



Owner: [REDACTED]	Number: Chem-Form-62
Author: [REDACTED]	Version: 1
Active: 15/06/2021	Review: <QPulse_DocReviewDate>
Title: Assay for Lipids in Vaccines by HPLC CAD (Bio-BPC-Method-24 Pfizer)	

TGA SAMPLE No. 2110003737

SUBSTANCES ASSAYED: ALC-0159, Cholesterol,

Lot number: FH3221

ALC-0315, DSPC

METHOD REFERENCE: TM100010322 (Pfizer)/BIO-BPC-Method-24

INSTRUMENT OR SYSTEM No. 20 with CAD detector... Method Modifications approved by:

SYSTEM SUITABILITY REQUIREMENTS MET (Y/N) ?..... ASSAY REQUIREMENTS MET (Y/N)?.....

RESULTS

TGA Sample number	Preparation	Lipid content (mg/mL)			
		ALC-0159	Cholesterol	ALC-0315	DSPC
2110003737	1	0.795	2.834	6.413	1.417
	2	0.787	2.823	6.400	1.402
	3	0.783	2.827	6.391	1.392
Average	-	0.79	2.83	6.40	1.40
% RSD ([REDACTED])	-	0.8	0.2	0.2	0.9

ATTACHMENTS: Analysts Notes worksheets ☐ Result summary report ☒ System suitability report ☒
 Example chromatograms ☒ Run and method summary ☒ Calibration plots ☒
 MP preparation details or refer to sample 2110003744 Other ☐.....

REQUIREMENTS (Manuf.) [REDACTED]

Identification RT requirements met ? (RT $\pm$ 5% compared to SST) (Y/N)

IDENTIFIED AS ALC-0159, Cholesterol, ALC-.0315 and DSPC

RESULT

PASS ☒FAIL ☐

Signature of Analyst Electronically signed by [REDACTED] Date.....28/10/2021....

Checked by Official Analyst...Electronically signed by [REDACTED].....Date...28/10/21.....

WORKING STANDARD CURVE PREPARATION DETAILS

Date Stock solution prepared: 27 Sep 2021 Prepared by: [REDACTED] Within expiry Y/N

Attached ☐ or Refer to (TRIM Record number/Sample number) D21-3147439

	ALC-0159	Cholesterol	ALC-0315	DSPC5
Concentration in stock solution (mg/mL)	0.30455	1.02467	2.37301	0.55431

Prepared by: [REDACTED] Date prepared 25 Oct 2021 POVA LIMS: 33271

Level	Mixed Lipid Soln (uL)	MeOH (uL)	DF	Final Target conc (mg/mL)		Actual conc (mg/mL)
1	50	950	20	ALC-0159	0.015	0.01523
				Cholesterol	0.050	0.05123
				ALC-0315	0.120	0.11865
				DSPC	0.028	0.02772
2	100	900	10	ALC-0159	0.030	0.03046
				Cholesterol	0.100	0.10247
				ALC-0315	0.240	0.23730
				DSPC	0.056	0.05543
3	100	300	4	ALC-0159	0.075	0.07614
				Cholesterol	0.250	0.25617
				ALC-0315	0.600	0.59325
				DSPC	0.140	0.13858
4	200	200	2	ALC-0159	0.150	0.15228
				Cholesterol	0.500	0.51234
				ALC-0315	1.200	1.18650
				DSPC	0.280	0.27716
5	225	75	1.33	ALC-0159	0.225	0.22841
				Cholesterol	0.750	0.76850
				ALC-0315	1.800	1.77975
				DSPC	0.420	0.41574

ASSAY CONTROL PREPARATION DETAILS

Date control solution prepared: 27 Sep 2021 Within expiry Y/N

Attached ☐ or Refer to (TRIM/ Record number/Sample number) D21-3147439

DP REFERENCE MATERIAL PREPARED Y/N

LIMS number	Lot number/Expiry	Sample solution (uL)	MeOH (uL)	DF
2103001141	EE8493 – 05/02/2022	50	950	20

SAMPLE PREPARATION DETAILS

Date prepared: 25 Oct 2021 Prepared by: [REDACTED] POVA LIMS: 33721

Preparation	Sample solution (uL)	MeOH (uL)	DF
1	50	950	20
2	50	950	20
3	50	950	20

Methanol LCMS grade; Supplier: Fisher

Lot No. 205074

METHOD MODIFICATIONS

Additional parameters required for eSATIN module

Environment	50 Hz
Sampling rate	2
Scale factor	1000

The range on the CAD detector was set to 500

Level 3 dilution for standard curve 200uL (100uL) mixed lipid stock solution added to 200uL (300uL) methanol instead of 100uL stock solution added to 100uL methanol. (to increase amount of solution, concentration not changed)

Level 4 dilution for standard curve 100uL (200uL) mixed lipid stock solution added to 300uL (200uL) methanol instead of 50uL stock solution added to 150uL methanol (to increase amount of solution, concentration not changed)

Above script amended by [REDACTED] on 27/10/2021

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AED1

Print Date: 27/10/2021

Vaccine System Suitability Report

No blank peak should appear within the retention time window of the lipid peaks (RT 4 to 20 mins) **Pass / Fail**

