLab CDS v2.6 Workstation Update

Completion Date: June 15, 2021

Certified By Company: Learning at Agilent

All Service and Support training certificates have the following specific limitations.

A certificate for Service and Support training is only valid while employed by Agilent Technologies or while working as an Agilent-authorized service provider, through which the service employee has ongoing access to Agilent's: Safety Alerts, Service Notes, internal technical updates, update training, current documentation, technical support, current parts, and parts updates. Completion of training alone, without being employed by Agilent Technologies, does not qualify an individual to safely install, service or maintain Agilent products.

Tools

Document Name: Certificate of Calibration Liquid Flowmeter

GJC Instruments Ltd.

North West House, Chester Road, Tattenhall, Cheshire, CH3 9AH, United Kingdom.

Tel: +44 (0) 1829 770087 Fax: +44 (0) 1829 771694

email: gjcinstr@btinternet.com

website: www.gjcinstruments.com

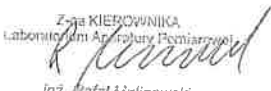
CERTIFICATE OF CALIBRATION						
DATE OF ISSUE:	26-September-2023		CERTIFICATE No:		2023-0933L	
APPROVED SIGNATORY:	Dr. A. Munday, Mr. J. Steen, Mr. M. J. Munday					
MANUFACTURER:	G J C Instruments Ltd, Tattenhall, Cheshire, U.K.					
MODEL No:	5025000	PART No:	2000			
SERIAL No:	4-2002	FIRMWARE Rev:	4.07			
RANGE OF FLOWMETER:	0.05 - 25.0 ml/min					
CUSTOMER:	ALTUM INTERNATIONAL, POLAND					
CUSTOMER REFERENCE:	-					
DATE OF CALIBRATION:	26-September-2023		NEXT DUE:		26-September-2024	
The manufacturer recommends an annual re-calibration.						
CALIBRATION DETAILS	Before	After data				Specification
NOMINAL FLOW ml/min:	1.0	0.5	1.0	2.0	20.0	
ACTUAL FLOW ml/min:	1.0059	0.5019	0.9997	2.0082	20.0308	Within $\pm 10\%$ of Nominal Flow
DISPLAYED FLOW ml/min:	0.9991	0.5005	0.9992	2.0083	20.0438	Within $\pm 1.0\%$ of Actual Flow
STANDARD DEVIATION %:	0.032	0.019	0.039	0.067	0.073	$\leq 0.5\%$
ERROR %:	-0.669	-0.293	-0.045	0.008	0.065	$\leq \pm 1.0\%$
CALIBRATION EQUIPMENT						
INSTRUMENT:	Balance	Balance	Univ Counter/Timer			
MANUFACTURER:	OHAUS	PRECISA	Black Star (RS Components)			
MODEL:	E01140	XT 920M	Apollo 100 (612-445)			
SERIAL No:	1118501519	W47044	43260			
UKAS CERTIFICATE No:	62214	62213	U367568			
DATE OF CALIBRATION:	12 January 2023	12 January 2023	12 April 2023			
NEXT CALIBRATION DUE:	12 January 2024	12 January 2024	12 April 2024			
TESTING LABORATORY:	Precisa Ltd.	Precisa Ltd.	ServiceCal Ltd. (0152)			
This certifies that the above product was calibrated in accordance with GJC Instruments Ltd calibration procedure CALPROC000. Calibration measurements were made using test equipment calibrated to United Kingdom Accreditation Service (UKAS) standards. It provides traceability of measurement to recognised national standards, and to units of measurement realised at the National Physical Laboratory or other recognised National Standards Laboratories.						
Work carried out:-						
☒ Recalibration		☐ Valve Serviced		☐ Flow-tube replaced		
☐ Sensors adjusted		☐ Valve Replaced		☒ Calibration potentiometer / factor adjusted		
Additional comments: Flow tube cleaned before recalibration.						
This calibrated flowmeter is linear ($\pm 1\%$) across range 0.05 - 25.0 ml/min. We recommend regular cleaning of the flowmeter to maintain accuracy between recalibrations. Cleaning kit Part : 201013 / 9 is available.						
The results quoted were found to meet the manufacturer's specification.						
Calibrated at:- G J C Instruments Ltd.		Calibrated by:-		 (J. Steen)		
		Verified by:-		 (A. Munday)		
GJC Instruments Ltd., North West House, Chester Road, Tattenhall, Cheshire, CH3 9AH, U.K.						
This certificate shall not be reproduced except in full, without the written approval of GJC Instruments Ltd.						

Date: August 9, 2024 1:45:42 PM
 System ID: KLC0004

Tools

Document Name:

Certificate of Calibration Thermometer and Probe

	INSTYTUT ENERGETYKI INSTYTUT BADAWCZY Laboratorium Aparatury Pomiarowej 02-981 Warszawa, ul. Augustówka 36, tel. (22) 34 51 438 fax: (22) 34 51 444, e-mail: lap@ien.com.pl, http://www.ien.com.pl Laboratorium wzorcujące akredytowane przez Polskie Centrum Akredytacji, sygnatariusza porozumień EA MLA i ILAC MRA dotyczących wzajemnego uznawania świadectw wzorcowania. Nr akredytacji AP 013	 AP 013 
ŚWIADECTWO WZORCOWANIA		
Data wydania: 28 września 2023 r. Nr świadectwa: 4333/2023		Strona 1/2
OBIEKT WZORCOWANIA	Termometr elektryczny składający się z zestawu: wskaźnik temperatury model ALMEMO MA25903S, wytwórca AHLBORN, oznaczony numerem seryjnym HI2010057 oraz numerem identyfikacyjnym TLC 6 wraz z trzema czujnikami zewnętrznymi typu K, oznaczonymi numerami identyfikacyjnymi: LC 6/1, LC 6/2, LC 6/3.	
ZGŁASZAJĄCY	Altium International Sp. z o.o. 02 – 785 Warszawa, ul. Puławska 303 Zlecenie: MAP.4032.1270.2023	
METODA WZORCOWANIA	Wzorcowania wykonano w siedzibie LAP IEn zgodnie z Instrukcją Pomiarową T/I 9/MAP „Wzorcowanie termometrów”, wydanie VII z dnia 30.05.2023 r.	
WARUNKI ŚRODOWISKOWE	Temperatura otoczenia (21,6 ± 23,0) °C Wilgotność względna (48,0 ± 62,0) %	
DATA WYKONANIA WZORCOWANIA	28 września 2023 r.	
SPÓJNOŚĆ POMIAROWA	Świadectwo jest wydane w ramach porozumienia EA MLA w zakresie wzorcowania i potwierdza spójność wyników pomiarów z jednostkami miar Międzynarodowego Układu Jednostek Miar (SI).	
WYNIKI WZORCOWANIA	Podano na stronie 2/2 niniejszego świadectwa wraz z wartościami niepewności pomiaru. Wyniki dotyczą wyłącznie obiektu wzorcowanego.	
NIEPEWNOŚĆ POMIARU	Niepewność pomiaru została określona zgodnie z dokumentem EA-4/02 M:2022. Podane wartości niepewności stanowią niepewności rozszerzone przy prawdopodobieństwie rozszerzenia ok. 95 % i współczynniku rozszerzenia $k = 2$.	
		 Z-ca KIEROWNIKA Laboratorium Aparatury Pomiarowej Inż. Rafał Melinowski
Niniejsze świadectwo może być okazywane lub kopiowane tylko w całości.		

