



SAMPLE ORGANIZER REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8821

Acquired By: Adam

Result Set Id: 8833

Project Path: RC1_SQT_E_QSMR_FTNR_2489_AP

The Sample Organizer Plate Positioning Test passes if each of the four plates transfers from the selected position within the Sample Organizer to the Sample Manager and back to its original position within the Sample Organizer.

The Sample Organizer Temperature Accuracy Test is a manual test that verifies the temperature of the sample compartment is driven to the set point defined in the instrument control software. The temperature is measured near the internal temperature probe. This test requires a calibrated temperature measuring device that is accurate to + or - 1.0°C. Two temperature set points are tested.

Sample Organizer Plate Positioning Results

	Serial Number	Sample Name	Sample Organizer Plate Position	Sample Organizer Plate Position Result	Result ID
1	ABC123	Top Plate Position	1	PASS	8861
2	ABC123	Second Plate Position	2	PASS	8862
3	ABC123	Third Plate Position	3	PASS	8863
4	ABC123	Bottom Plate Position	4	PASS	8864

Sample Organizer Temperature Accuracy Results

	Serial Number	Sample Name	Temperature Accuracy Specification (°C)	Set Temperature (°C)	Temperature Observed (°C)	Temperature Accuracy Result	Result ID
1	ABC123	SO Temperature 1	-2.0 to +4.0 of Set Point	4.0	4.1	PASS	8865
2	ABC123	SO Temperature 2	-2.0 to +4.0 of Set Point	35.0	38.8	PASS	8866

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



SAMPLE MANAGER TEMPERATURE ACCURACY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8290

Acquired By: Adam

Result Set Id: 8307

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

The Sample Heater / Cooler Temperature Accuracy Test is a manual test that verifies the internal electronics which drive the temperature inside the Sample Heater / Cooler to the set point defined by the instrument control software. This verifies functionality of the Sample Heater / Cooler electronics, internal probe and control software. The temperature is measured near to the internal temperature probe.

The test requires a calibrated temperature measuring device that is accurate to + or - 1.0°C. Two temperature set-points per sensor zone are tested.

Sample Heater / Cooler Temperature Accuracy Results

Serial Number	Sample Name	Temperature Accuracy Specification (°C)	Set Temperature (°C)	Temperature Observed (°C)	Temperature Accuracy Result	Result ID	
1	234234	SM Temperature 1	-2.0 to +4.0 of Set Point	10.0	10.0	PASS	8316
2	234234	SM Temperature 2	-2.0 to +4.0 of Set Point	40.0	40.0	PASS	8317

Certification

Comments

The undersigned performer attests that the values recorded above are accurate and complete.

Performer

Signature Date _____

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer

Signature Date _____



COLUMN HEATER OR COLUMN HEATER/COOLER TEMPERATURE ACCURACY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
Acquired By: Adam
Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Sample Set Id: 8315
Result Set Id: 8323

The Column Heater or Column Heater/Cooler Temperature Accuracy Test is a manual test that verifies the internal electronics which drive the temperature inside the Column Heater or Column Heater/Cooler to the set point defined by the instrument control software. This verifies functionality of the Column Heater or Column Heater/Cooler electronics, internal probe and control software. The temperature is measured near the internal temperature probe.

The test requires a calibrated temperature measuring device that is accurate to + or - 1.0°C. Two temperature set-points per sensor zone are tested.

Column Heater or Column Heater / Cooler Temperature Accuracy Results

Serial Number	Sample Name	Temperature Accuracy Specification (°C)	Set Temperature (°C)	Temperature Observed (°C)	Temperature Accuracy Result	Result ID	
1	4567567	CH or CHC Temperature 1	Set Point +/- 2.0 °C	10.0	10.0	PASS	8332
2	fghhgj	CH or CHC Temperature 2	Set Point +/- 2.0 °C	90.0	90.0	PASS	8334

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



FLOW RATE ACCURACY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Acquired By: Adam

Project Path: RC1_SQT_E_QSMR_FTNR_2489_AP

Sample Set Id: 8882

Result Set Id: 8888

Flow Rate Accuracy is determined manually by recording the delivery of a set volume of mobile phase into a Class A volumetric flask utilizing a calibrated stop watch.

The specification for Flow Rate Accuracy takes into account the error from the stop watch, the flask error, and an operator error allowance.

FlowRate Accuracy 0.5 mL/min Results

Serial Number	Sample Name	Flow Rate Specification (mL/min)	Observed Minutes	Observed Seconds	Flow Rate (mL/min)	Accuracy Pass/Fail	Result ID	
1	123456	QSMR Flow Accuracy	0.494 to 0.506	20.0	2.0	0.499	PASS	8893

FlowRate Accuracy 5.0 mL/min Results

Serial Number	Sample Name	Flow Rate Specification (mL/min)	Observed Minutes	Observed Seconds	Flow Rate (mL/min)	Accuracy Pass/Fail	Result ID	
1	123456	QSMR Flow Accuracy	4.94 to 5.06	4.0	58.0	5.03	PASS	8894

Certification

Comments

The undersigned performer attests that the values recorded above are accurate and complete.

Performer

Signature Date _____

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer

Signature Date _____



SYSTEM READINESS CHECK REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
Processing Method: 01a System Readiness Check PM
Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
Sample Kit Lot Number: W13071706
Report Method: 01a System Readiness Check RM Acquired By: Adam
Sample Set Name: System Readiness Check SSM Column Serial Number: 01903731313692
Sample Set Id: 8346 Result Set Id: 8351

The System Readiness Check is performed prior to the qualification to demonstrate the system and column are in an equilibrated, ready state for qualification.

The check also confirms that the peak height is in an appropriate range for the chosen injection volume.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Caffeine Peak Area and Height Results

	Area Specification	%RSD Area	Area System Status	Height Specification	%RSD Height	Height System Status
1	%RSD < or = 0.75	0.07	System Ready	%RSD < or = 2.4	0.1	System Ready

Caffeine Peak RT Results

	Retention Time Specification	Standard Deviation Retention Time (sec)	Retention Time System Status
1	SD RT < or = 1.5 sec	0.0	System Ready

Detector Response (Caffeine Peak) Result

	Sample Name	Detector Response Specification	Injection Volume (µL)	Average Height (µV)	Average Height (AU)	Detector Response System Status
1	Caffeine 0.160 mg/mL	1.80 to 2.40 AU	15.0	1928866	1.93	System Ready



SYSTEM READINESS CHECK REPORT

ACQUISITION INFORMATION

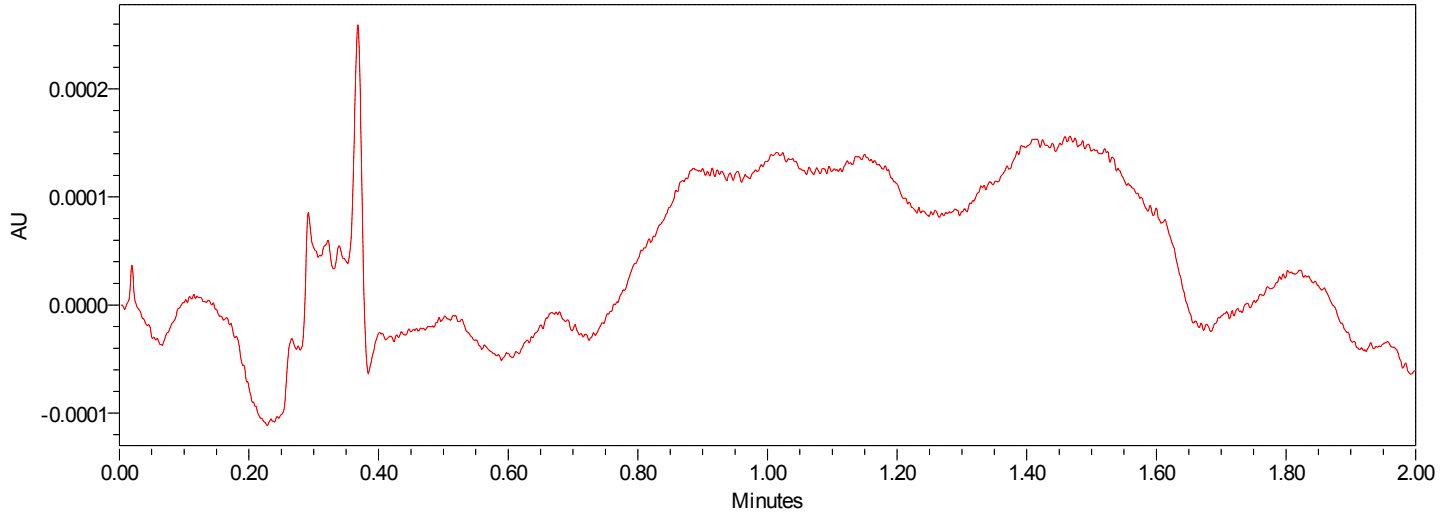
System Name: ArcBio_2489

Sample Set Id: 8346

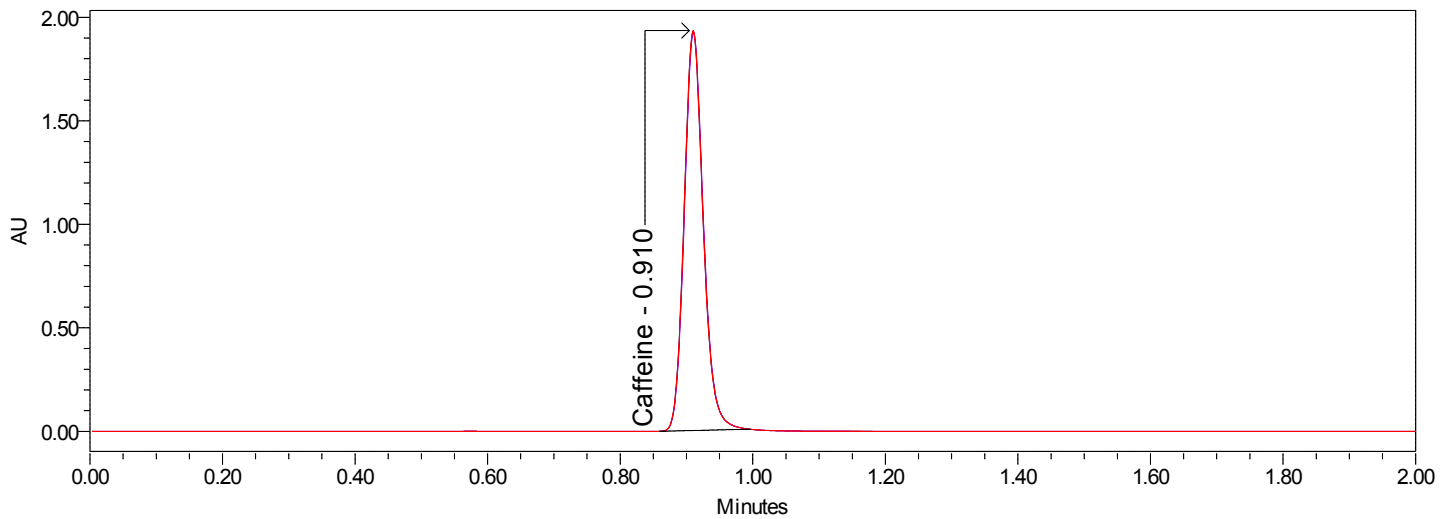
Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8351