The %RSD of the peak area and retention time of the first 3 SST injections must be NMT 5.0% **Pass / Fail**

Peak Results Retention Time Summarized by Name					
	Result Id	ALC-0159 (min)	cholesterol (min)	ALC-0315 (min)	DSPC (min)
1	5964	5.991	10.129	13.798	18.127
2	5966	5.988	10.124	13.807	18.119
3	5968	5.969	10.117	13.787	18.103
Mean		5.983	10.123	13.797	18.116
% RSD		0.20	0.06	0.07	0.07

Peak Results Area Summarized by Name					
	Result Id	ALC-0159 (μV*sec)	cholesterol (μV*sec)	ALC-0315 (μV*sec)	DSPC (μV*sec)
1	5964	867097	2293501	5490731	1364534
2	5966	863232	2259887	5475375	1378598
3	5968	865427	2254296	5502960	1381800
Mean		865251.9	2269228.2	5489688.9	1374977.5
% RSD		0.22	0.93	0.25	0.67

The %RSD of the peak area and retention time of the all 5 SST injections must be NMT 5.0% **Pass / Fail**

Peak Results Retention Time Summarized by Name					
	Result Id	ALC-0159 (min)	cholesterol (min)	ALC-0315 (min)	DSPC (min)
1	5968	5.969	10.117	13.787	18.103
2	5970	5.987	10.145	13.960	18.152
3	5966	5.988	10.124	13.807	18.119
4	5964	5.991	10.129	13.798	18.127
5	5972	5.997	10.155	13.971	18.161
Mean		5.986	10.134	13.865	18.132
% RSD		0.18	0.16	0.67	0.13

Peak Results Area Summarized by Name					
	Result Id	ALC-0159 (μV*sec)	cholesterol (μV*sec)	ALC-0315 (μV*sec)	DSPC (μV*sec)
1	5968	865427	2254296	5502960	1381800
2	5970	869355	2271031	5595748	1420440
3	5966	863232	2259887	5475375	1378598
4	5964	867097	2293501	5490731	1364534
5	5972	870437	2238208	5547641	1409410
Mean		867109.6	2263384.7	5522491.3	1390956.5
% RSD		0.34	0.91	0.89	1.66

The % Recovery of the lipids in the assay control must be within 85% - 115% (% Deviation within ±15%) **Pass / Fail**

Peak Results Percent LipidRecovery Summarized by Name					
	Result Id	ALC-0159	cholesterol	ALC-0315	DSPC
1	5934	101.742	97.796	98.450	102.950
2	5936	98.131	97.421	96.823	99.116
Mean		99.936	97.608	97.637	101.033

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Vaccine System Suitability Report

The % RT difference between sample preparations and SST must be within
95% - 105% (% Deviation within $\pm 5\%$)

Pass / Fail

Peak Results
RT_Dev Summarized by Name

	SampleName	Result Id	ALC-0159	cholesterol	ALC-0315	DSPC
1	2110003737 Prep 1	5938	99.397	100.079	102.117	100.085
2	2110003737 Prep 1	5940	99.397	100.079	102.117	100.085
3	2110003737 Prep 2	5942	99.397	100.079	102.117	100.085
4	2110003737 Prep 2	5944	99.397	100.079	102.117	100.085
5	2110003737 Prep 3	5946	99.397	100.079	102.117	100.085
6	2110003737 Prep 3	5948	99.397	100.079	102.117	100.085
Mean			99.4	100.1	102.1	100.1

Project Name: Chemistry\System20_2021_09 Lipids

Sample LIMS No. 2110003737

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Id: 5819

Sample Set Acquired By [REDACTED]

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Vaccine System Suitability Report

The R2 values for the Cal Curves must be greater than 0.995

Pass / Fail

Peak: ALC-0159

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0159	Level 1	0.015230	180603.629475	0.014987	-1.595	No	No	0.999705
2	ALC-0159	Level 1	0.015230	179194.947553	0.014864	-2.401	No	No	0.999705
3	ALC-0159	Level 2	0.030460	357240.794499	0.030465	0.018	No	No	0.999705
4	ALC-0159	Level 2	0.030460	362955.241368	0.030969	1.672	No	No	0.999705
5	ALC-0159	Level 3	0.076140	869133.134926	0.076394	0.334	No	No	0.999705
6	ALC-0159	Level 3	0.076140	869034.335225	0.076385	0.322	No	No	0.999705
7	ALC-0159	Level 4	0.152280	1668827.387104	0.151700	-0.381	No	No	0.999705
8	ALC-0159	Level 4	0.152280	1674223.725131	0.152224	-0.037	No	No	0.999705
9	ALC-0159	Level 5	0.228410	2465438.728652	0.231802	1.485	No	No	0.999705
10	ALC-0159	Level 5	0.228410	2402452.705952	0.225259	-1.380	No	No	0.999705
Mean									1.0