Document Name:

Certificate of Calibration Thermometer and Probe

ŚWIADECTWO WZORCOWANIA wydane przez LABORATORIUM AKREDYTOWANE Nr AP 013.

Data wydania: 28 września 2023 r.

Nr świadectwa: 4333/2023

Strona 2/2

**WYNIKI
WZORCOWANIA**

Wyniki przeprowadzonego wzorcowania przedstawiono poniżej:

WARTOŚĆ TEMPERATURY ODNIESIENIA W_p °C	WARTOŚĆ TEMPERATURY ZMIERZONA W_w °C			BŁĄD POMIARU $W_w - W_p$ °C			NIEPEWNOŚĆ POMIARU U °C
	M0	M1	M2	M0	M1	M2	
nr kanału →	LC 6/1	LC 6/2	LC 6/3	LC 6/1	LC 6/2	LC 6/3	
nr czujnika →							
0,0	0,5	0,4	0,7	0,5	0,4	0,7	0,3
40,0	39,8	39,8	39,5	-0,2	-0,2	-0,5	0,3
100,0	98,9	98,9	98,8	-1,1	-1,1	-1,2	0,3

Głębokość zanurzenia czujników wzorcowanych: 100 mm.

Podane wartości temperatury odnoszą się do Międzynarodowej Skali Temperatury z 1990 roku (MST-90).

Autoryzował:

KIEROWNIK TECHNICZNY
Laboratorium Aparatury Pomiarowej

Inż. Rafal Mellnowski

Date:

August 9, 2024 1:45:42 PM

System ID:

KLC0004

Materials

Document Name: Certificate of Analysis Caffeine Standard



Agilent Technologies

Certificate of Analysis

Enterprise Edition Caffeine Standards Kit

Agilent Part
Number: 5190-0488Sample Lot
Number: 0006746075

This analytical reference material was manufactured and verified in accordance with an ISO 9001 registered quality system, and the analyte concentrations were verified by an ISO 17025 accredited laboratory. The certified value for each analyte was determined gravimetrically.

Vial	Lot #	Analyte	CAS#	Purity	Certified Value	Analytical Value
5190-0488-1	0006739923	Caffeine	000058-08-2	99+%	0.501 µg/mL	0.494 ± 0.003 µg/mL
5190-0488-2	0006739924	Caffeine	000058-08-2	99+%	1.00 µg/mL	0.993 ± 0.006 µg/mL
5190-0488-3	0006739925	Caffeine	000058-08-2	99+%	2.00 µg/mL	1.99 ± 0.01 µg/mL
5190-0488-4	0006739926	Caffeine	000058-08-2	99+%	5.01 µg/mL	4.97 ± 0.01 µg/mL
5190-0488-5	0006739927	Caffeine	000058-08-2	99+%	25.1 µg/mL	24.8 ± 0.1 µg/mL
5190-0488-6	0006739928	Caffeine	000058-08-2	99+%	50.1 µg/mL	50.1 ± 0.6 µg/mL
5190-0488-7	0006739929	Caffeine	000058-08-2	99+%	100.2 µg/mL	99.6 ± 1.4 µg/mL
5190-0488-8	0006739930	Caffeine	000058-08-2	99+%	200.5 µg/mL	202.7 ± 0.5 µg/mL

Solvent: water (low TOC, < 50 µg/L)

Calibrated Class A glassware and clean bottles were used in the manufacture of this standard. Balances used in the manufacture of this standard are calibrated with weights traceable to NIST in compliance with ANSI/NCSL Z-540-1 and ISO 9001.

Date of release: 23 May 2023
Date of expiration: 30 June 2025
Monica Bourgeois
QMS Representative

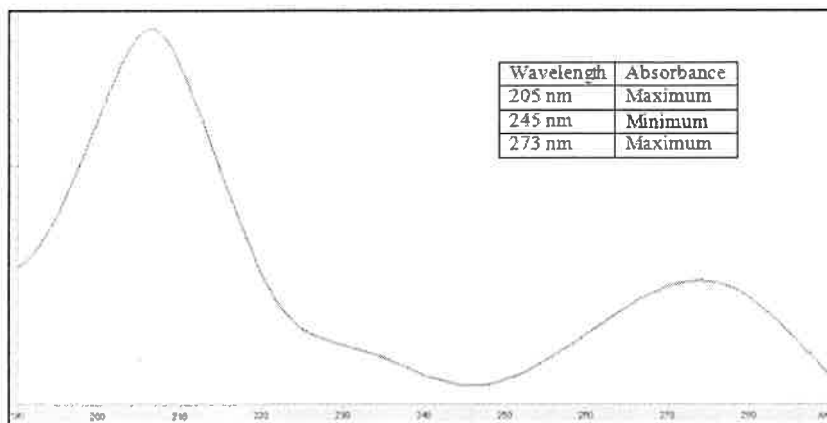
Document Name:

Certificate of Analysis Caffeine Standard



Agilent Technologies

UV/VIS Spectrum: 5190-0488-5 Caffeine in Water, 25µg/mL



Date of release: 23 May 2023

Date of expiration: 30 June 2025

Monica Bourgeois
Monica Bourgeois
QMS Representative

Materials

Document Name: Certificate of Analysis Glycerin Standard



Agilent Technologies

Certificate of Analysis

OQ/PV Test Sample for Refractive Index Detector

Agilent Part
Number: 5064-8220Sample Lot
Number: 0006735262

This analytical reference material (RM) was manufactured and verified in accordance with an ISO 9001 registered quality system, and the analyte concentrations were verified by an ISO 17025 accredited laboratory. The certified value for each analyte was determined gravimetrically.

Vial	Lot #	Analyte	CAS#	Purity	Certified Value	Analytical Value
5064-8220-1	0006732095	glycerin	000056-81-5	99.9 %	5.02 mg/mL	5.00 ± 0.01 mg/mL
5064-8220-2	0006732096	glycerin	000056-81-5	99.9 %	10.0 mg/mL	10.1 ± 0.1 mg/mL
5064-8220-3	0006732097	glycerin	000056-81-5	99.9 %	15.0 mg/mL	15.1 ± 0.1 mg/mL
5064-8220-4	0006732098	glycerin	000056-81-5	99.9 %	25.1 mg/mL	25.1 ± 0.1 mg/mL
5064-8220-5	0006732099	glycerin	000056-81-5	99.9 %	50.1 mg/mL	49.9 ± 0.1 mg/mL

Solvent: water (low TOC, < 50 µg/L)

Calibrated Class A glassware and clean bottles were used in the manufacture of this standard. Balances used in the manufacture of this standard are calibrated with weights traceable to NIST in compliance with ANSI/NCCL Z-540-1 and ISO 9001.

Date of release: 10 March 2023

Date of expiration: 30 April 2025

Monica Bourgeois
QMS RepresentativeDate: August 9, 2024 1:45:42 PM
System ID: KLC0004

Materials

This section lists details for materials added with the ACE Attachments tool.

Name:	Water		
Specification:	HPLC grade (or higher for LCMS)		
Part/Lot No.:	NA	NA	
Expiration Date:	August 9, 2024 1:37:52 PM		

Materials

This section lists details for materials added with the ACE Attachments tool.