Blank Chromatogram



Overlaid Caffeine Chromatograms





SYSTEM READINESS CHECK REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8346

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8351

System Readiness Check Blank Injection Result

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Peak Type	Result ID
1	Blank	2:A,4	1	15.0	Missing	8367

System Readiness Check Caffeine Peak Results

	Sample Name	Vial	Injection Number	Injection Volume (µL)	RT (min)	RT (sec)	Area (µV*sec)	Height (µV)	Peak Type	Result ID
1	Caffeine 0.160 mg/mL	2:C,5	1	15.0	0.910	54.6	3866929	1932035	Found	8364
2	Caffeine 0.160 mg/mL	2:C,5	2	15.0	0.911	54.6	3864652	1926374	Found	8365
3	Caffeine 0.160 mg/mL	2:C,5	3	15.0	0.910	54.6	3861710	1928189	Found	8366

System Readiness Check Summary Results

	Standard Deviation Retention Time (sec)	% RSD Area	% RSD Height	Average Height (AU)
1	0.0	0.07	0.1	1.93



SYSTEM PRECISION REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
 Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
 Processing Method: 020 System Precision PM
 Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
 Sample Kit Lot Number: W13071706
 Report Method: 020 System Prec RM
 Sample Set Name: System Precision SSM
 Sample Set Id: 8750

Acquired By: Adam
 Column Serial Number: 01903731313692
 Result Set Id: 8755

System precision is determined by running injections of a caffeine solution at the same concentration and injection volume. The %RSD of the area and height gives the injection precision, and the standard deviation of the retention time is the system precision.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Caffeine Area and Height Results

	Area Specification	%RSD Area	Area Pass/Fail	Height Specification	%RSD Height	Height Pass/Fail
1	%RSD < or = 0.25	0.08	PASS	%RSD < or = 1.1	0.1	PASS

Caffeine Retention Time Results

	Retention Time Specification	Standard Deviation Retention Time (sec)	Retention Time Pass/Fail
1	SD RT < or = 1.0 sec	0.0	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



SYSTEM PRECISION REPORT

ACQUISITION INFORMATION

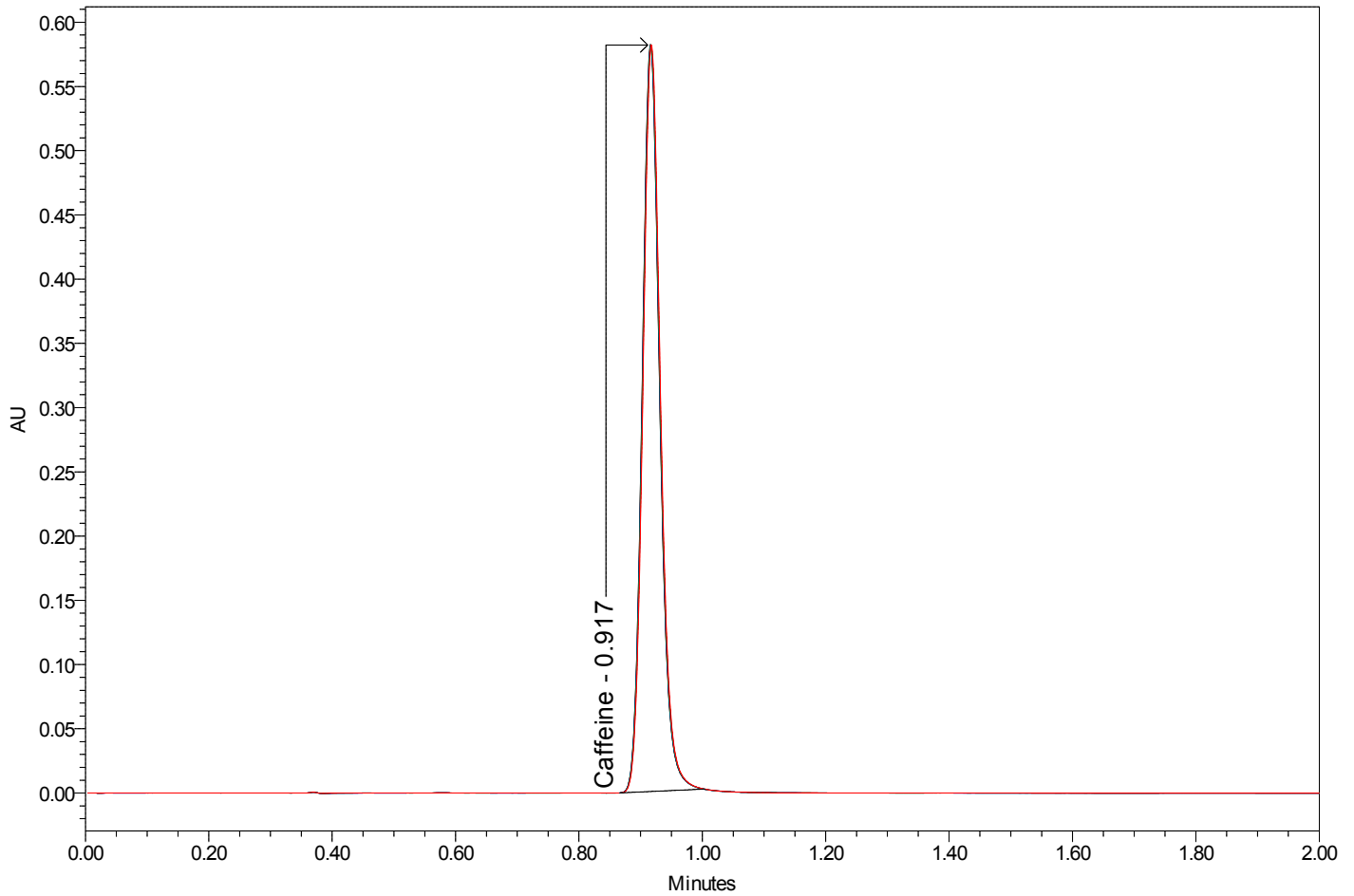
System Name: ArcBio_2489

Sample Set Id: 8750

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8755

System Precision Overlaid Chromatograms





SYSTEM PRECISION REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8750

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8755

System Precision Peak Results

	Sample Name	Vial	Injection Number	Injection Volume (µL)	RT (min)	RT (sec)	Area (µV*sec)	Height (µV)	Result ID
1	Caffeine 0.050 mg/mL	2:F,2	1	14.0	0.917	55.0	1155765	581258	8774
2	Caffeine 0.050 mg/mL	2:F,2	2	14.0	0.917	55.0	1154964	580721	8775
3	Caffeine 0.050 mg/mL	2:F,2	3	14.0	0.917	55.0	1154169	580423	8776
4	Caffeine 0.050 mg/mL	2:F,2	4	14.0	0.916	55.0	1154301	581692	8777
5	Caffeine 0.050 mg/mL	2:F,2	5	14.0	0.916	55.0	1153848	579920	8778
6	Caffeine 0.050 mg/mL	2:F,2	6	14.0	0.916	55.0	1153231	580736	8779

System Precision Summary Results

	Standard Deviation Retention Time (sec)	%RSD Area	%RSD Height
1	0.0	0.08	0.1



WAVELENGTH ACCURACY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
 Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
 Processing Method: 030 Wavelength Accuracy PM
 Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
 Sample Kit Lot Number: W13071706
 Report Method: 030 Wavelength Acc RM
 Sample Set Name: Wavelength Accuracy SSM
 Sample Set Id: 8391

Acquired By: Adam
 Column Serial Number: 01903731313692
 Result Set Id: 8402

Wavelength accuracy is determined by identifying the two (2) lambda max values of caffeine. The spectrum of caffeine is well defined with a lambda max of 205nm and 273nm. The deviation from these wavelengths is measured to determine the accuracy of the detector. In combination with power-on diagnostic, the SystemsQT provides accuracy verification across a range of 205nm to 656nm.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Wavelength Accuracy Results

	Maximum Wavelength Specification 1	Lambda Max (nm)	Lambda Max Pass/Fail
1	203nm-207nm	205	PASS

	Maximum Wavelength Specification 2	Lambda Max (nm)	Lambda Max Pass/Fail
1	271nm-275nm	274	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