Peak: cholesterol

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	cholesterol	Level 1	0.051230	431456.099521	0.051535	0.595	No	No	0.999381
2	cholesterol	Level 1	0.051230	418877.432955	0.050178	-2.054	No	No	0.999381
3	cholesterol	Level 2	0.102470	894388.818221	0.102153	-0.310	No	No	0.999381
4	cholesterol	Level 2	0.102470	886731.591844	0.101304	-1.138	No	No	0.999381
5	cholesterol	Level 3	0.256170	2250163.076931	0.258960	1.089	No	No	0.999381
6	cholesterol	Level 3	0.256170	2249300.746297	0.258856	1.048	No	No	0.999381
7	cholesterol	Level 4	0.512340	4162121.899087	0.508301	-0.788	No	No	0.999381
8	cholesterol	Level 4	0.512340	4182732.119732	0.511220	-0.219	No	No	0.999381
9	cholesterol	Level 5	0.768500	5952093.272443	0.788273	2.573	No	No	0.999381
10	cholesterol	Level 5	0.768500	5735460.348997	0.750980	-2.280	No	No	0.999381
Mean									1.0

Peak: ALC-0315

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0315	Level 1	0.118650	1208005.190335	0.115271	-2.848	No	No	0.999542
2	ALC-0315	Level 1	0.118650	1188812.584678	0.113197	-4.596	No	No	0.999542
3	ALC-0315	Level 2	0.237300	2356683.379711	0.240882	1.509	No	No	0.999542
4	ALC-0315	Level 2	0.237300	2325072.779608	0.237385	0.036	No	No	0.999542
5	ALC-0315	Level 3	0.593250	5512661.385244	0.602584	1.573	No	No	0.999542
6	ALC-0315	Level 3	0.593250	5492409.755423	0.600178	1.168	No	No	0.999542
7	ALC-0315	Level 4	1.186500	10102581.641525	1.182484	-0.338	No	No	0.999542
8	ALC-0315	Level 4	1.186500	10030790.953798	1.172814	-1.153	No	No	0.999542
9	ALC-0315	Level 5	1.779750	14449765.649339	1.815121	1.987	No	No	0.999542
10	ALC-0315	Level 5	1.779750	14042945.146771	1.751375	-1.594	No	No	0.999542
Mean									1.0

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Vaccine System Suitability Report

Peak: DSPC

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	DSPC	Level 1	0.027720	284364.886665	0.026655	-3.843	No	No	0.999669
2	DSPC	Level 1	0.027720	284800.739351	0.026697	-3.690	No	No	0.999669
3	DSPC	Level 2	0.055430	580233.081199	0.055911	0.868	No	No	0.999669
4	DSPC	Level 2	0.055430	573508.787333	0.055237	-0.348	No	No	0.999669
5	DSPC	Level 3	0.138580	1401177.715268	0.141709	2.258	No	No	0.999669
6	DSPC	Level 3	0.138580	1391676.495016	0.140673	1.510	No	No	0.999669
7	DSPC	Level 4	0.277160	2533412.359845	0.274381	-1.003	No	No	0.999669
8	DSPC	Level 4	0.277160	2533850.483587	0.274436	-0.983	No	No	0.999669
9	DSPC	Level 5	0.415740	3598714.464085	0.422209	1.556	No	No	0.999669
10	DSPC	Level 5	0.415740	3528154.972702	0.411449	-1.032	No	No	0.999669
Mean									1.0

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003737

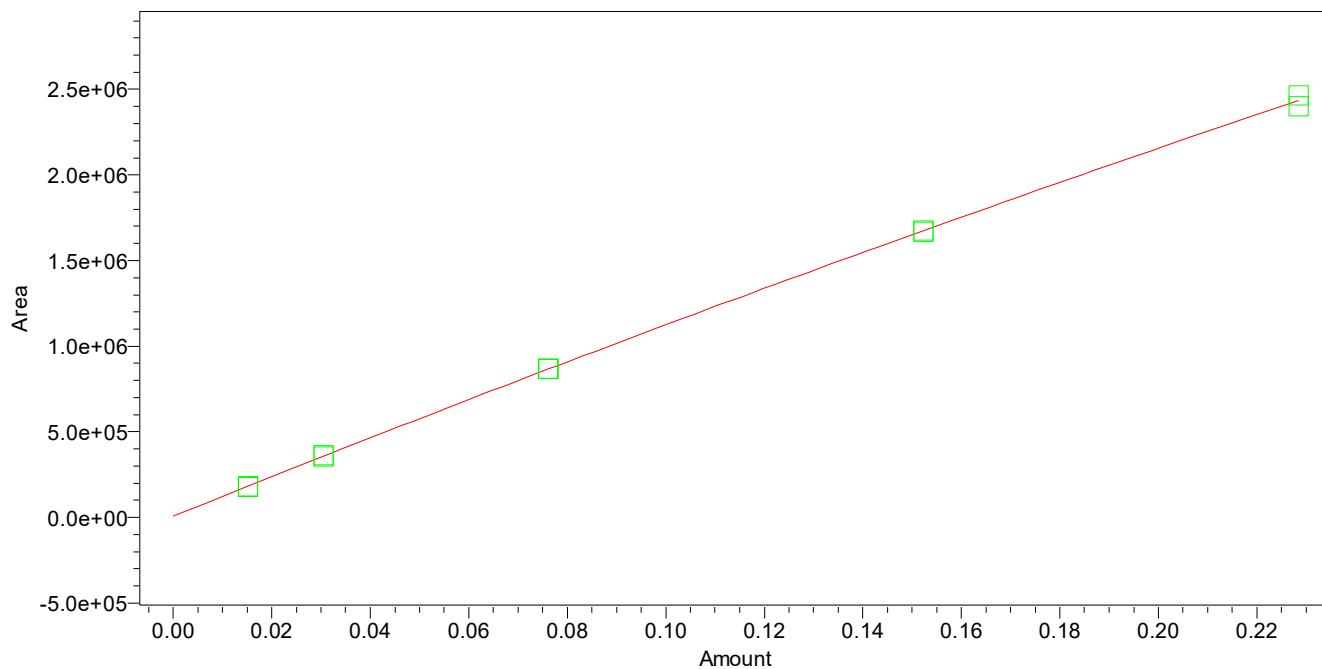
Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Cal Curve Report