Name:	Acetone		
Specification:	Laboratory-grade acetone		
Part/Lot No.:	1.00014.2500	K52408814021	
Expiration Date:	April 30, 2025		

Agilent Technologies Materials: LC/LCMS

This section lists a set of Agilent materials required for all qualifications. (Valve capillaries are the exception, required for external valve testing only.) If several part numbers are listed for an item, only the one(s) that apply to the tested configuration are used. Items may apply to specific detectors and/or system scales. If specific detectors or system scales are not listed, the item applies to all types.

Part No.	Specification
----------	---------------

Restriction Capillary

5022-2159	Stainless steel 2000 x 0.12 mm i.d. (analytical standard UV/RID/ELSD/FLD)
G1375-87314	Fused silica 400 nm i.d. 50 µm (capillary UV)
5042-6462	PEEK tubing 1/16 inch, .007/0.18 mm i.d., 5 m (analytical standard LCMS/CD; analytical Bio-Inert UV/FLD)
5065-4493	Stainless steel 4000 x 0.25 mm i.d. (preparative UV except with G7158B inj/FC)
G4240-87303	Fused silica/PEEK capillary 75 µm, 100 cm (capillary LCMS)

T-Piece

0100-0969	1/16 inch stainless steel low dead volume (analytical standard UV/RID/ELSD/FLD/LCMS; capillary UV)
5022-2144	1/16 inch PEEK low dead volume (analytical Bio-Inert UV/FLD; analytical CD)
5022-2184	Universal ZDV union (preparative UV)
G7116-67110	1/16 inch triangular-shaped (for Agilent G7116x and G7129x models only) (analytical standard UV/RID/ELSD/FLD/LCMS; capillary UV)

PEEK Fittings and Unions

0100-1516	PEEK finger-tight fittings (analytical standard UV/FLD; capillary and preparative UV)
5062-8541	PEEK finger-tight fittings (analytical Bio-Inert UV/FLD)
0100-2441	PEEK union for PEEK finger-tight fittings (analytical Bio-Inert UV/FLD)
5067-4741	SS union for SS-encased PEEK fittings (analytical Bio-Inert UV/FLD)

Guard Fittings Kit

820999-901	Stainless steel (analytical standard UV/RID/ELSD; analytical Bio-Inert UV; capillary UV) (preparative UV with G7158B inj/FC)
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Guard Column Cartridge

820950-925	Zorbax Eclipse XDB-C18 5 µm 12.5 x 4.6 mm i.d. (analytical standard UV/RID/ELSD; analytical Bio-Inert UV) (analytical FLD for IP, CO, and scouting run) (preparative UV with G7158B inj/FC)
821125-926	Zorbax Eclipse XDB-C8 5 µm 12.5 x 2.1 mm i.d. (capillary UV)

Capillaries for Valve Tests

5065-9963	Short (1) - 0.17 mm x 900 mm (analytical)
5022-2159	Long (1) - 2 m x 0.12 mm (analytical)
G1316-87300	Bridge (2) - 0.17 mm x 90 mm (analytical)
5062-2418	Stainless steel fittings (analytical)

Waste Tubing

5062-2462	Clear waste tubing (analytical standard UV; Bio-Inert UV)
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Electronic Signature

Purpose

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Details

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Logged On User Name:	snowak@perlan.com.pl
Signature Creation Date:	August 9, 2024
Reason for Signature:	Executed protocol and published this original version of document

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Certificate of System Qualification

LC-OQ

System ID: KLC0004
Organization Name: Synektik Pharma Sp. z o.o.
Organization Location: Artwinskiego 3, 25-734 Kielce

Date: August 9, 2024 1:45:42 PM
EQP Name: AgilentRecommended
EQP Revision: LC.02.61
Overall Qualification Status: Pass

CDS Logon Verification - LC

Logon: oqadmin

Overall CDS Logon Verification - LC Test Status

Pass

Pump Flow Accuracy

Model/Serial No.: G1311B DEAB702535
Channel: A

Setpoint Status: Pass

Setpoint/Average

Pump Flow Rate:	0.500	0.50017	mL/min
Accuracy (as % error):		0.03	%
Agilent Recommended:	<=	3.00	

Setpoint Status: Pass

Setpoint/Average

Pump Flow Rate:	5.000	5.00317	mL/min
Accuracy (as % error):		0.06	%
Agilent Recommended:	<=	3.00	

Overall Pump Flow Accuracy Test Status

Pass

Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

Pump Flow Precision

Model/Serial No.: G1311B DEAB702535
Channel: A

Setpoint Status: Pass

Setpoint/Average

Pump Flow Rate:	0.500	0.50017	mL/min
Precision RSD:		0.08	%
Agilent Recommended:	<=	0.50	

Setpoint Status: Pass

Setpoint/Average

Pump Flow Rate:	5.000	5.00317	mL/min
Precision RSD:		0.14	%
Agilent Recommended:	<=	0.50	

Overall Pump Flow Precision Test Status

Pass

Scouting Run

Detector Type: UV or UV-Vis
Model/Serial No.: G1328C DEABG00847
Model/Serial No.: G1314F DEABB01463

Setpoint Status: Completed

Overall Scouting Run Status

Completed

Wavelength Accuracy

Detector Type: UV or UV-Vis
Model/Serial No.: G1314F DEABB01463

Setpoint Status:

Pass

Setpoint:	WL 1:	205	nm	WL 2:	245	nm
Actual:		205.00	nm		245.00	nm
Acc.:*		0	nm		0	nm
Agilent Recommended:		<= 2			<= 2	
Setpoint:	WL 3:	273	nm			
Actual:		273.00	nm			
Acc.:*		0	nm			
Agilent Recommended:		<= 2				

* Accuracy (error in nm)

Overall Wavelength Accuracy Test Status

Pass

Noise and Drift

Detector Type: UV or UV-Vis

Model/Serial No.: G1314F

DEABB01463

Setpoint Status:

Pass

Detection Wavelength: 254 nm

	ASTM Noise	Drift
	mAU	mAU/hour
	0.007	0.260
Agilent Recommended:	<= 0.040	<= 0.500
Status:	Pass	Pass

Overall Noise and Drift Test Status

Pass

Injection Precision

Detector Type: UV or UV-Vis

Model/Serial No.: G1328C

DEABG00847

Model/Serial No.: G1314F

DEABB01463

Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Setpoint Status:

Pass

From EQP

Actual

Injection Volume on Column:

10

/

20

µL

(The injection volume from the EQP is adjusted for this delivery.)

Area RSD:

0.53

%

Height RSD:

0.38

%

Agilent Recommended:

<=

1.00

<=

2.00

Overall Injection Precision Test Status

Pass

Injection Carry Over

Detector Type:

UV or UV-Vis

Model/Serial No.:

G1328C

DEABG00847

Model/Serial No.:

G1314F

DEABB01463

Setpoint Status:

Pass

From EQP

Actual

Injection Volume on Column:

10

/

20

µL

(The injection volume from the EQP is adjusted for this delivery.)