WAVELENGTH ACCURACY REPORT

ACQUISITION INFORMATION

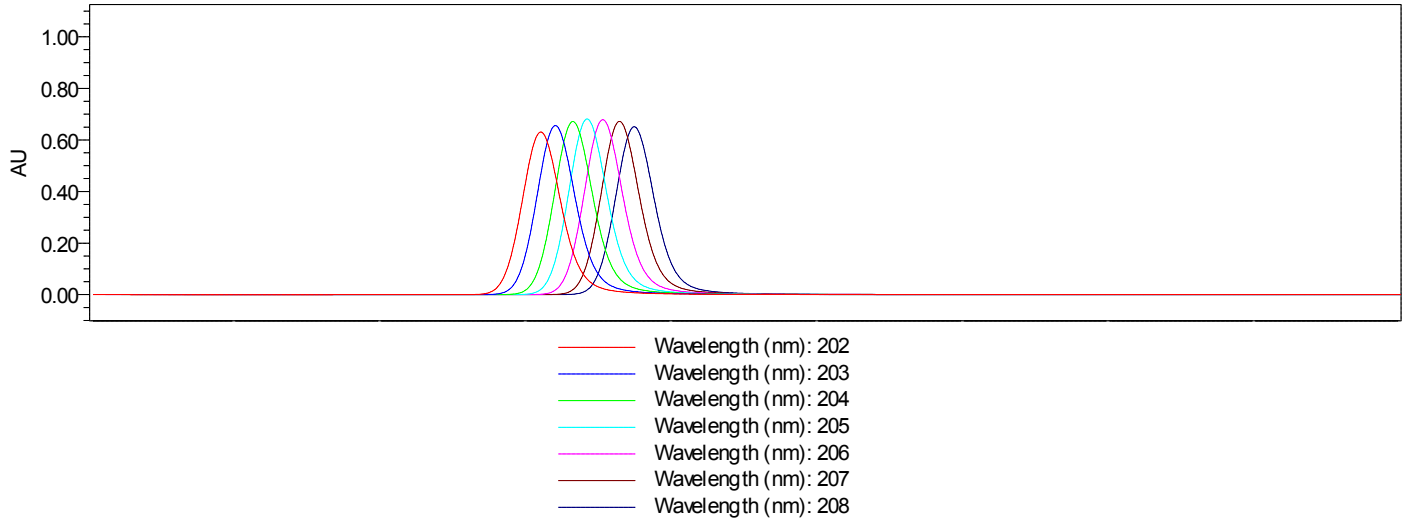
System Name: ArcBio_2489

Sample Set Id: 8391

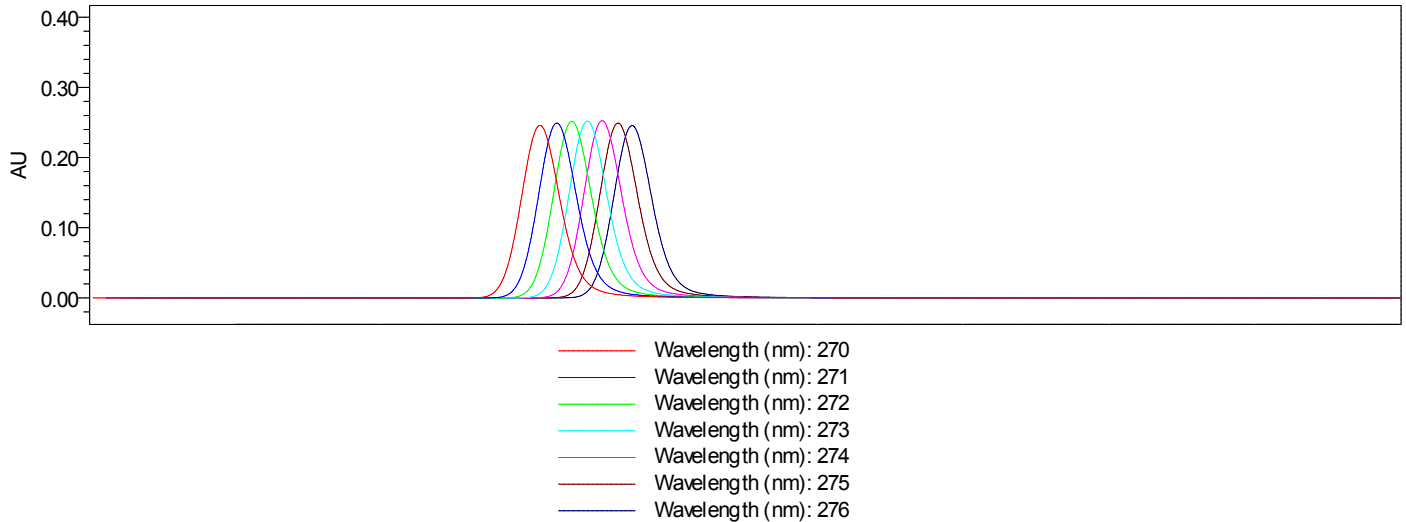
Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8402

Wavelength Accuracy Overlaid Chromatograms (Caffeine peak) 202 nm - 208 nm (Overlaid Chromatograms have offset X axis)



Wavelength Accuracy Overlaid Chromatograms (Caffeine peak) 270 nm - 276 nm (Overlaid Chromatograms have offset X axis)





WAVELENGTH ACCURACY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8391

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8402

Lambda-1 Results (In Order By Descending Height)

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Wavelength (nm)	Height (µV)	Result ID
1	Caffeine 0.030 mg/mL	2:A,8	1	10.0	205	680026	8645
2	Caffeine 0.030 mg/mL	2:A,8	1	10.0	206	677337	8646
3	Caffeine 0.030 mg/mL	2:A,8	1	10.0	207	670603	8647
4	Caffeine 0.030 mg/mL	2:A,8	1	10.0	204	670406	8644
5	Caffeine 0.030 mg/mL	2:A,8	1	10.0	203	654219	8643
6	Caffeine 0.030 mg/mL	2:A,8	1	10.0	208	649828	8648
7	Caffeine 0.030 mg/mL	2:A,8	1	10.0	202	629553	8642

Lambda-2 Results (In Order By Descending Height)

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Wavelength (nm)	Height (µV)	Result ID
1	Caffeine 0.030 mg/mL	2:A,8	1	10.0	274	252005	8653
2	Caffeine 0.030 mg/mL	2:A,8	1	10.0	273	251492	8652
3	Caffeine 0.030 mg/mL	2:A,8	1	10.0	272	251149	8651
4	Caffeine 0.030 mg/mL	2:A,8	1	10.0	271	248826	8650
5	Caffeine 0.030 mg/mL	2:A,8	1	10.0	275	248639	8654
6	Caffeine 0.030 mg/mL	2:A,8	1	10.0	270	245411	8649
7	Caffeine 0.030 mg/mL	2:A,8	1	10.0	276	245140	8655



DETECTOR LINEARITY & SENSITIVITY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
 Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
 Processing Method: 04b Detector Lin Sens Ht PM, 04b Detector Lin Sens Area PM
 Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
 Sample Kit Lot Number: W13071706
 Report Method: 04b Det Lin Sens RM Acquired By: Adam
 Sample Set Name: Detector Lin Sens SSM Column Serial Number: 01903731313692
 Sample Set Id: 8455 Result Set Id: 8460

Detector linearity is performed to ensure that the detector has a linear response within its specified range. The system makes several injections of a caffeine standard at different concentrations using the same injection volume, and the area and height are plotted against the amount. The coefficient of determination (R^2) is used to measure the detector's linearity. The UV detector's sensitivity is determined by dividing the height by the amount and the area by the amount. The blank injection is not incorporated into the linearity calculation.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Detector Area Linearity and Sensitivity Results

	Area Linearity Specification	Area Linearity (R^2)	Area Linearity Pass/Fail	Area Sensitivity Specification	%RSD Area Sensitivity	Area Sensitivity Pass/Fail
1	$R^2 > \text{or} = 0.9990$	0.9999	PASS	%RSD $< \text{or} = 3.5$	1.2	PASS

Detector Height Linearity and Sensitivity Results

	Height Linearity Specification	Height Linearity (R^2)	Height Linearity Pass/Fail	Height Sensitivity Specification	%RSD Height Sensitivity	Height Sensitivity Pass/Fail
1	$R^2 > \text{or} = 0.990$	1.000	PASS	%RSD $< \text{or} = 4.5$	1.2	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



DETECTOR LINEARITY & SENSITIVITY REPORT

ACQUISITION INFORMATION

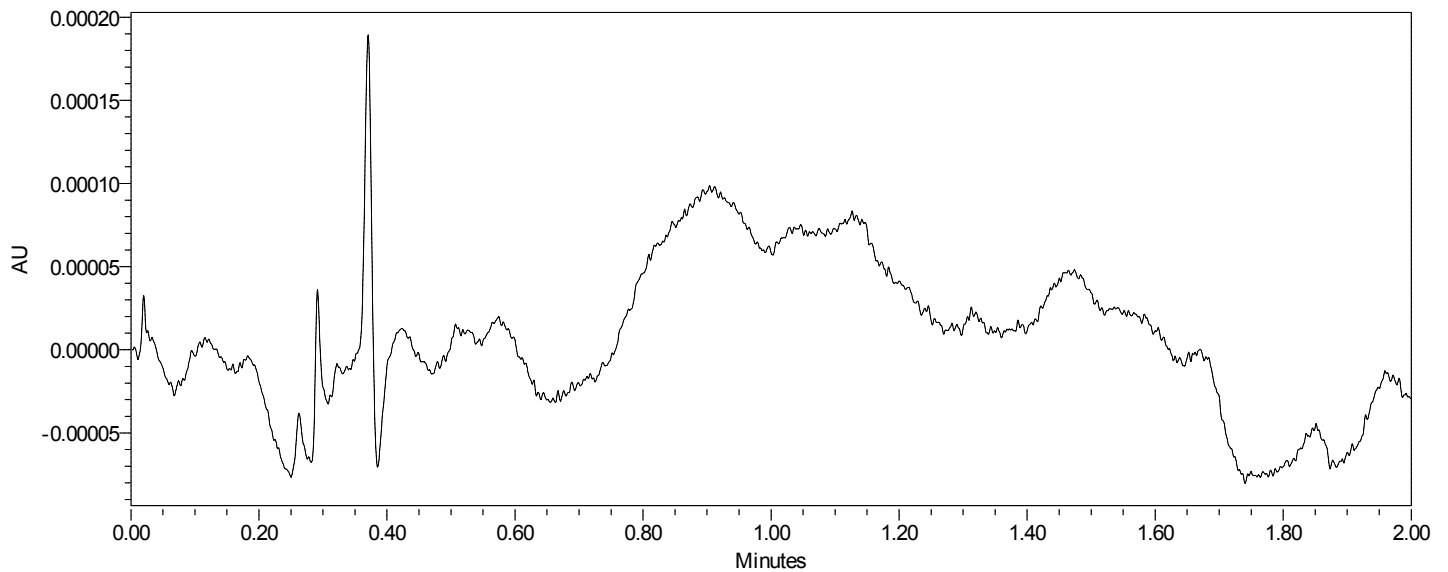
System Name: ArcBio_2489

Sample Set Id: 8455

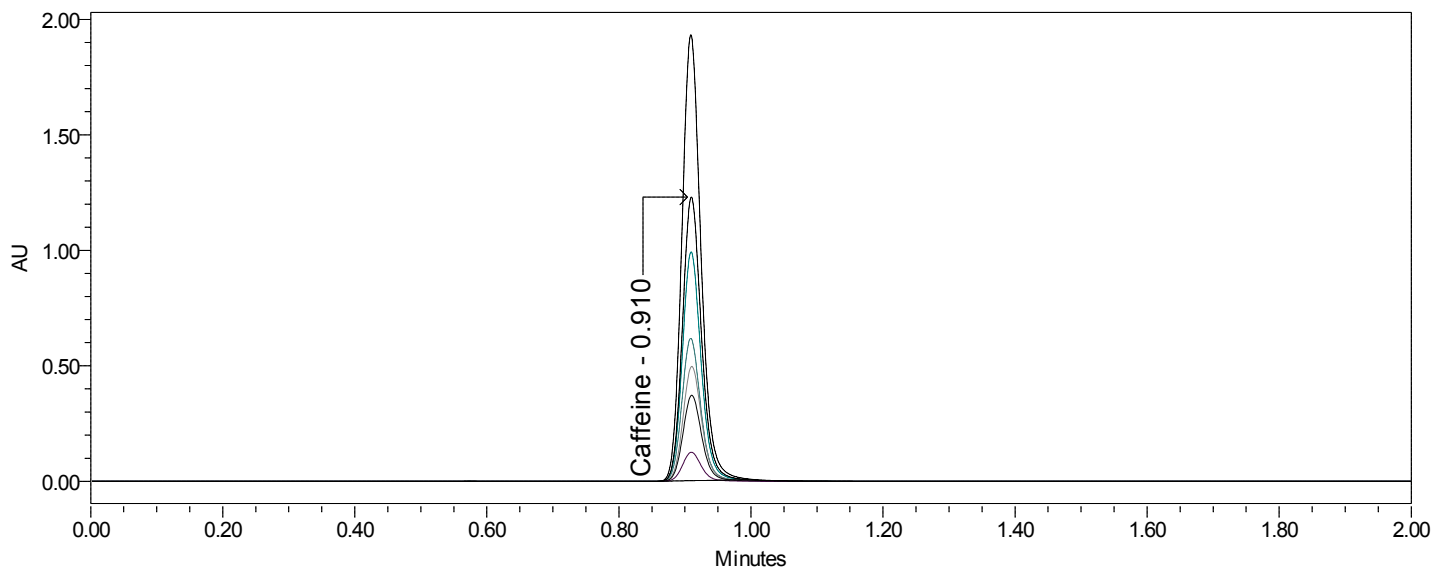
Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8460