Calibration Plot



Name: ALC-0159; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order);

Cal Curve Id: 5899; A: 7.592237e+03; B: 1.160910e+07; C: -4.339490e+06; D: 0.000000e+00; R^2: 0.999705

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003737

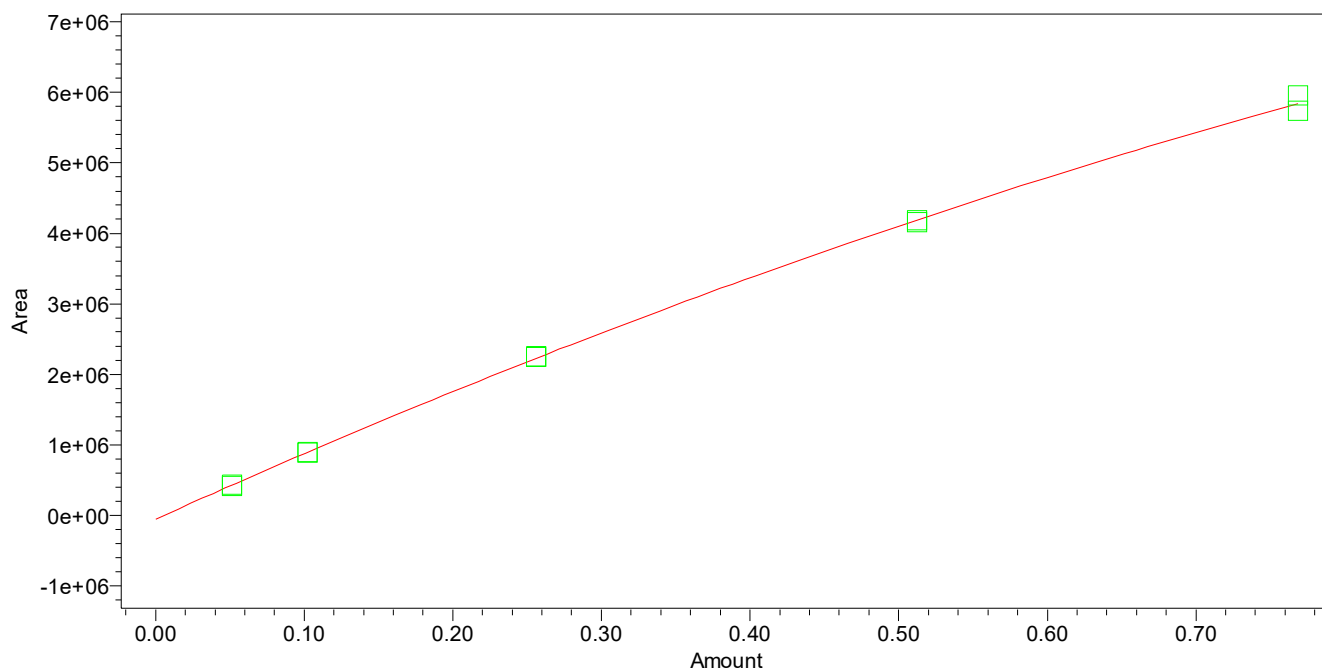
Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Cal Curve Report

Calibration Plot



Name: cholesterol; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order);
Cal Curve Id: 5900; A: -5.253816e+04; B: 9.515732e+06; C: -2.408147e+06; D: 0.000000e+00;
R^2: 0.999381