Area Carry Over:

0.06

%

Height Carry Over:

0.07

%

Agilent Recommended:

<=

0.10

<=

0.20

Overall Injection Carry Over Test Status

Pass

Signal to Noise

Detector Type:

UV or UV-Vis

Model/Serial No.:

G1314F

DEABB01463

Setpoint Status:

Pass

Signal to Noise:

22352

Agilent Recommended:

>=

3000

Overall Signal to Noise Test Status

Pass

Date:

August 9, 2024 1:45:42 PM

System ID:

KLC0004

Response Linearity

Detector Type: UV or UV-Vis
Model/Serial No.: G1314F DEABB01463

Setpoint Status: Pass

Coefficient of Determination (r2): 0.99994 R/F Precision 1.88 %
Agilent Recommended: $\geq$ 0.99900 RSD: $\leq$ 5.00

Overall Response Linearity Test Status

Pass

Gradient Composition

Detector Type: UV or UV-Vis
Pump Details: Quaternary Primary
Model/Serial No.: G1311B DEAB702535
Model/Serial No.: G1314F DEABB01463

Setpoint Status: Pass

Delay Volume: 0.81667 ml

	Step 1:	Step 2:	Step 3:	Step 4:
Setpoint:	20.00	40.00	60.00	80.00
Actual:	20.92634	40.98032	61.21099	81.03720
Composition Error (%):	0.93	0.98	1.21	1.04
Agilent Recommended:	$\leq$ 2.00	$\leq$ 2.00	$\leq$ 2.00	$\leq$ 2.00
Composition Noise (%):	1.19	0.55	0.33	1.09
Agilent Recommended:	$\leq$ 2.00	$\leq$ 2.00	$\leq$ 2.00	$\leq$ 2.00
Composition Drift (%):	0.65	0.28	0.15	0.29
Agilent Recommended:	$\leq$ 2.00	$\leq$ 2.00	$\leq$ 2.00	$\leq$ 2.00

Gradient Linearity	Start of Gradient:	50:50 Zone:	End of Gradient:
	95.00 %	75.00 %	25.00 %
Coefficient of Determination (r2):	0.99990	0.99996	0.99987
Agilent Recommended:	$\geq$ 0.99900	$\geq$ 0.99900	$\geq$ 0.99900

Overall Gradient Composition Test Status

Pass

Scouting Run

Detector Type: RID

Model/Serial No.: G1328C

DEABG00847

Model/Serial No.: G1362A

DEAA601257

Setpoint Status: Completed

Overall Scouting Run Status

Completed

Noise and Drift

Detector Type: RID

Model/Serial No.: G1362A

DEAA601257

Setpoint Status: Pass

	ASTM Noise		Drift	
		nRIU		nRIU/hour
		5.144		332.643
Agilent Recommended:	<=	10.000	<=	400.000
Status:	Pass		Pass	

Overall Noise and Drift Test Status

Pass

Signal to Noise

Detector Type: RID

Model/Serial No.: G1362A

DEAA601257

Setpoint Status: Pass

Signal to Noise: 29116

Agilent Recommended: >= 2000

Date: August 9, 2024 1:45:42 PM

System ID: KLC0004

Overall Signal to Noise Test Status

Pass

Response Linearity

Detector Type: RID

Model/Serial No.: G1362A

DEAA601257

Setpoint Status: Pass

Coefficient of Determination (r2):

0.99985

R/F Precision

1.51

%

Agilent Recommended:

>=

0.99500

RSD:

<=

10.00

Overall Response Linearity Test Status

Pass

User Name: snowak
Hostname: LAB01

System Id: KLC0004
Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 10:51:38 AM	Audit	SessionCreated	Session	None
August 9, 2024 10:51:38 AM	Start	Configuration	Session	None
August 9, 2024 10:51:38 AM	Audit	Entitlement	Licensing	Session identifier generated: 0800-0001-0000-06MJ-9M70
August 9, 2024 10:54:24 AM	Audit	Entitlement	Licensing	Successfully unlocked session identified by 0800-0001-0000-06MJ-9M70 with unlock code WXS2-18PQ-CMSX-2ZR0-YW50
August 9, 2024 10:55:05 AM	Audit	EqpLoaded	Session	EQP details for primary technique [Lc] - File path: [ProtocolPacks/Lc/Configurations/02.61/Lc.02.61.eqp], EQP File Name: [Lc.02.61.eqp], EQP Name: [AgilentRecommended], Protocol Revision :[Lc.02.61]
August 9, 2024 10:55:09 AM	End	Configuration	Session	None
August 9, 2024 10:55:13 AM	Start	Qualification	Session	OQ
August 9, 2024 10:55:14 AM	Start	Execution	CDS Logon Verification - LC : Qualitative Test	None
August 9, 2024 10:55:55 AM	End	Execution	CDS Logon Verification - LC : Qualitative Test	Run Count : 1
August 9, 2024 10:55:57 AM	Start	Execution	Pump Flow Accuracy : Pumps 1, G1311B, Channel 1: Flow 1	None
August 9, 2024 10:56:22 AM	Audit	Data	Pump Flow Accuracy : Pumps 1, G1311B, Channel 1: Flow 1	Manual Data Entry

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User Name: snowak
 Hostname: LAB01

System Id: KLC0004
 Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 10:56:24 AM	End	Execution	Pump Flow Accuracy : Pumps 1, G1311B, Channel 1: Flow 1	Run Count : 1
August 9, 2024 10:56:31 AM	Start	Execution	Pump Flow Accuracy : Pumps 1, G1311B, Channel 1: Flow 2	None
August 9, 2024 10:57:07 AM	Audit	Data	Pump Flow Accuracy : Pumps 1, G1311B, Channel 1: Flow 2	Manual Data Entry
August 9, 2024 10:57:09 AM	End	Execution	Pump Flow Accuracy : Pumps 1, G1311B, Channel 1: Flow 2	Run Count : 1
August 9, 2024 10:57:12 AM	Start	Execution	Pump Flow Precision : Pumps 1, G1311B, Channel 1: Flow 1	None
August 9, 2024 10:57:20 AM	Audit	Data	Pump Flow Precision : Pumps 1, G1311B, Channel 1: Flow 1	Manual Data Entry
August 9, 2024 10:57:21 AM	End	Execution	Pump Flow Precision : Pumps 1, G1311B, Channel 1: Flow 1	Run Count : 1
August 9, 2024 10:57:23 AM	Start	Execution	Pump Flow Precision : Pumps 1, G1311B, Channel 1: Flow 2	None
August 9, 2024 10:57:30 AM	Audit	Data	Pump Flow Precision : Pumps 1, G1311B, Channel 1: Flow 2	Manual Data Entry
August 9, 2024 10:57:31 AM	End	Execution	Pump Flow Precision : Pumps 1, G1311B, Channel 1: Flow 2	Run Count : 1
August 9, 2024 10:57:34 AM	Start	Execution	Scouting Run : Detectors 1, G1314F, UV or UV-Vis: Scouting Run 1	None
August 9, 2024 10:57:56 AM	Audit	Data	Scouting Run : Detectors 1, G1314F, UV or UV-Vis: Scouting Run 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\VWD.olax
August 9, 2024 10:58:11 AM	End	Execution	Scouting Run : Detectors 1, G1314F, UV or UV-Vis: Scouting Run 1	Run Count : 1