Detector Linearity Blank Chromatogram



Caffeine Detector Linearity Overlaid Chromatograms





DETECTOR LINEARITY & SENSITIVITY REPORT

ACQUISITION INFORMATION

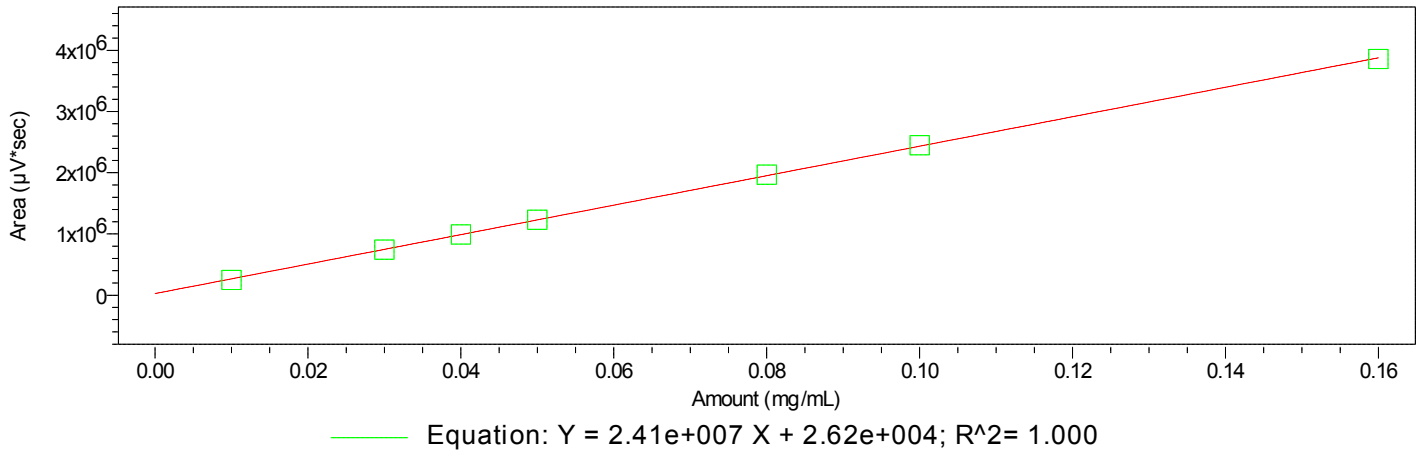
System Name: ArcBio_2489

Sample Set Id: 8455

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8460

Area Calibration Plot



Blank Area Result

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Peak Type	Result ID
1	Blank	2:A,4	1	15.0	Missing	8674

Detector Linearity Area Results

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Level	Area (µV*sec)	Amount (mg/mL)	Area Sensitivity	Peak Type	Result ID
1	Caffeine 0.010 mg/mL	2:A,1	1	15.0	1	250351	0.010	25035083	Found	8660
2	Caffeine 0.030 mg/mL	2:A,8	1	15.0	2	743908	0.030	24796922	Found	8662
3	Caffeine 0.040 mg/mL	2:F,7	1	15.0	3	991003	0.040	24775083	Found	8664
4	Caffeine 0.050 mg/mL	2:F,2	1	15.0	4	1233937	0.050	24678742	Found	8666
5	Caffeine 0.080 mg/mL	2:A,3	1	15.0	5	1970307	0.080	24628839	Found	8668
6	Caffeine 0.100 mg/mL	2:D,4	1	15.0	6	2449026	0.100	24490265	Found	8670
7	Caffeine 0.160 mg/mL	2:C,5	1	15.0	7	3859084	0.160	24119274	Found	8672

Detector Area Sensitivity Result

	%RSD Area Sensitivity
1	1.2



DETECTOR LINEARITY & SENSITIVITY REPORT

ACQUISITION INFORMATION

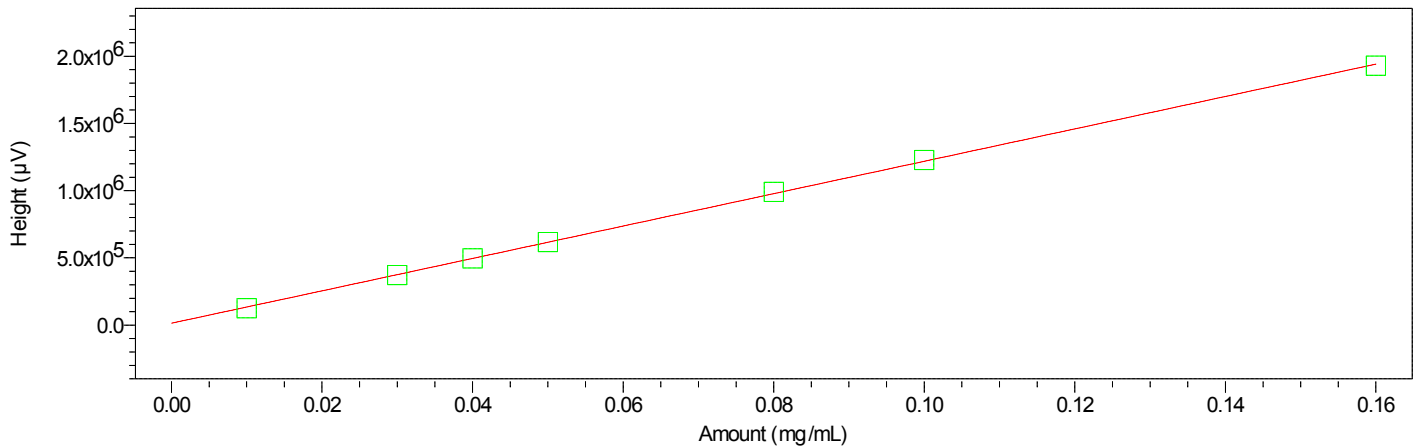
System Name: ArcBio_2489

Sample Set Id: 8455

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8460

Height Calibration Plot



Blank Area Result

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Peak Type	Result ID
1	Blank	2:A,4	1	15.0	Missing	8675

Height Results

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Level	Height (µV)	Amount (mg/mL)	Height Sensitivity	Peak Type	Result ID
1	Caffeine 0.010 mg/mL	2:A,1	1	15.0	1	125445	0.010	12544474	Found	8661
2	Caffeine 0.030 mg/mL	2:A,8	1	15.0	2	371705	0.030	12390167	Found	8663
3	Caffeine 0.040 mg/mL	2:F,7	1	15.0	3	496466	0.040	12411655	Found	8665
4	Caffeine 0.050 mg/mL	2:F,2	1	15.0	4	617407	0.050	12348138	Found	8667
5	Caffeine 0.080 mg/mL	2:A,3	1	15.0	5	990962	0.080	12387027	Found	8669
6	Caffeine 0.100 mg/mL	2:D,4	1	15.0	6	1228589	0.100	12285885	Found	8671
7	Caffeine 0.160 mg/mL	2:C,5	1	15.0	7	1929464	0.160	12059150	Found	8673

Detector Height Sensitivity Result

	% RSD Height Sensitivity
1	1.2



INJECTOR LINEARITY & ACCURACY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
 Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
 Processing Method: 050 Injector Lin Acc PM
 Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
 Sample Kit Lot Number: W13071706 Acquired By: Adam
 Report Method: 050 Injector Lin Acc RM Column Serial Number: 01903731313692
 Sample Set Name: Injector Lin Acc SSM Sample Set Id: 8489 Result Set Id: 8494

Injector linearity and accuracy is performed to determine whether the injection volume delivered is linear within the specified criteria. The system makes injections using different injection volumes of one concentration of caffeine from the same vial. The area is plotted against the amount, the coefficient of determination (R^2) is used to measure the injector linearity. The accuracy is determined by dividing the y-intercept by the slope.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Injector Linearity & Accuracy Results

	Injector Linearity Specification	Injector Linearity (R^2)	Injector Linearity Pass/Fail	Injector Accuracy Specification	Injector Accuracy (μ L)	Injector Accuracy Pass/Fail
1	$R^2 > \text{or} = 0.999$	1.000	PASS	$< \text{or} = 0.2 \mu\text{L}$	0.0	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