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003737

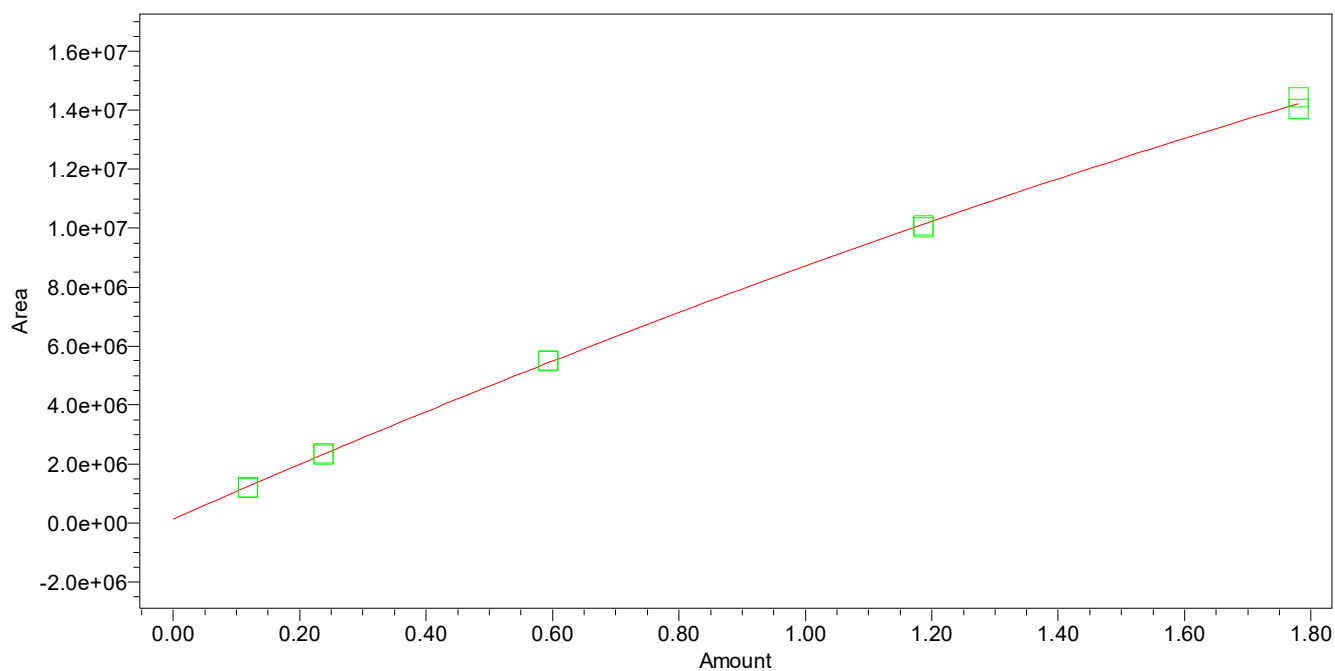
Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Cal Curve Report

Calibration Plot



Name: ALC-0315; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order);

Cal Curve Id: 5901; A: 1.299924e+05; B: 9.451219e+06; C: -8.605829e+05; D: 0.000000e+00; R^2: 0.999542

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003737

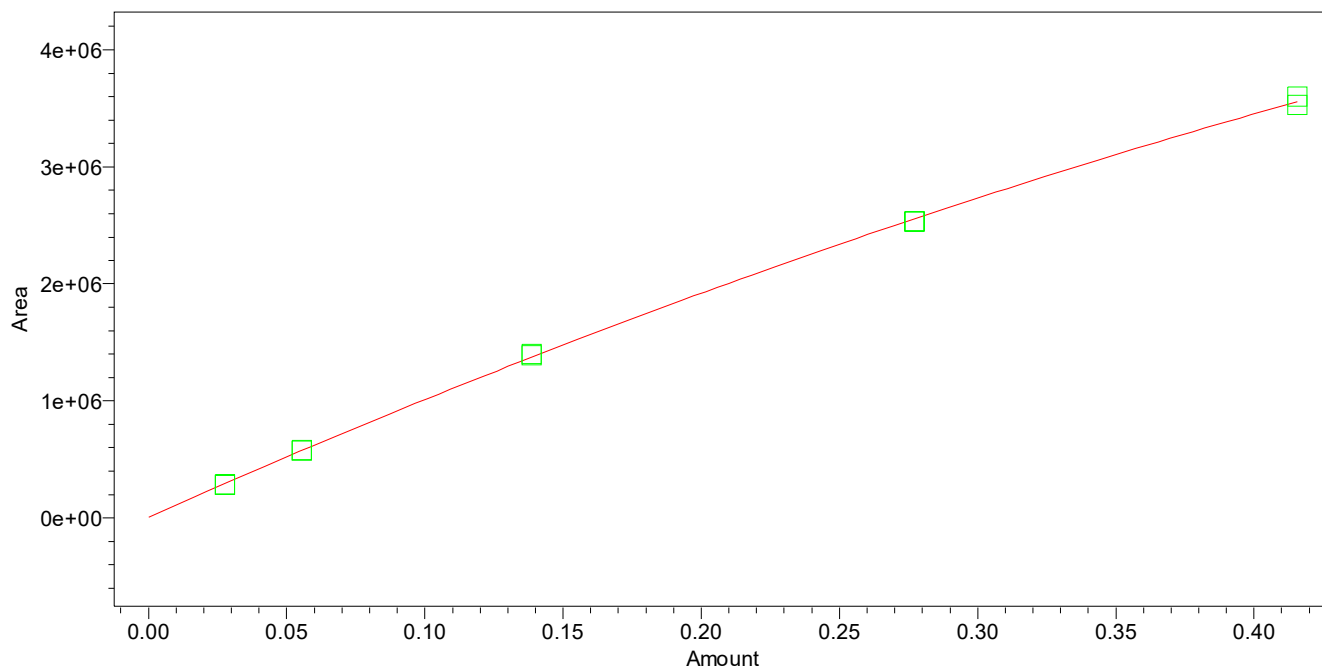
Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Cal Curve Report