User Name: snowak

System Id: KLC0004

Hostname: LAB01

Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 10:58:13 AM	Start	Execution	Wavelength Accuracy : Detectors 1, G1314F, UV or UV-Vis: Wavelengths 1	None
August 9, 2024 10:58:44 AM	Audit	Data	Wavelength Accuracy : Detectors 1, G1314F, UV or UV-Vis: Wavelengths 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\SpectralScan_DEA BB01463_09-08-2024_10-14- 37.csv
August 9, 2024 10:59:15 AM	End	Execution	Wavelength Accuracy : Detectors 1, G1314F, UV or UV-Vis: Wavelengths 1	Run Count : 1
August 9, 2024 10:59:17 AM	Start	Execution	Noise and Drift : Detectors 1, G1314F, UV or UV-Vis: Noise and Drift 1	None
August 9, 2024 10:59:36 AM	Audit	Data	Noise and Drift : Detectors 1, G1314F, UV or UV-Vis: Noise and Drift 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\ND.olax
August 9, 2024 10:59:38 AM	End	Execution	Noise and Drift : Detectors 1, G1314F, UV or UV-Vis: Noise and Drift 1	Run Count : 1
August 9, 2024 10:59:40 AM	Start	Execution	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	None
August 9, 2024 11:00:16 AM	Audit	Data	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\IP.olax
August 9, 2024 11:00:16 AM	Audit	Data	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\IP.olax
August 9, 2024 11:00:16 AM	Audit	Data	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\IP.olax

User Name: snowak
 Hostname: LAB01

System Id: KLC0004
 Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 11:00:16 AM	Audit	Data	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\IP.olax
August 9, 2024 11:00:16 AM	Audit	Data	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\IP.olax
August 9, 2024 11:00:16 AM	Audit	Data	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\IP.olax
August 9, 2024 11:00:25 AM	End	Execution	Injection Precision : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Run Count : 1
August 9, 2024 11:00:46 AM	Start	Execution	Injection Carry Over : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	None
August 9, 2024 11:02:33 AM	Audit	Data	Injection Carry Over : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\CO.olax
August 9, 2024 11:02:33 AM	Audit	Data	Injection Carry Over : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\CO.olax
August 9, 2024 11:03:19 AM	End	Execution	Injection Carry Over : Injectors 1, G1328C - G1314F, UV or UV-Vis: Injection Volume 1	Run Count : 1
August 9, 2024 11:03:26 AM	Start	Execution	Signal To Noise : Detectors 1, G1314F, UV or UV-Vis: Signal To Noise 1	None
August 9, 2024 11:04:14 AM	Audit	Data	Signal To Noise : Detectors 1, G1314F, UV or UV-Vis: Signal To Noise 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\SN.olax
August 9, 2024 11:04:17 AM	End	Execution	Signal To Noise : Detectors 1, G1314F, UV or UV-Vis: Signal To Noise 1	Run Count : 1

User Name: snowak

System Id: KLC0004

Hostname: LAB01

Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 11:04:19 AM	Start	Execution	Response Linearity : Detectors 1, G1314F, UV or UV-Vis: Response Linearity 1	None
August 9, 2024 11:05:44 AM	Audit	Data	Response Linearity : Detectors 1, G1314F, UV or UV-Vis: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\Resp_lin.olax
August 9, 2024 11:05:44 AM	Audit	Data	Response Linearity : Detectors 1, G1314F, UV or UV-Vis: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\Resp_lin.olax
August 9, 2024 11:05:44 AM	Audit	Data	Response Linearity : Detectors 1, G1314F, UV or UV-Vis: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\Resp_lin.olax
August 9, 2024 11:05:44 AM	Audit	Data	Response Linearity : Detectors 1, G1314F, UV or UV-Vis: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\Resp_lin.olax
August 9, 2024 11:05:44 AM	Audit	Data	Response Linearity : Detectors 1, G1314F, UV or UV-Vis: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\Resp_lin.olax
August 9, 2024 11:06:09 AM	End	Execution	Response Linearity : Detectors 1, G1314F, UV or UV-Vis: Response Linearity 1	Run Count : 1
August 9, 2024 11:06:18 AM	Start	Execution	Noise and Drift : Detectors 2, G1362A, RID: Noise and Drift 1	None
August 9, 2024 11:06:25 AM	End	Qualification	Session	OQ
August 9, 2024 11:06:25 AM	Start	Configuration	Session	None
August 9, 2024 11:06:59 AM	End	Configuration	Session	None
August 9, 2024 11:06:59 AM	Start	Qualification	Session	OQ

User Name: snowak

System Id: KLC0004

Hostname: LAB01

Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 11:06:59 AM	Start	Execution	Noise and Drift : Detectors 2, G1362A, RID: Noise and Drift 1	None
August 9, 2024 11:07:54 AM	Audit	Data	Noise and Drift : Detectors 2, G1362A, RID: Noise and Drift 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\ND_RI.olax
August 9, 2024 11:07:57 AM	End	Execution	Noise and Drift : Detectors 2, G1362A, RID: Noise and Drift 1	Run Count : 1
August 9, 2024 11:08:04 AM	Start	Execution	Scouting Run : Detectors 2, G1362A, RID: Scouting Run 1	None
August 9, 2024 11:16:52 AM	Start	Execution	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	None
August 9, 2024 11:20:51 AM	Start	Execution	Scouting Run : Detectors 2, G1362A, RID: Scouting Run 1	None
August 9, 2024 11:21:09 AM	Audit	Data	Scouting Run : Detectors 2, G1362A, RID: Scouting Run 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\Scout_RI.olax
August 9, 2024 11:21:32 AM	End	Execution	Scouting Run : Detectors 2, G1362A, RID: Scouting Run 1	Run Count : 1
August 9, 2024 11:21:35 AM	Start	Execution	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	None
August 9, 2024 11:36:44 AM	Audit	Data	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\RespLin_RI.olax
August 9, 2024 11:36:44 AM	Audit	Data	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\RespLin_RI.olax
August 9, 2024 11:36:44 AM	Audit	Data	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\RespLin_RI.olax

User Name: snowak

Hostname: LAB01

System Id: KLC0004

Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 11:36:44 AM	Audit	Data	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\RespLin_RI.olax
August 9, 2024 11:36:44 AM	Audit	Data	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\RespLin_RI.olax
August 9, 2024 11:36:53 AM	End	Execution	Response Linearity : Detectors 2, G1362A, RID: Response Linearity 1	Run Count : 1
August 9, 2024 11:36:58 AM	Start	Execution	Signal To Noise : Detectors 2, G1362A, RID: Signal To Noise 1	None
August 9, 2024 11:49:12 AM	Audit	Data	Signal To Noise : Detectors 2, G1362A, RID: Signal To Noise 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\SN_RI.olax
August 9, 2024 11:49:15 AM	End	Execution	Signal To Noise : Detectors 2, G1362A, RID: Signal To Noise 1	Run Count : 1
August 9, 2024 11:49:20 AM	Start	Execution	Gradient Composition : Primary Logical Pumps, Quaternary - G1314F, UV or UV-Vis, Single Gradient: Gradient 1	None
August 9, 2024 12:04:55 PM	Audit	AceClosed	Session	None
August 9, 2024 12:08:09 PM	Audit	AceRestarted	Session	None
August 9, 2024 12:08:12 PM	Audit	SessionReloaded	Session	None
August 9, 2024 12:08:19 PM	Start	Qualification	Session	OQ
August 9, 2024 12:08:19 PM	Start	Execution	Gradient Composition : Primary Logical Pumps, Quaternary - G1314F, UV or UV-Vis, Single Gradient: Gradient 1	None

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Date: August 9, 2024 1:45:42 PM
System ID: KLC0004

User Name: snowak
Hostname: LAB01

System Id: KLC0004
Print Date: August 9, 2024 1:45:50 PM

OQ2024_KLC004 Transaction log :