INJECTOR LINEARITY & ACCURACY REPORT

ACQUISITION INFORMATION

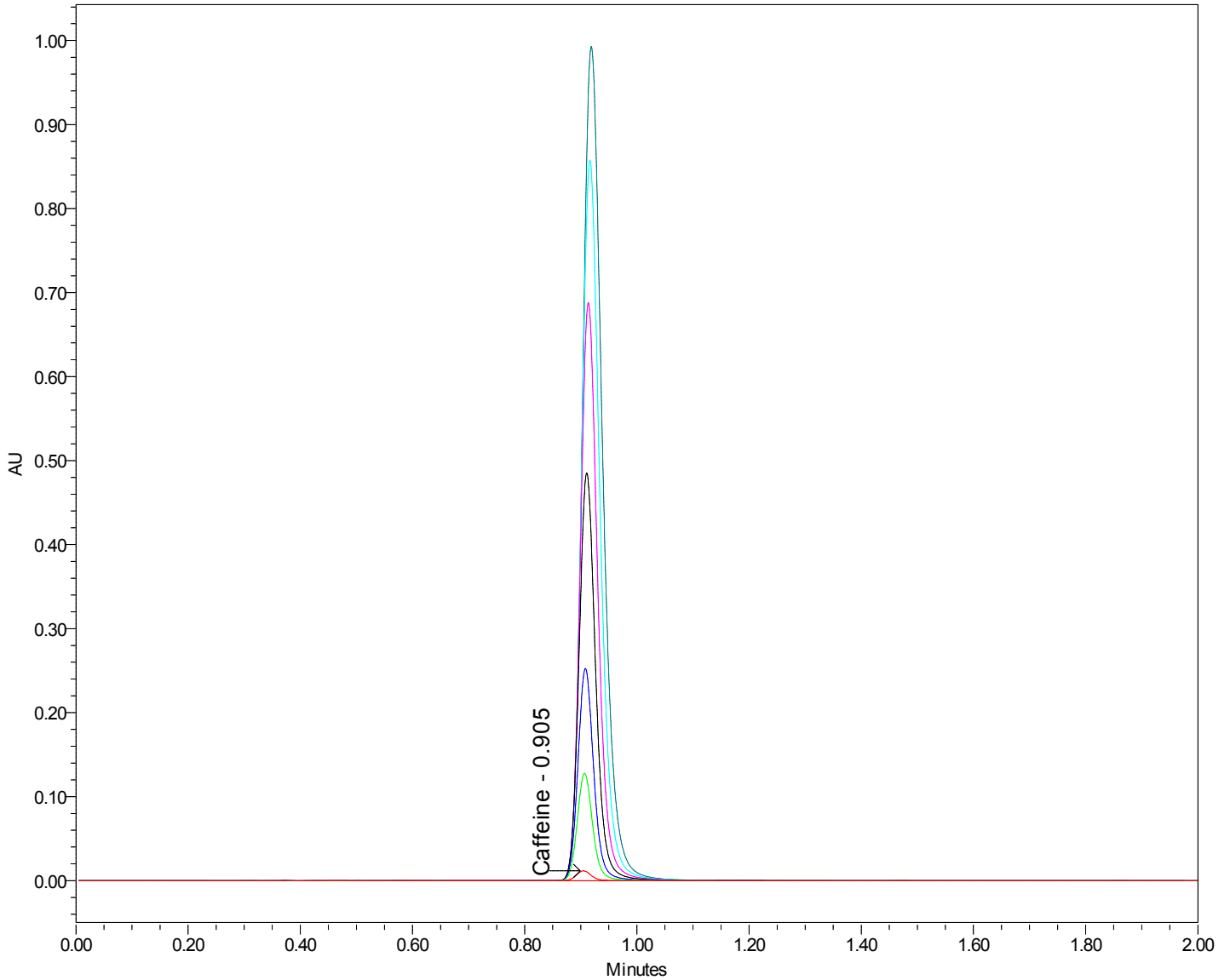
System Name: ArcBio_2489

Sample Set Id: 8489

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8494

Injector Linearity Overlaid Chromatograms





INJECTOR LINEARITY & ACCURACY REPORT

ACQUISITION INFORMATION

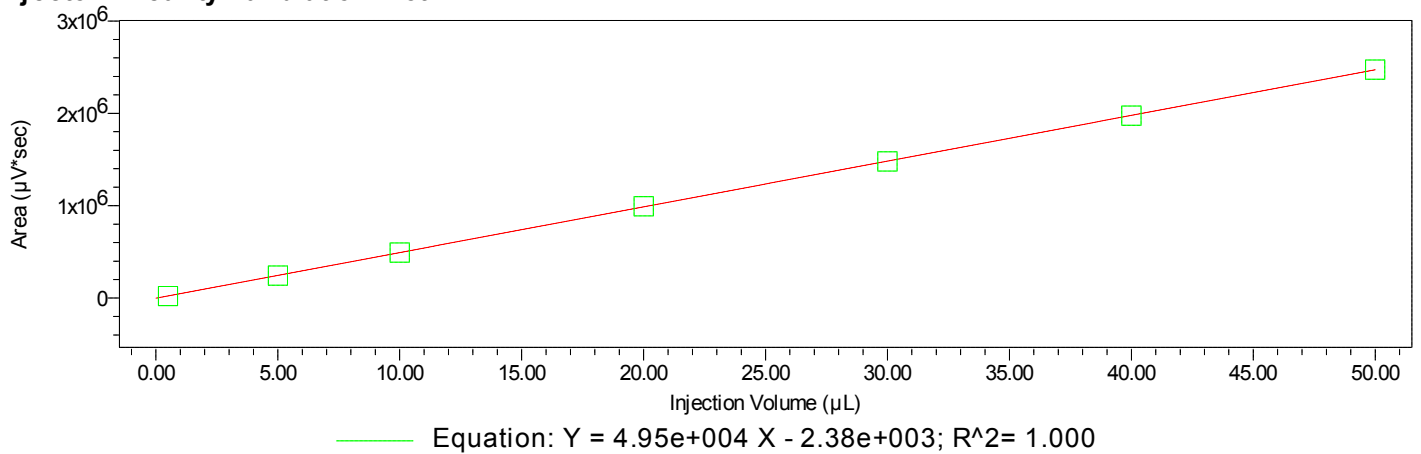
System Name: ArcBio_2489

Sample Set Id: 8489

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8494

Injector Linearity Calibration Plot



Injector Linearity Results

	Sample Name	Vial	Injection Number	Injection Volume (µL)	Level	Area (µV*sec)	Peak Type	Result ID
1	Caffeine 0.030 mg/mL	2:A,8	1	0.5	1	21890	Found	8678
2	Caffeine 0.030 mg/mL	2:A,8	1	5.0	2	243908	Found	8679
3	Caffeine 0.030 mg/mL	2:A,8	1	10.0	3	492501	Found	8680
4	Caffeine 0.030 mg/mL	2:A,8	1	20.0	4	993439	Found	8681
5	Caffeine 0.030 mg/mL	2:A,8	1	30.0	5	1478607	Found	8682
6	Caffeine 0.030 mg/mL	2:A,8	1	40.0	6	1975308	Found	8683
7	Caffeine 0.030 mg/mL	2:A,8	1	50.0	7	2474132	Found	8684

Accuracy Calculation:

Injector Accuracy = | Y intercept / Slope |

Y intercept = -2383

Slope = 49495

Injector Accuracy = | -2383 / 49495 | = 0.0



INJECTOR CARRYOVER REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
 Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
 Processing Method: 060 Injector Carryover PM
 Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
 Sample Kit Lot Number: W13071706
 Report Method: 060 Injector Carryover RM
 Sample Set Name: Injector Carryover SSM
 Sample Set Id: 8519

Acquired By: Adam
 Column Serial Number: 01903731313692
 Result Set Id: 8524

The Injector Carryover Test determines the presence of sample carryover from one injection to the next. In the Injector Carryover Test, two pre-blank injections are performed to determine whether the system is clean enough to measure injector carryover. These injections are followed by three caffeine calibration injections at a concentration of 0.08 µg/mL with an injection volume of 5.0 µL, which corresponds to 0.002% of the challenge injection. The challenge injection is made and at a concentration of 4.000 mg/mL with an injection volume of 5.0 µL, then followed by three post blank injections.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Injector Carryover Peak Results

	Sample Name	Carryover Specification	% Carryover	Carryover Pass/Fail
1	Post Blank	< or = 0.002%	Not Detected	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



INJECTOR CARRYOVER REPORT

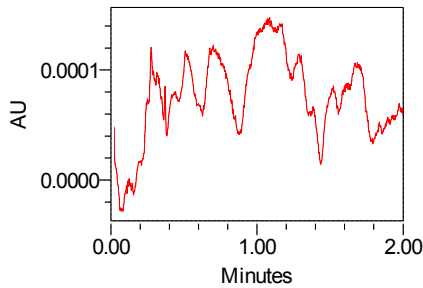
ACQUISITION INFORMATION

System Name: ArcBio_2489

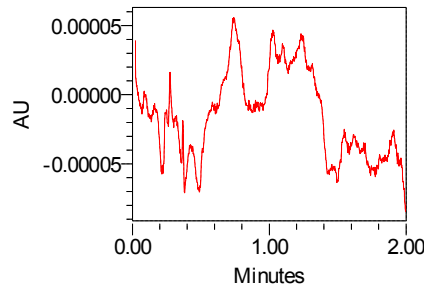
Sample Set Id: 8519

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

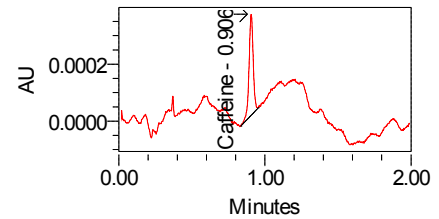
Result Set Id: 8524



Sample Name: PreBlank

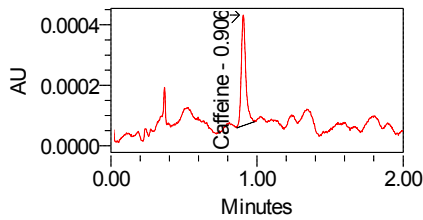


Sample Name: PreBlank



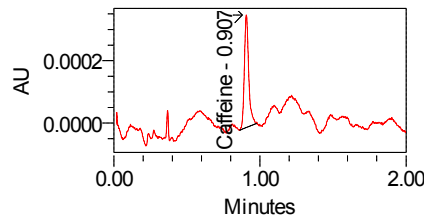
Sample Name: 0.080

Caffeine $\mu\text{g/mL}$
(0.002%)



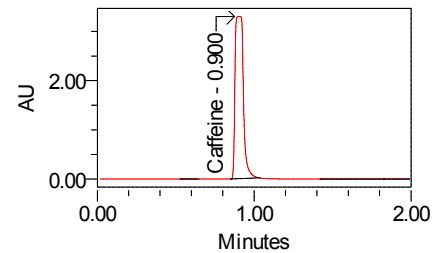
Sample Name: 0.080

Caffeine $\mu\text{g/mL}$
(0.002%)



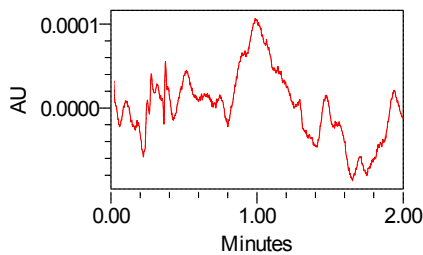
Sample Name: 0.080

Caffeine $\mu\text{g/mL}$
(0.002%)

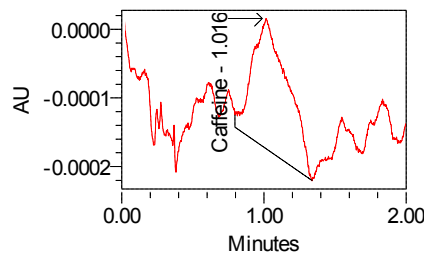


Sample Name: 4.000

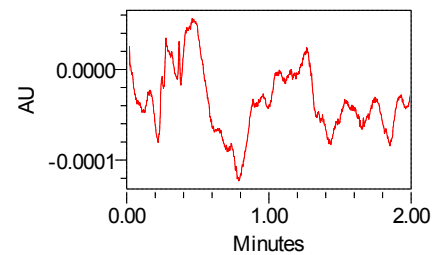
Caffeine mg/mL (100%)



Sample Name: Post Blank



Sample Name: Post Blank



Sample Name: Post Blank



INJECTOR CARRYOVER REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8519

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8524

Chromatographic Peak Results

	Sample Name	Vial	Injection Number	Injection Volume (µL)	RT (min)	RT (sec)	Area (µV*sec)	Height (µV)	Peak Type	% Carryover	Result ID
1	PreBlank	2:A,4	1	5.0	NA	NA	NA	NA	Missing	Not Detected	8691
2	PreBlank	2:A,4	2	5.0	NA	NA	NA	NA	Missing	Not Detected	8692
3	0.080 Caffeine µg/mL (0.002%)	2:D,6	1	5.0	0.906	54.4	703	356	Found	0.002	8687
4	0.080 Caffeine µg/mL (0.002%)	2:D,6	2	5.0	0.906	54.4	781	365	Found	0.002	8688
5	0.080 Caffeine µg/mL (0.002%)	2:D,6	3	5.0	0.907	54.4	745	361	Found	0.002	8689
6	Post Blank	2:A,5	1	5.0	NA	NA	NA	NA	Missing	Not Detected	8693
7	Post Blank	2:A,5	2	5.0	1.016	60.9	3323	190	Found	0.009	8694
8	Post Blank	2:A,5	3	5.0	NA	NA	NA	NA	Missing	Not Detected	8695

Injector Carryover

Summary Result

	Sample Name	% Carryover
1	Post Blank	Not Detected



FLOW RATE LINEARITY REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
 Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
 Processing Method: 070 Flow Rate Lin PM
 Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
 Sample Kit Lot Number: W13071706
 Report Method: 070 Flow Rate Lin RM
 Sample Set Name: Flow Rate Lin SSM
 Sample Set Id: 8552

Acquired By: Adam
 Column Serial Number: 01903731313692
 Result Set Id: 8557

Flow Rate Linearity is performed to determine whether the system's flow rate is linear. The sample set injects a constant volume of thiourea solution and varies the flow rate. The plot generated is the reciprocal of the thiourea retention time (1/RT) vs. the flow rate (mL/min). The flow accuracy is determined by dividing the y-intercept by the slope and multiplying by 1000 (to convert from mL to μ L).