Calibration Plot



Name: DSPC; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order); Cal Curve Id: 5902; A: 7.752355e+03; B: 1.050380e+07; C: -4.733742e+06; D: 0.000000e+00; R^2: 0.999669

Peak: ALC-0159

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0159	Level 1	0.015230	180603.629475	0.014987	-1.595	No	No	0.999705
2	ALC-0159	Level 1	0.015230	179194.947553	0.014864	-2.401	No	No	0.999705
3	ALC-0159	Level 2	0.030460	357240.794499	0.030465	0.018	No	No	0.999705
4	ALC-0159	Level 2	0.030460	362955.241368	0.030969	1.672	No	No	0.999705
5	ALC-0159	Level 3	0.076140	869133.134926	0.076394	0.334	No	No	0.999705
6	ALC-0159	Level 3	0.076140	869034.335225	0.076385	0.322	No	No	0.999705
7	ALC-0159	Level 4	0.152280	1668827.387104	0.151700	-0.381	No	No	0.999705
8	ALC-0159	Level 4	0.152280	1674223.725131	0.152224	-0.037	No	No	0.999705
9	ALC-0159	Level 5	0.228410	2465438.728652	0.231802	1.485	No	No	0.999705
10	ALC-0159	Level 5	0.228410	2402452.705952	0.225259	-1.380	No	No	0.999705

Peak: cholesterol

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	cholesterol	Level 1	0.051230	431456.099521	0.051535	0.595	No	No	0.999381
2	cholesterol	Level 1	0.051230	418877.432955	0.050178	-2.054	No	No	0.999381
3	cholesterol	Level 2	0.102470	894388.818221	0.102153	-0.310	No	No	0.999381

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Cal Curve Report

Peak: cholesterol

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
4	cholesterol	Level 2	0.102470	886731.591844	0.101304	-1.138	No	No	0.999381
5	cholesterol	Level 3	0.256170	2250163.076931	0.258960	1.089	No	No	0.999381
6	cholesterol	Level 3	0.256170	2249300.746297	0.258856	1.048	No	No	0.999381
7	cholesterol	Level 4	0.512340	4162121.899087	0.508301	-0.788	No	No	0.999381
8	cholesterol	Level 4	0.512340	4182732.119732	0.511220	-0.219	No	No	0.999381
9	cholesterol	Level 5	0.768500	5952093.272443	0.788273	2.573	No	No	0.999381
10	cholesterol	Level 5	0.768500	5735460.348997	0.750980	-2.280	No	No	0.999381

Peak: ALC-0315

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0315	Level 1	0.118650	1208005.190335	0.115271	-2.848	No	No	0.999542
2	ALC-0315	Level 1	0.118650	1188812.584678	0.113197	-4.596	No	No	0.999542
3	ALC-0315	Level 2	0.237300	2356683.379711	0.240882	1.509	No	No	0.999542
4	ALC-0315	Level 2	0.237300	2325072.779608	0.237385	0.036	No	No	0.999542
5	ALC-0315	Level 3	0.593250	5512661.385244	0.602584	1.573	No	No	0.999542
6	ALC-0315	Level 3	0.593250	5492409.755423	0.600178	1.168	No	No	0.999542
7	ALC-0315	Level 4	1.186500	10102581.641525	1.182484	-0.338	No	No	0.999542
8	ALC-0315	Level 4	1.186500	10030790.953798	1.172814	-1.153	No	No	0.999542
9	ALC-0315	Level 5	1.779750	14449765.649339	1.815121	1.987	No	No	0.999542
10	ALC-0315	Level 5	1.779750	14042945.146771	1.751375	-1.594	No	No	0.999542

Peak: DSPC

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	DSPC	Level 1	0.027720	284364.886665	0.026655	-3.843	No	No	0.999669
2	DSPC	Level 1	0.027720	284800.739351	0.026697	-3.690	No	No	0.999669
3	DSPC	Level 2	0.055430	580233.081199	0.055911	0.868	No	No	0.999669
4	DSPC	Level 2	0.055430	573508.787333	0.055237	-0.348	No	No	0.999669
5	DSPC	Level 3	0.138580	1401177.715268	0.141709	2.258	No	No	0.999669
6	DSPC	Level 3	0.138580	1391676.495016	0.140673	1.510	No	No	0.999669
7	DSPC	Level 4	0.277160	2533412.359845	0.274381	-1.003	No	No	0.999669
8	DSPC	Level 4	0.277160	2533850.483587	0.274436	-0.983	No	No	0.999669
9	DSPC	Level 5	0.415740	3598714.464085	0.422209	1.556	No	No	0.999669
10	DSPC	Level 5	0.415740	3528154.972702	0.411449	-1.032	No	No	0.999669

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Result Summary Report

Result Summary Table (peak area)
Ave_Conc Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	5783	5938	2110003737 Prep 1	0.795	2.834	6.413	1.417
2	5790	5942	2110003737 Prep 2	0.787	2.823	6.400	1.402
3	5797	5946	2110003737 Prep 3	0.783	2.827	6.391	1.392
Mean				0.79	2.83	6.40	1.40
Std. Dev.				0.01	0.01	0.01	0.01
% RSD				0.8	0.2	0.2	0.9