Time	Transaction State	Activity Performed	Type of Transaction	Optional Information
August 9, 2024 1:41:02 PM	Audit	Data	Gradient Composition : Primary Logical Pumps, Quaternary - G1314F, UV or UV-Vis, Single Gradient: Gradient 1	Data files Path : C:\Users\User\Desktop\OQ LC\2024\Grad.olax
August 9, 2024 1:41:14 PM	End	Execution	Gradient Composition : Primary Logical Pumps, Quaternary - G1314F, UV or UV-Vis, Single Gradient: Gradient 1	Run Count : 1
August 9, 2024 1:41:23 PM	End	Qualification	Session	OQ
August 9, 2024 1:41:23 PM	Start	Reporting	Session	None
August 9, 2024 1:44:29 PM	Audit	Reporting	Session	Report Generated : Report with Certificate

Intimowane Atty po wykonaniu 09.08.2024 *Howi Ban*



Agilent Technologies

Agilent Maintenance Report

Synektik_1260

Maintenance Info

Maintenance started Thursday, August 8, 2024 8:52:12 AM
Maintenance completed Thursday, August 8, 2024 10:57:54 AM
Report printed Thursday, August 8, 2024 10:58:47 AM

Revisions

Maintenance Checklist Default Maintenance (FSE)
Edition: FSE 2
Issued on: Monday, November 28, 2016
Maintenance Wizard A.01.03 [055]
Lab Advisor 2.20.543

Serviced Devices

G1311B - 1260 Quat Pump (DEAB702535) G1314F - 1260 VWD (DEABB01463)
G1362A - 1260 RID (DEAA601257)

Not Serviced Devices

G1390B - 1200 UIB II (DEABU01730)

Report Attachments

System Pressure Test (Passed)
Pump Leak Rate Test (Passed)
Holmium Oxide Test (Passed)
Intensity Test (Passed)
Wavelength Calibration (Done)
Dark Current Test (Passed)
Filter/Grating Motor Test (Passed)

Service Information

Maintenance Provider: Sebastian Nowak
FSE

G1311B - 1260 Quat Pump (DEAB702535)

1.	Power off the pump.	Done
2.	Remove pump head.	Done
3.	Disassemble the pump head.	Done
4.	Remove and clean pistons.	Done
5.	Clean support rings.	Done
6.	Replace piston seals.	Passed
7.	Replace wash seals and gaskets.	Done
8.	Reassemble the pump head and install it.	Done
9.	Reconnect the AIV to the connector (if installed).	Skipped
10.	Outlet valve: replace seal cap assemblies for outlet valve(s) (if applicable). Note that the latest version of outlet valve uses integrated seals and does not require seal caps.	Done
11.	Replace the seal wash peristaltic pump.	Done
12.	Power on the module.	Done
13.	For standard (PTFE) or PE seals perform the seal wear-in procedure.	Passed
14.	While running, begin maintenance on the sampler and column compartment if applicable.	Done
15.	Purge valve: replace the PTFE frit, replace the seal cap assembly if deformed or damaged.	Done
16.	Review the correct installation of seal wash function in non-recycle mode. Manually activate the seal wash and check if there is a flow.	Done
17.	Perform the system pressure test.	Passed
18.	Perform the leak rate test.	Passed
19.	Reset EMF counters.	Done
20.	Complete maintenance on module and reset appropriate EMF counters.	Passed

Resetted EMF Counters

Counter Name	Old Value
--------------	-----------

Seal Wear	326120
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G1314F - 1260 VWD (DEABB01463)

1.	Inspect flow cell for leaks.	Done
2.	Perform holmium oxide test.	Passed
3.	Perform Intensity Test.	Passed
4.	Perform Wavelength Verification Test.	Passed
5.	Perform Dark Current Test.	Passed
6.	Perform Filter Test.	Passed
7.	Complete maintenance on module and reset appropriate EMF counters.	Passed

G1362A - 1260 RID (DEAA601257)

1.	Purge the reference and sample cells with water for 5 min.	Passed
2.	Check diode balance with pure water in both, the reference and the sample cell, instrument stable as specified. Adjust optical balance if value > ± 0.2 .	Passed
3.	Complete maintenance on module and reset appropriate EMF counters.	Passed

Lab Advisor Diagnostic Result

Synektik_1260

G1311B

System Pressure Test

Passed

DEAB702535
A.06.33[004]
1260 Quat Pump

The test determines the leak tightness of the system between pump and blank nut.
For bio-compatible or bio-inert Multisampler (for example G7137A) it is essential to use the PEEK Blank Nut, part number 5043-0277. Otherwise use the Blank Nut SL, part number 5067-6127.

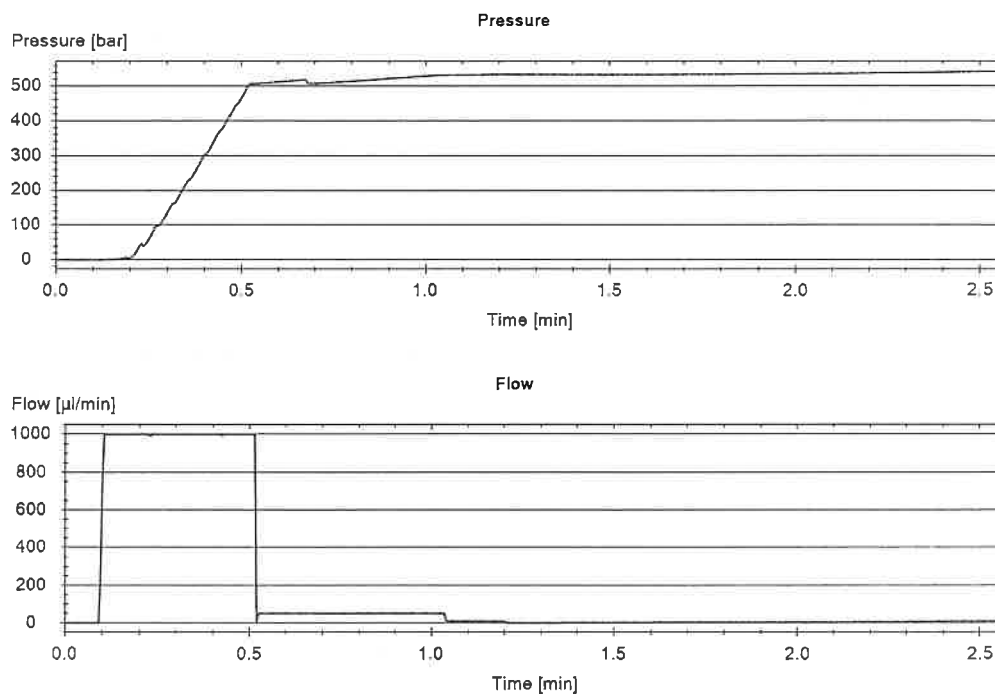
Started at 8/8/2024 10:14:39 AM by DESKTOP-E9SIOFM\Sebastian Nowak on DESKTOP-E9SIOFM

Results

Item	Value	Result
Maximum system pressure	600 bar	Done
Blank nut location	Pump outlet	Done
Purge Channel A	Skipped purging	Done
Resulting flow value	1.51 µl/min	
System leak	5 µl/min	Passed

Finished at 8/8/2024 10:17:37 AM

Signals



Lab Advisor Diagnostic Result

Synektik_1260

G1311B

Pump Leak Rate Test

Passed

DEAB702535
A.06.33[004]
1260 Quat Pump

The test determines the leak rates in the primary and the secondary pump chambers for component level diagnostic.