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Flow Rate Linearity Result

	FlowRate Linearity Specification	FlowRate Linearity (R ²)	FlowRate Linearity Pass/Fail
1	R ² > or = 0.990	1.000	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



FLOW RATE LINEARITY REPORT

ACQUISITION INFORMATION

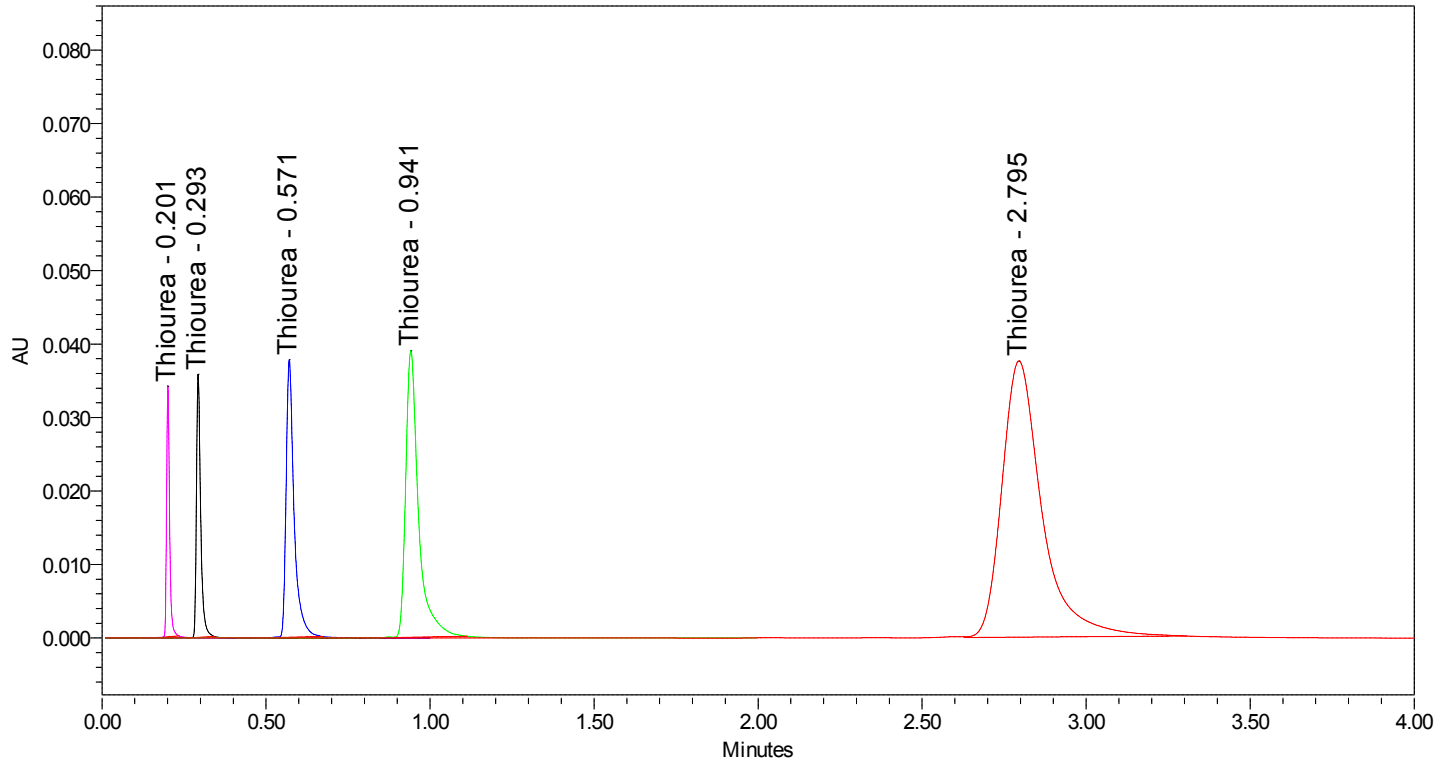
System Name: ArcBio_2489

Sample Set Id: 8552

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8557

Thiourea Overlaid Chromatograms



Flow Rate Linearity Results

Peak: Thiourea

	Sample Name	Vial	Injection Number	Injection Volume (µL)	RT (min)	Reciprocal Retention Time	FlowRate (mL/min)	Height (µV)	Area (µV*sec)	Result ID
1	Thiourea 0.1 mg/mL	2:E,4	1	5.0	2.80	0.36	0.20	37592	318003	8698
2	Thiourea 0.1 mg/mL	2:E,4	1	5.0	0.94	1.06	0.60	39001	105401	8699
3	Thiourea 0.1 mg/mL	2:E,4	1	5.0	0.57	1.75	1.00	37789	63471	8700
4	Thiourea 0.1 mg/mL	2:E,4	1	5.0	0.29	3.41	2.00	35843	31933	8701
5	Thiourea 0.1 mg/mL	2:E,4	1	5.0	0.20	4.98	3.00	34173	21458	8702



FLOW RATE LINEARITY REPORT

ACQUISITION INFORMATION

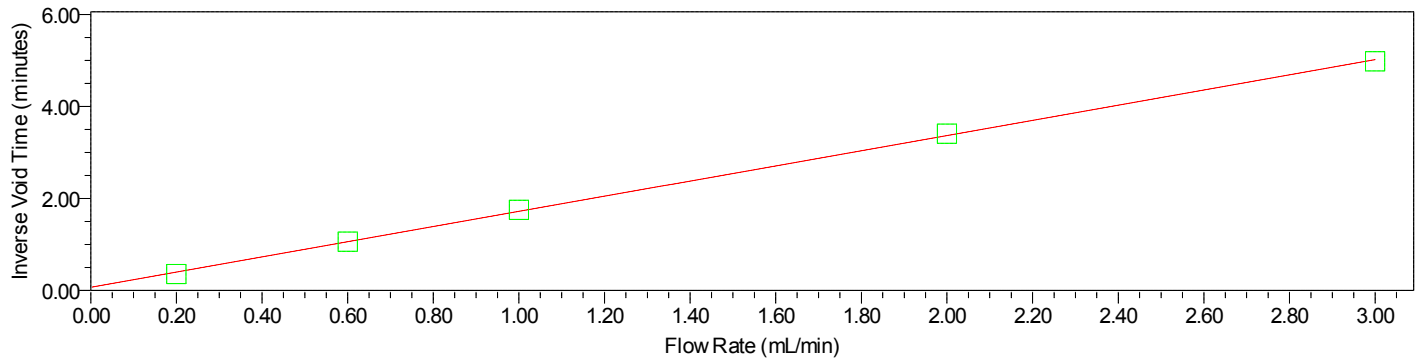
System Name: ArcBio_2489

Sample Set Id: 8552

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8557

Thiourea Flow Rate Linearity Calibration Plot



Equation: $Y = 1.65e+000 X + 6.92e-002$; $R^2 = 1.000$

GRADIENT PERFORMANCE REPORT



ACQUISITION INFORMATION

System Name: ArcBio_2489
Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
Processing Method: 080 Gradient Performance PM
Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
Sample Kit Lot Number: W13071706 Acquired By: Adam
Report Method: 080 Gradient Performance RM Column Serial Number: 01903731313692
Sample Set Name: Gradient Performance SSM Sample Set Id: 8574 Result Set Id: 8582

The Gradient Performance Test determines whether the solvent management system can deliver a solvent mixture within an acceptable criteria. A multi-component mixture is delivered using different combinations of solvent reservoirs and the retention time of each component is used as a measure of the gradient performance.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Gradient Performance Overall Test Results

	Gradient Specification	Component	Standard Deviation Retention Time (sec)	Gradient Pass/Fail
1	SD RT < or = 1.0 sec	2-acetylfuran	0.1	PASS
2	SD RT < or = 1.0 sec	acetanilide	0.2	PASS
3	SD RT < or = 1.0 sec	acetophenone	0.1	PASS
4	SD RT < or = 1.0 sec	benzophenone	0.0	PASS
5	SD RT < or = 1.0 sec	butylparaben	0.1	PASS
6	SD RT < or = 1.0 sec	valerophenone	0.0	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



GRADIENT PERFORMANCE REPORT

ACQUISITION INFORMATION

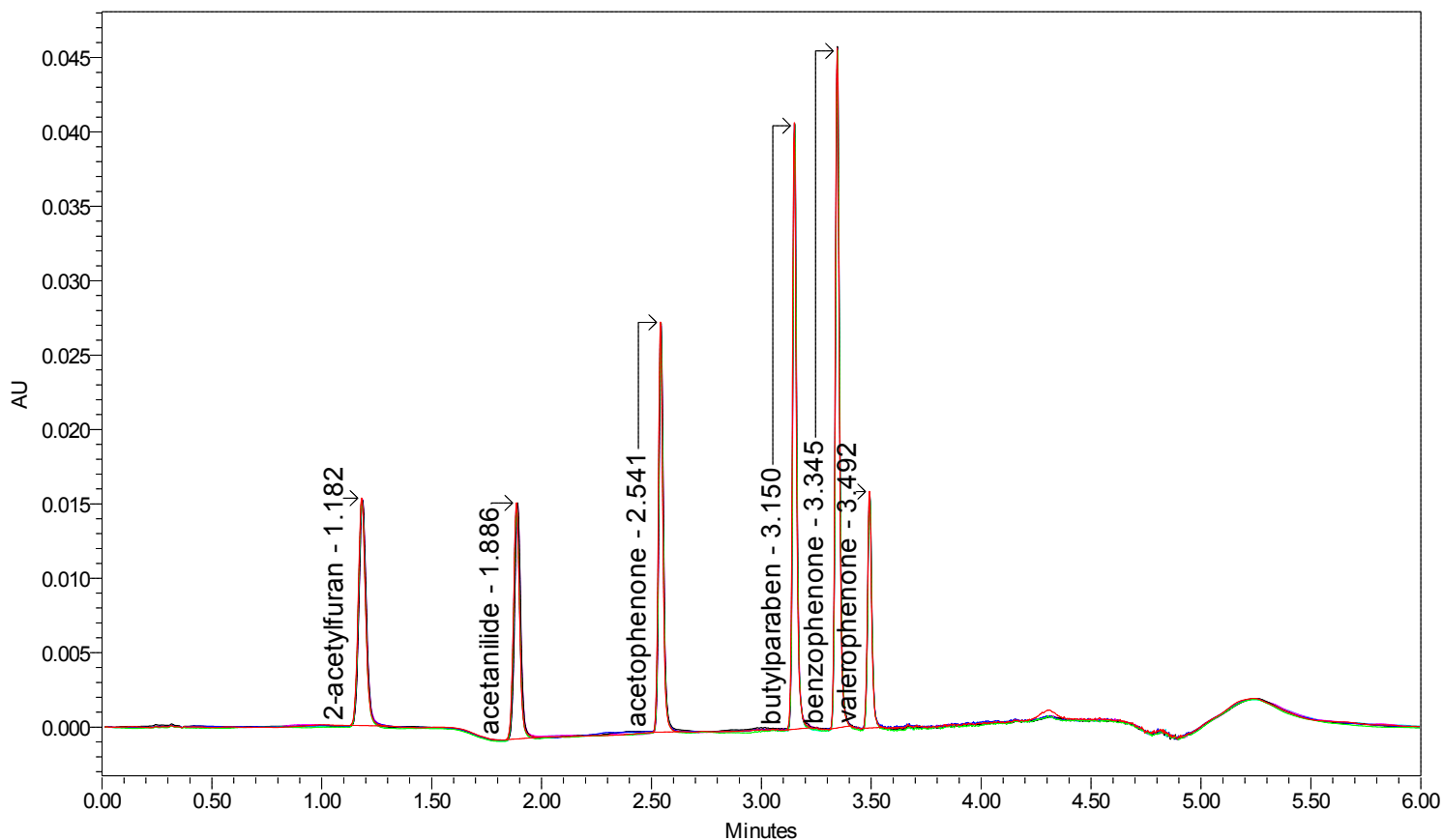
System Name: ArcBio_2489

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Sample Set Id: 8574

Result Set Id: 8582

Gradient Performance Overlaid Chromatograms



- Sample Name: Gradient AB; Injection: 1
- Sample Name: Gradient AB; Injection: 2
- Sample Name: Gradient AB; Injection: 3
- Sample Name: Gradient CD; Injection: 1
- Sample Name: Gradient CD; Injection: 2
- Sample Name: Gradient CD; Injection: 3