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	5783	5938	2110003737 Prep 1	0.796	2.834	6.406	1.410
2	5786	5940	2110003737 Prep 1	0.795	2.834	6.421	1.425
3	5790	5942	2110003737 Prep 2	0.786	2.821	6.406	1.396
4	5793	5944	2110003737 Prep 2	0.788	2.825	6.394	1.408
5	5797	5946	2110003737 Prep 3	0.776	2.824	6.372	1.391
6	5800	5948	2110003737 Prep 3	0.790	2.830	6.411	1.392
Mean				0.79	2.83	6.40	1.40

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	5765	5950	2103001141 Ref Material	0.805	2.867	6.594	1.422
2	5768	5952	2103001141 Ref Material	0.806	2.898	6.591	1.408
Mean				0.806	2.882	6.593	1.415

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	5772	5934	Assay control	0.076	0.242	0.618	0.143
2	5775	5936	Assay control	0.074	0.241	0.608	0.138
Mean				0.075	0.241	0.613	0.140

Results Summary Report

Calibration Data Table
Peak: ALC-0159

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	5603	5914	ALC-0159	0.015230	180604	5899
2	5732	5916	ALC-0159	0.015230	179195	5899
3	5736	5918	ALC-0159	0.030460	357241	5899
4	5739	5920	ALC-0159	0.030460	362955	5899
5	5743	5922	ALC-0159	0.076140	869133	5899
6	5747	5924	ALC-0159	0.076140	869034	5899
7	5751	5926	ALC-0159	0.152280	1668827	5899
8	5754	5928	ALC-0159	0.152280	1674224	5899
9	5758	5930	ALC-0159	0.228410	2465439	5899
10	5761	5932	ALC-0159	0.228410	2402453	5899

Calibration Data Table
Peak: cholesterol

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	5603	5914	cholesterol	0.051230	431456	5900
2	5732	5916	cholesterol	0.051230	418877	5900
3	5736	5918	cholesterol	0.102470	894389	5900
4	5739	5920	cholesterol	0.102470	886732	5900
5	5743	5922	cholesterol	0.256170	2250163	5900
6	5747	5924	cholesterol	0.256170	2249301	5900
7	5751	5926	cholesterol	0.512340	4162122	5900
8	5754	5928	cholesterol	0.512340	4182732	5900
9	5758	5930	cholesterol	0.768500	5952093	5900
10	5761	5932	cholesterol	0.768500	5735460	5900

Calibration Data Table
Peak: ALC-0315

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	5603	5914	ALC-0315	0.118650	1208005	5901
2	5732	5916	ALC-0315	0.118650	1188813	5901
3	5736	5918	ALC-0315	0.237300	2356683	5901
4	5739	5920	ALC-0315	0.237300	2325073	5901
5	5743	5922	ALC-0315	0.593250	5512661	5901
6	5747	5924	ALC-0315	0.593250	5492410	5901
7	5751	5926	ALC-0315	1.186500	10102582	5901
8	5754	5928	ALC-0315	1.186500	10030791	5901
9	5758	5930	ALC-0315	1.779750	14449766	5901
10	5761	5932	ALC-0315	1.779750	14042945	5901

Results Summary Report

Calibration Data Table
Peak: DSPC

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	5603	5914	DSPC	0.027720	284365	5902
2	5732	5916	DSPC	0.027720	284801	5902
3	5736	5918	DSPC	0.055430	580233	5902
4	5739	5920	DSPC	0.055430	573509	5902
5	5743	5922	DSPC	0.138580	1401178	5902
6	5747	5924	DSPC	0.138580	1391676	5902
7	5751	5926	DSPC	0.277160	2533412	5902
8	5754	5928	DSPC	0.277160	2533850	5902
9	5758	5930	DSPC	0.415740	3598714	5902
10	5761	5932	DSPC	0.415740	3528155	5902

Project Name: Chemistry\System20_2021_09 Lipids
Sample Set Name: 20211026 Pfizer vaccine testin

LIMS Number:
Sample Set Id: 5819
Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT
Print Date: 27/10/2021

Analyst [REDACTED]