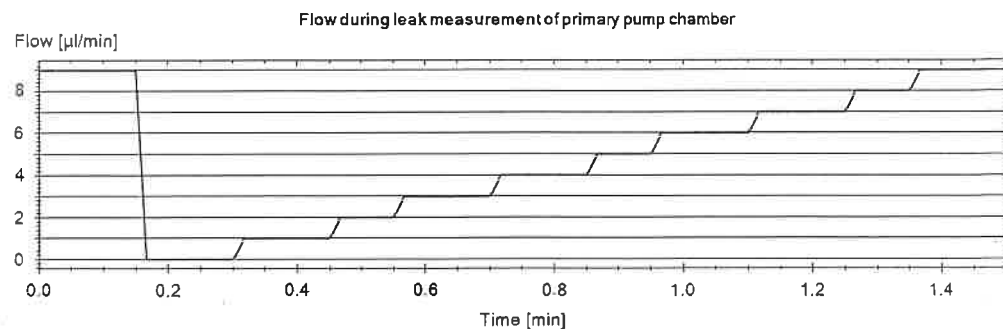
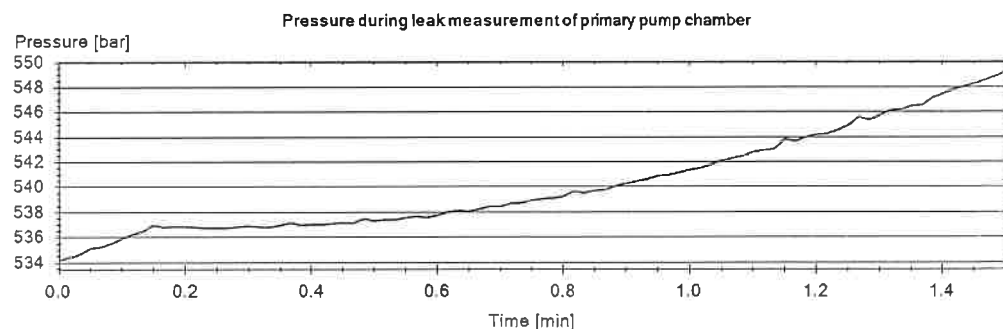
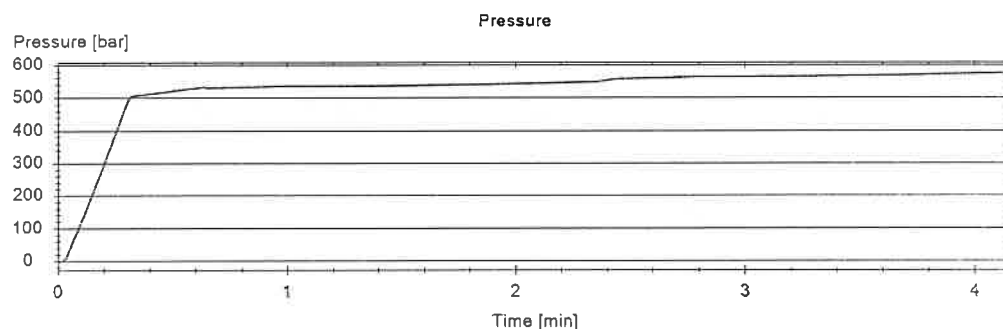
Started at 8/8/2024 10:49:53 AM by DESKTOP-E9SIOFM\Sebastian Nowak on DESKTOP-E9SIOFM

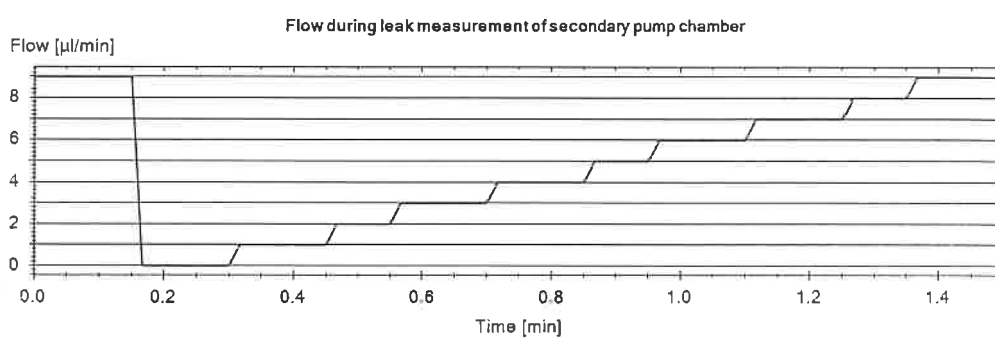
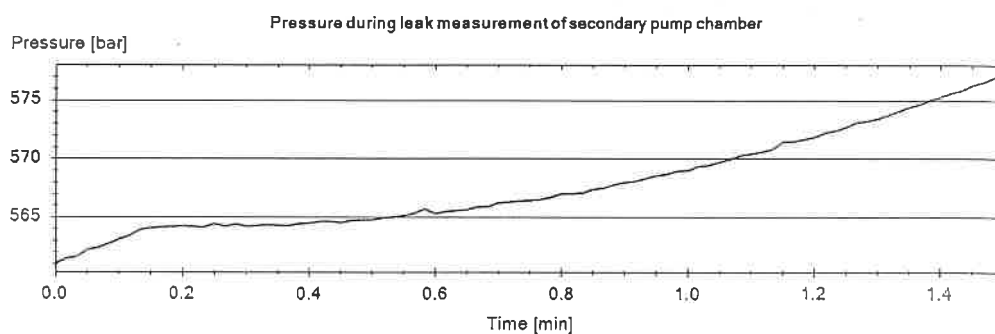
Results

Item	Value	Result
Maximum system pressure	600 bar	Done
Leak of primary pump chamber	0.4 µl/min	
Leak rate limit	3 µl/min	Passed
Leak of secondary pump chamber	< 0.1 µl/min	
Leak rate limit	3 µl/min	Passed

Finished at 8/8/2024 10:57:23 AM

Signals





Lab Advisor Diagnostic Result

Synektik_1260

G1314F

Holmium Oxide Test

Passed

DEABB01463
B.07.28[0006]
1260 VWD

The test measures the Holmium spectrum from the built-in Holmium filter. The spectrum is evaluated for peaks at different wavelengths.