GRADIENT PERFORMANCE REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8574

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8582

Gradient Performance Results (minutes)

	Sample Name	Vial	Injection Number	Result ID	2-acetyfuran	acetanilide	acetophenone	butylparaben	benzophenone	valerophenone
1	Gradient AB	2:F,4	1	8710	1.182	1.886	2.541	3.150	3.345	3.492
2	Gradient AB	2:F,4	2	8711	1.182	1.887	2.543	3.151	3.346	3.493
3	Gradient AB	2:F,4	3	8712	1.183	1.886	2.542	3.150	3.345	3.492
4	Gradient CD	2:F,4	1	8713	1.186	1.891	2.544	3.151	3.346	3.493
5	Gradient CD	2:F,4	2	8714	1.186	1.891	2.545	3.152	3.347	3.494
6	Gradient CD	2:F,4	3	8715	1.185	1.891	2.543	3.151	3.346	3.493

Gradient Performance Results (seconds)

	Sample Name	Vial	Injection Number	Result ID	2-acetyfuran	acetanilide	acetophenone	butylparaben	benzophenone	valerophenone
1	Gradient AB	2:F,4	1	8710	70.9	113.1	152.5	189.0	200.7	209.5
2	Gradient AB	2:F,4	2	8711	70.9	113.2	152.6	189.1	200.8	209.6
3	Gradient AB	2:F,4	3	8712	71.0	113.2	152.5	189.0	200.7	209.5
4	Gradient CD	2:F,4	1	8713	71.1	113.5	152.6	189.1	200.8	209.6
5	Gradient CD	2:F,4	2	8714	71.1	113.5	152.7	189.1	200.8	209.6
6	Gradient CD	2:F,4	3	8715	71.1	113.4	152.6	189.1	200.8	209.6

Gradient Performance Summary Results

	Component	Standard Deviation Retention Time (sec)
1	2-acetyfuran	0.1
2	acetanilide	0.2
3	acetophenone	0.1
4	benzophenone	0.0
5	butylparaben	0.1
6	valerophenone	0.0



NOISE AND DRIFT REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
 Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
 Processing Method: 090 Noise and Drift PM
 Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
 Sample Kit Lot Number: W13071706
 Report Method: 090 Noise and Drift RM
 Sample Set Name: Noise and Drift SSM
 Sample Set Id: 8614

Acquired By: Adam
 Column Serial Number: 01903731313692
 Result Set Id: 8619

In the Noise and Drift Test, mobile phase (90% water: 10% acetonitrile) is pumped at 1.8 mL/min. An "Inject immediate standards" 15 minutes chromatogram is collected at two points per second, using the extracted wavelength setting of 254nm with a normal filter time constant.

Average peak to peak noise and detector drift is calculated from 30 second noise intervals taken from the recorded 3 to 15 minutes time period.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Noise Result

	Noise Specification	Average Peak to Peak Noise (μ AU)	Noise Pass/Fail
1	< or = 60 μ AU	59	PASS

Drift Result

	Drift Specification	Drift (mAU/Hr)	Drift Pass/Fail
1	< or = 10 mAU/Hr	0	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



NOISE AND DRIFT REPORT

ACQUISITION INFORMATION

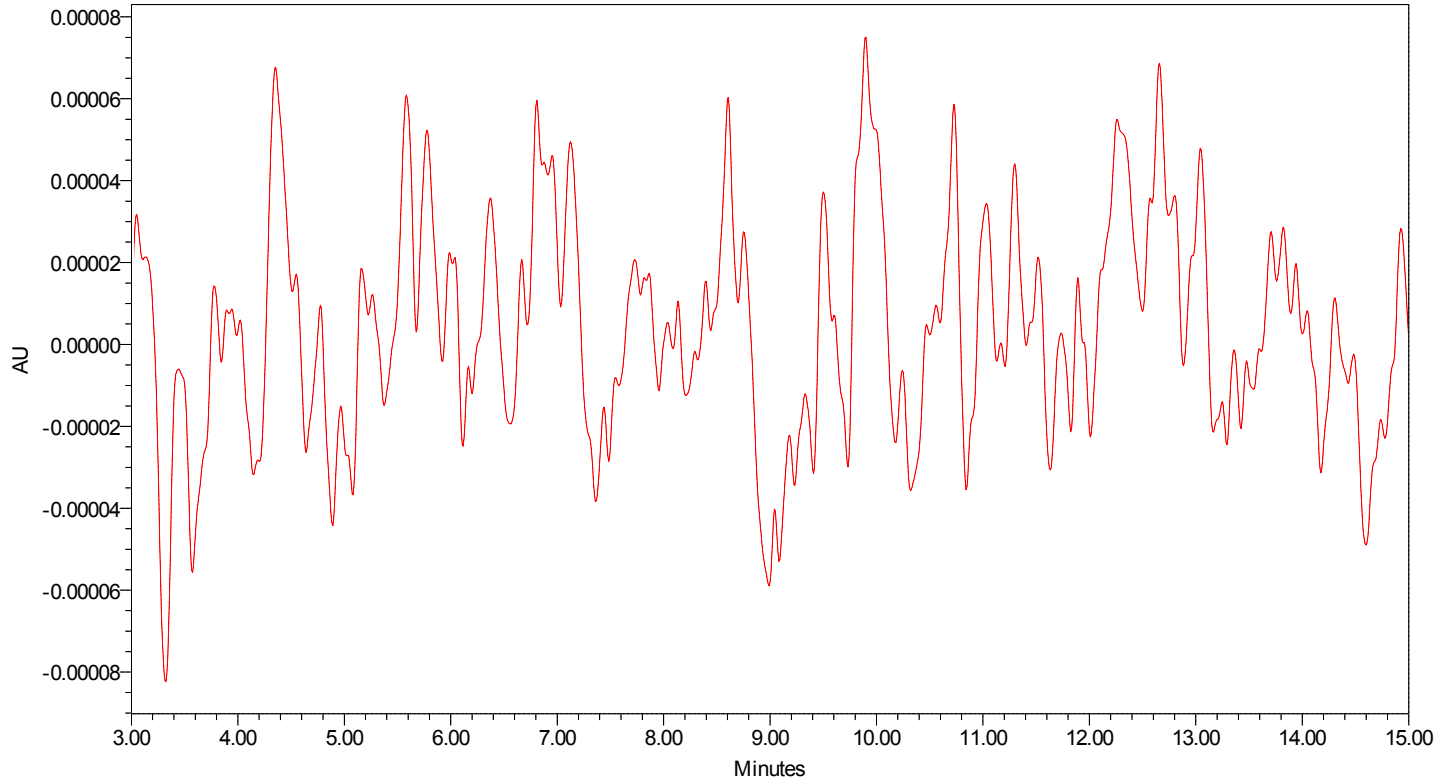
System Name: ArcBio_2489

Sample Set Id: 8614

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8619

Noise and Drift Chromatogram



Noise and Drift Results

	Sample Name	Average Peak to Peak Noise (μ AU)	Detector Drift (mAU/Hr)	Result ID
1	Noise and Drift	59	0	8720



SIGNAL TO NOISE REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489
Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP
Processing Method: 100 Signal to Noise PM
Sample Kit Expiration Date: 7/13/2019 12:00:00 AM EDT
Sample Kit Lot Number: W13071706
Report Method: 100 Signal to Noise RM
Sample Set Name: Signal to Noise SSM
Sample Set Id: 8620
Acquired By: Adam
Column Serial Number: 01903731313692
Result Set Id: 8625

To define the sensitivity of the detector, it is necessary to determine that for a known concentration and condition, a peak can be unambiguously distinguished from noise when eluted from the column.

Results are rounded to the same precision as displayed by the acceptance criterion prior to comparing against the specification.

Signal to Noise Result

	Signal to Noise Specification	Signal to Noise	Signal to Noise Pass/Fail
1	> or = 1000	6162	PASS

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature



SIGNAL TO NOISE REPORT

ACQUISITION INFORMATION

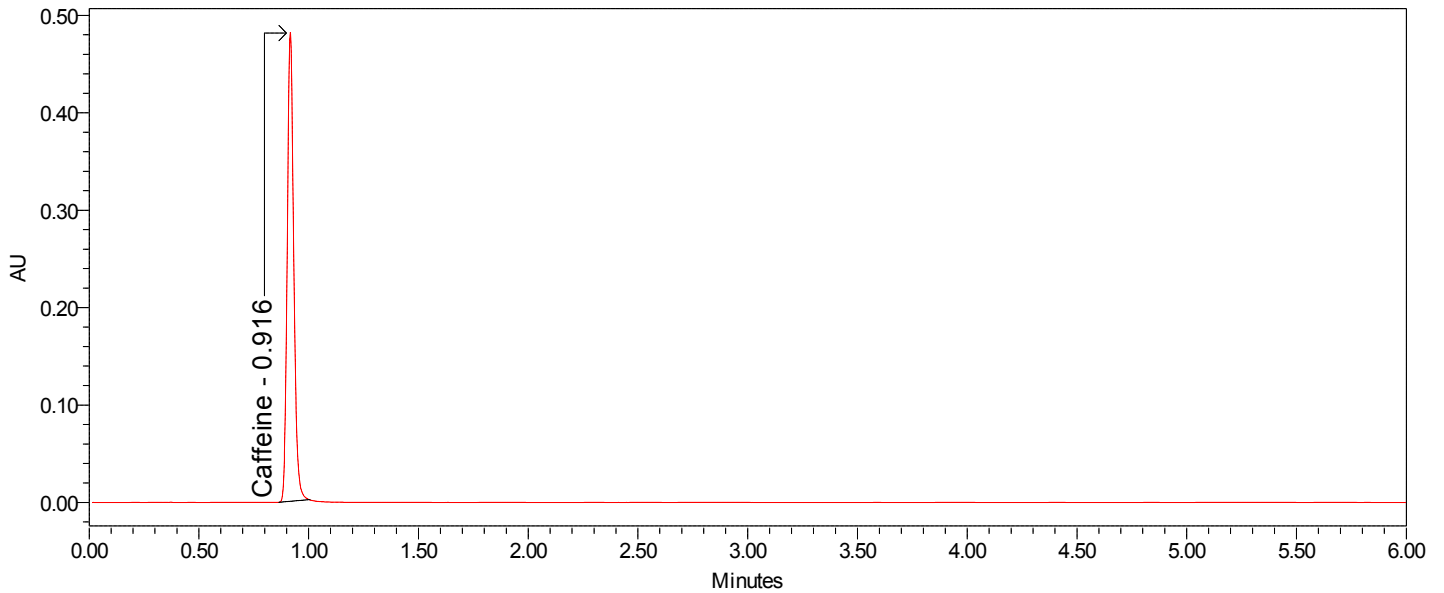
System Name: ArcBio_2489

Sample Set Id: 8620

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Result Set Id: 8625

Signal to Noise Chromatogram



Signal to Noise Peak Result

	Sample Name	Vial	Injection Number	Injection Volume (µL)	RT (min)	RT (sec)	Height (µV)	Peak to Peak Noise (Plot Units)	Signal to Noise	Result ID
1	Caffeine 0.030 mg/mL	2:A,8	1	20.0	0.916	55.0	481480	0.000078	6162	8724



DETECTOR RESPONSE CHECK REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

Sample Set Id: 8276

Acquired By: Adam

Result Set Id: 8281

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

The Detector response check injection is a 0.160 mg/mL caffeine solution injected at 7.0 μ L once the system and column have been equilibrated.

The observed height of the caffeine peak from the detector response check injection is used to scale up the injection volume of System Readiness Check and Detector Linearity & Sensitivity, such that the height of the System Readiness Check and Detector Linearity & Sensitivity injection will be between 1.80 and 2.40 AU.

This test is only for informational and diagnostic purpose. No acceptance criteria are associated with the detector response check injection.

Injection Volume (μ L) for Linear Detector Response : 15

The relationship between injection volume and peak height is approximately one-to-one. (e.g. 10% increase in injection volume results in 10% increase in peak height). Using this relationship between the injection volume and peak height for the detector response check, an injection volume as mentioned above should produce a caffeine peak with a height of approximately 1.90 AU.

Chromatographic Peak Results

	Sample Name	Injection Number	Injection Volume (μ L)	RT (min)	RT (sec)	Height (μ V)	Result ID
1	Caffeine 0.160 mg/mL	1	7.0	0.910	54.6	955041	8284



DETECTOR RESPONSE CHECK REPORT

ACQUISITION INFORMATION

System Name: ArcBio_2489

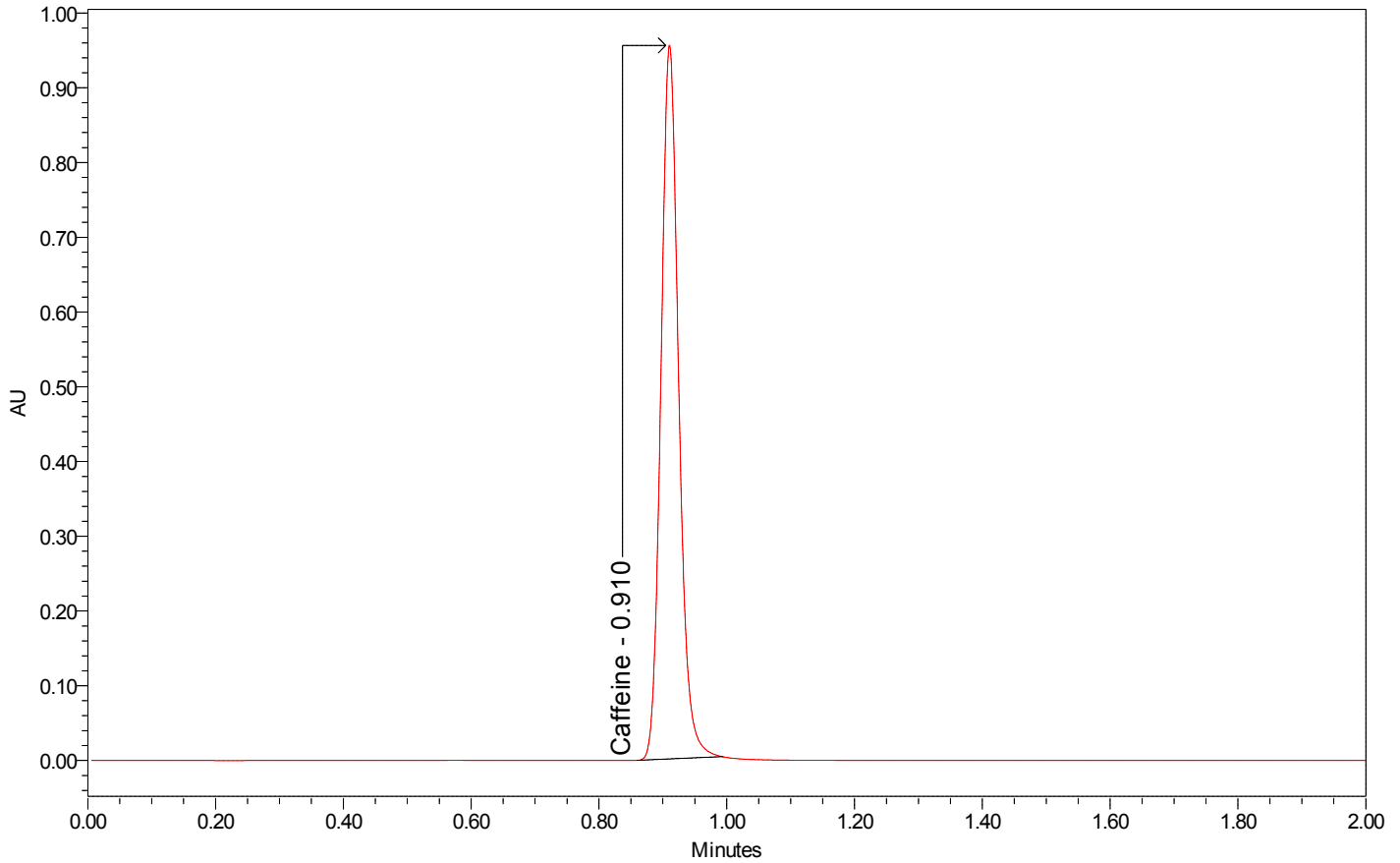
Sample Set Id: 8276

Acquired By: Adam

Result Set Id: 8281

Project Path: RC1_SQT_E_QSM-R_FTN-R_2489_AP

Caffeine Peak for 7.0 μ L injection volume of 0.160 mg/mL solution





QUALIFICATION SUMMARY REPORT

System Name: ArcBio_2489

Processing Node: Wgsqd-s4amcav

Project Path: RC1_SQT_E_QSMR_FTN-R_2489_AP

Automated Qualification Tests Summary

	Qualification Test Parameters	Qualification Test Specifications	Qualification Test Pass / Fail
1	Wavelength Accuracy 1	203nm to 207nm	PASS
2	Wavelength Accuracy 2	271nm to 275nm	PASS
3	Detector Linearity Height	R ² > or = 0.990	PASS
4	Detector Linearity Area	R ² > or = 0.9990	PASS
5	Detector Height Sensitivity	%RSD < or = 4.5	PASS
6	Detector Area Sensitivity	%RSD < or = 3.5	PASS
7	Injector Linearity	R ² > or = 0.999	PASS
8	Injector Accuracy	< or = 0.2 µL	PASS
9	Injector Carryover	< or = 0.002 %	PASS
10	Flow Rate Linearity	R ² > or = 0.990	PASS
11	Gradient Performance	SDRT < or = 1.0 sec	PASS
12	Detector Drift	< or = 10 mAU/Hr	PASS
13	Detector Noise	< or = 60 µAU	PASS
14	Signal to Noise	> or = 1000	PASS
15	System Precision Area	%RSD < or = 0.25	PASS
16	System Precision Height	%RSD < or = 1.1	PASS
17	System Precision Retention Time	SDRT < or = 1.0 sec	PASS

Manual Qualification Tests Summary

	Qualification Test Parameters	Qualification Test Specifications	Qualification Test Pass / Fail
1	Sample Temperature Set Point 1	-2.0 to +4.0 °C of Set-Point Temperature	PASS
2	Sample Temperature Set Point 2	-2.0 to +4.0 °C of Set-Point Temperature	PASS
3	Column Temperature Set Point 1	± 2.0 °C of Set-Point Temperature	PASS
4	Column Temperature Set Point 2	± 2.0 °C of Set-Point Temperature	PASS
5	Top Plate Position	Pass or Fail	PASS
6	Sample Organizer Temperature Set Point 2	-2.0 to +4.0 °C of Set-Point Temperature	PASS
7	Sample Organizer Temperature Set Point 1	-2.0 to +4.0 °C of Set-Point Temperature	PASS
8	Bottom Plate Position	Pass or Fail	PASS
9	Third Plate Position	Pass or Fail	PASS
10	Second Plate Position	Pass or Fail	PASS
11	Flow Rate Accuracy for 5.0 mL/min	4.94 to 5.06 mL/min	PASS
12	Flow Rate Accuracy for 0.5 mL/min	0.494 to 0.506 mL/min	PASS



QUALIFICATION SUMMARY REPORT

System Name: ArcBio_2489

Processing Node: Wgsq-s4amcav

Project Path: RC1_SQT_E_QSMR_FTNR_2489_AP

Automated Qualification Sample Set Details

	Sample Set ID	Result Set ID	Sample Set Name	Sample Set Start Date
1	8391	8402	Wavelength Accuracy SSM	2/23/2018 2:28:26 PMEST
2	8455	8460	Detector Lin Sens SSM	2/23/2018 3:05:04 PMEST
3	8489	8494	Injector Lin Acc SSM	2/23/2018 3:26:06 PMEST
4	8519	8524	Injector Carryover SSM	2/23/2018 3:44:58 PMEST
5	8552	8557	Flow Rate Lin SSM	2/23/2018 4:21:00 PMEST
6	8574	8582	Gradient Performance SSM	2/23/2018 4:45:54 PMEST
7	8614	8619	Noise and Drift SSM	2/23/2018 5:50:03 PMEST
8	8620	8625	Signal to Noise SSM	2/23/2018 6:10:23 PMEST
9	8750	8755	System Precision SSM	2/26/2018 8:33:12 AMEST

Manual Qualification Sample Set Details

	Sample Set ID	Result Set ID	Sample Set Name	Sample Set Start Date
1	8290	8307	SM Temperature Acc SSM	2/23/2018 12:27:02 PMEST
2	8315	8323	Column Temp Acc SSM	2/23/2018 12:27:37 PMEST
3	8821	8833	001 SO Manual CQ_b SSM	2/27/2018 1:39:39 PMEST
4	8882	8888	004 Flow Rate Acc SSM	2/27/2018 1:49:54 PMEST



TEST EQUIPMENT CALIBRATION INFORMATION

ACQUISITION INFORMATION

System Name: ArcBio_2489

Acquired By: Adam

Project Path: RC1_SQT_E_QSMR_FTNR_2489_AP

Sample Set Id: 8780

Result Set Id: 8784

Test equipment calibration information about the test equipment used in the qualification.

	Equipment Name	Equipment Serial Number	Equipment ID	Equipment Last Calibration Date	Equipment Next Calibration Date
1	Stopwatch	213423	1234	21 Feb 2017	23 Feb 2018
2	Temperature Meter	234324	3453345	21 Feb 2017	23 Feb 2018
3	Temperature Probe	23423423	345245435	21 Feb 2017	23 Feb 2018

Certification

Comments _____

The undersigned performer attests that the values recorded above are accurate and complete.

Performer _____ Date _____
Signature

The undersigned reviewer accepts that the values recorded above are accurate and complete.

Reviewer _____ Date _____
Signature