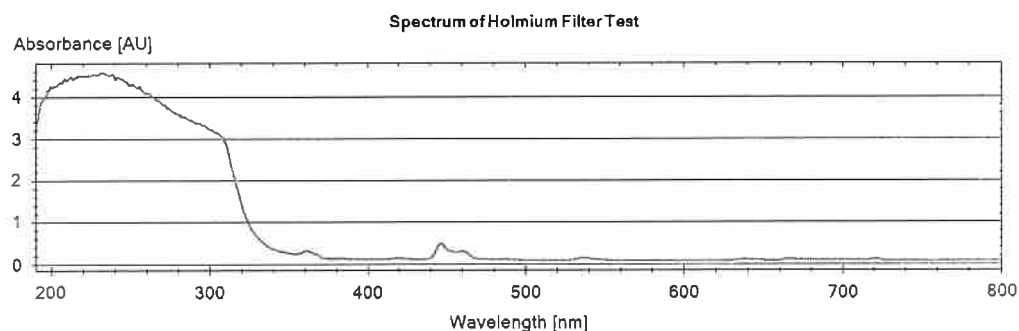
Started at 8/8/2024 9:14:23 AM by DESKTOP-E9SIOFM\Sebastian Nowak on DESKTOP-E9SIOFM

Results

Item	Value	Result
Accumulated UV Lamp On-Time	0.00 h	Done
UV Lamp On-Time	0.00 h	Done
Holmium Deviation to 360.8 nm	0.10 nm	
<i>Holmium Deviation Limit</i>	<i>-1 ... 1 nm</i>	Passed
Holmium Deviation to 418.5 nm	0.00 nm	
<i>Holmium Deviation Limit</i>	<i>-1 ... 1 nm</i>	Passed
Holmium Deviation to 536.4 nm	-0.30 nm	
<i>Holmium Deviation Limit</i>	<i>-1 ... 1 nm</i>	Passed

Finished at 8/8/2024 9:18:04 AM

Signals



Lab Advisor Diagnostic Result

Synektik_1260

G1314F

Intensity Test

Passed

DEABB01463
B.07.28[0006]
1260 VWD

The test scans the Intensity spectrum generated by the UV Lamp.

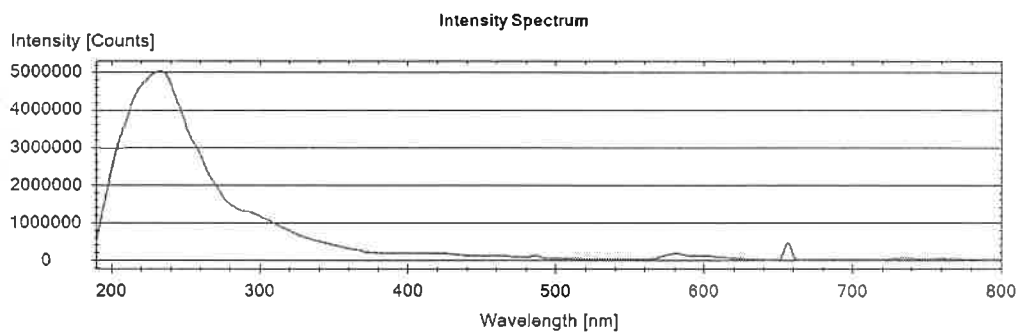
Started at 8/8/2024 9:18:42 AM by DESKTOP-E9SIOFM\Sebastian Nowak on DESKTOP-E9SIOFM

Results

Item	Value	Result
Accumulated UV Lamp On-Time	0.08 h	Done
UV Lamp On-Time	0.08 h	Done
Cell Product Number	G1314-60186	Done
Cell Serial Number	DE823L2416	Done
Lowest Intensity	19552 Counts	
<i>Lowest Intensity Limit</i>	<i>6400 Counts</i>	Passed
Average Intensity	672816 Counts	
<i>Average Intensity Limit</i>	<i>160000 Counts</i>	Passed
Highest Intensity	5044149 Counts	
<i>Highest Intensity Limit</i>	<i>320000 Counts</i>	Passed

Finished at 8/8/2024 9:19:11 AM

Signals



Lab Advisor Diagnostic Result

Synektik_1260

G1314F

Wavelength Calibration

Done

DEABB01463
B.07.28[0006]
1260 VWD

This procedure performs a Wavelength Verification and Recalibration.

Started at 8/8/2024 9:24:21 AM by DESKTOP-E9SIOFM\Sebastian Nowak on DESKTOP-E9SIOFM

Results

Item	Value	Result
Accumulated UV Lamp On-Time	0.17 h	Done
UV Lamp On-Time	0.17 h	Done
Time to Wait Before Wavelength Calibration Can Be Started	0.00 min	
<i>Time to Wait Before Wavelength Calibration Can Be Started</i>	<i>0 ... 0 min</i>	Passed
Wavelength Deviation of 0-order Calibration	0.100 nm	Done
Wavelength Deviation of alpha line Calibration	0.000 nm	Done

Finished at 8/8/2024 9:26:38 AM

Lab Advisor Diagnostic Result

Synektik_1260

G1314F

Dark Current Test

Passed

DEABB01463
B.07.28[0006]
1260 VWD

The test measures the dark current from the detector optic.

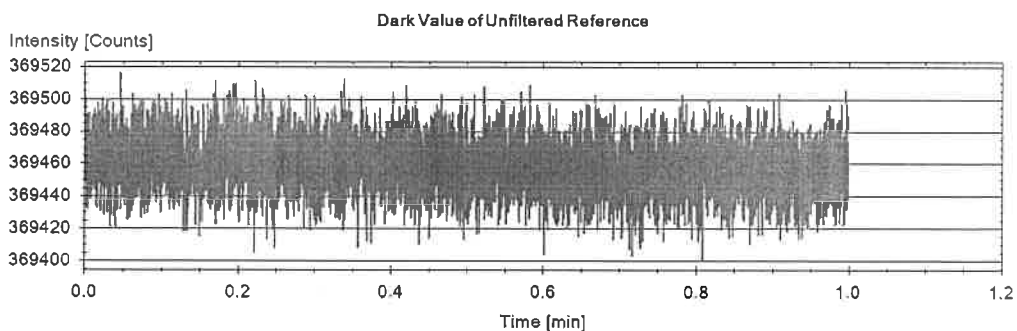
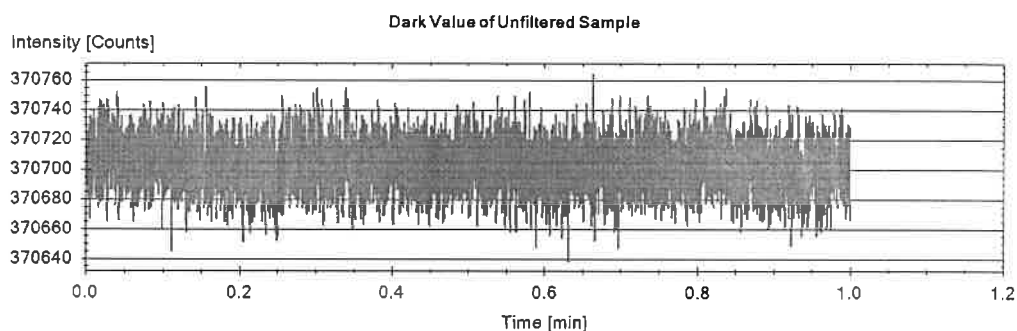
Started at 8/8/2024 9:29:17 AM by DESKTOP-E9SIOFM\Sebastian Nowak on DESKTOP-E9SIOFM

Results

Item	Value	Result
Maximum Sample Intensity Measured	370765 Counts	
Maximum Sample Intensity	790000 Counts	Passed
Maximum Reference Intensity Measured	369517 Counts	
Maximum Reference Intensity	790000 Counts	Passed

Finished at 8/8/2024 9:30:23 AM

Signals



Lab Advisor Diagnostic Result**Synektik_1260****G1314F****Filter/Grating Motor Test****Passed**

DEABB01463
B.07.28[0006]
1260 VWD

The test checks the operation of the filter and grating motor assemblies.

Started at 8/8/2024 9:20:45 AM by DESKTOP-E9SIOFM\Sebastian Nowak
on DESKTOP-E9SIOFM
Finished at 8/8/2024 9:20:49 AM