Results Summary Report

Result Summary Table (peak area)
Peak Name: ALC-0159

	Inj Id	Result Id	Sample Name	RT	Area ($\mu V \cdot sec$)	Height (μV)	Lipid Content
1	5329	5964	SST	5.991	867097	18247	0.076
2	5463	5966	SST	5.988	863232	18301	0.076
3	5599	5968	SST	5.969	865427	18426	0.076
4	5603	5914	Level 1	5.988	180604	3825	0.015
5	5732	5916	Level 1	5.983	179195	3777	0.015
6	5736	5918	Level 2	5.972	357241	7446	0.030
7	5739	5920	Level 2	5.972	362955	7448	0.030
8	5743	5922	Level 3	5.959	869133	18219	0.076
9	5747	5924	Level 3	6.033	869034	18187	0.076
10	5751	5926	Level 4	5.996	1668827	34725	0.152
11	5754	5928	Level 4	5.995	1674224	34954	0.152
12	5758	5930	Level 5	5.952	2465439	50614	0.228
13	5761	5932	Level 5	5.999	2402453	49344	0.228
14	5765	5950	2103001141 Ref Material	6.021	467727	9467	0.805
15	5768	5952	2103001141 Ref Material	6.041	468665	9464	0.806
16	5772	5934	Assay control	5.979	867394	18299	0.076
17	5775	5936	Assay control	6.002	837741	17601	0.074
18	5783	5938	2110003737 Prep 1	5.985	462503	9838	0.796
19	5786	5940	2110003737 Prep 1	5.987	461988	9909	0.795
20	5790	5942	2110003737 Prep 2	5.972	457081	10014	0.786
21	5793	5944	2110003737 Prep 2	5.922	458254	9962	0.788
22	5797	5946	2110003737 Prep 3	5.918	451586	9847	0.776
23	5800	5948	2110003737 Prep 3	5.919	459234	9837	0.790
24	5808	5970	SST	5.987	869355	18414	0.076
25	5811	5972	SST	5.997	870437	18201	0.077

Result Summary Table (peak area)
Peak Name: ALC-0315

	Inj Id	Result Id	Sample Name	RT	Area ($\mu V \cdot sec$)	Height (μV)	Lipid Content
1	5329	5964	SST	13.798	5490731	153987	0.600
2	5463	5966	SST	13.807	5475375	154602	0.598
3	5599	5968	SST	13.787	5502960	154080	0.601
4	5603	5914	Level 1	14.272	1208005	57377	0.119
5	5732	5916	Level 1	14.310	1188813	56495	0.119
6	5736	5918	Level 2	14.157	2356683	90135	0.237
7	5739	5920	Level 2	14.157	2325073	91024	0.237
8	5743	5922	Level 3	13.862	5512661	152400	0.593
9	5747	5924	Level 3	13.861	5492410	147547	0.593
10	5751	5926	Level 4	13.544	10102582	213947	1.187
11	5754	5928	Level 4	13.544	10030791	211589	1.187
12	5758	5930	Level 5	13.325	14449766	261325	1.780
13	5761	5932	Level 5	13.353	14042945	255924	1.780

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Analyst XXXXXXXXXX

LIMS Number:

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Results Summary Report

Result Summary Table (peak area)

Peak Name: ALC-0315

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
14	5765	5950	2103001141 Ref Material	14.113	3152522	109482	6.594
15	5768	5952	2103001141 Ref Material	14.135	3151389	109794	6.591
16	5772	5934	Assay control	13.885	5640029	152726	0.618
17	5775	5936	Assay control	13.912	5554319	152950	0.608
18	5783	5938	2110003737 Prep 1	14.113	3068857	107682	6.406
19	5786	5940	2110003737 Prep 1	14.144	3075537	108380	6.421
20	5790	5942	2110003737 Prep 2	14.141	3069031	109449	6.406
21	5793	5944	2110003737 Prep 2	14.154	3063390	107224	6.394
22	5797	5946	2110003737 Prep 3	14.170	3053834	108543	6.372
23	5800	5948	2110003737 Prep 3	14.228	3071111	107335	6.411
24	5808	5970	SST	13.960	5595748	151891	0.612
25	5811	5972	SST	13.971	5547641	149673	0.607

Result Summary Table (peak area)

Peak Name: DSPC

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	5329	5964	SST	18.127	1364534	93047	0.138
2	5463	5966	SST	18.119	1378598	93706	0.139
3	5599	5968	SST	18.103	1381800	93816	0.140
4	5603	5914	Level 1	18.135	284365	19603	0.028
5	5732	5916	Level 1	18.153	284801	20112	0.028
6	5736	5918	Level 2	18.143	580233	39942	0.055
7	5739	5920	Level 2	18.129	573509	39106	0.055
8	5743	5922	Level 3	18.130	1401178	95267	0.139
9	5747	5924	Level 3	18.143	1391676	95137	0.139
10	5751	5926	Level 4	18.124	2533412	166186	0.277
11	5754	5928	Level 4	18.128	2533850	171065	0.277
12	5758	5930	Level 5	18.148	3598714	235195	0.416
13	5761	5932	Level 5	18.152	3528155	232005	0.416
14	5765	5950	2103001141 Ref Material	18.151	730886	50112	1.422
15	5768	5952	2103001141 Ref Material	18.137	723873	49041	1.408
16	5772	5934	Assay control	18.126	1412596	95855	0.143
17	5775	5936	Assay control	18.126	1363743	91288	0.138
18	5783	5938	2110003737 Prep 1	18.131	724641	49700	1.410
19	5786	5940	2110003737 Prep 1	18.136	732123	50366	1.425
20	5790	5942	2110003737 Prep 2	18.136	717776	48666	1.396
21	5793	5944	2110003737 Prep 2	18.136	723685	49133	1.408
22	5797	5946	2110003737 Prep 3	18.156	715585	49304	1.391
23	5800	5948	2110003737 Prep 3	18.190	716092	49706	1.392
24	5808	5970	SST	18.152	1420440	96066	0.144
25	5811	5972	SST	18.161	1409410	95883	0.143

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Analyst XXXXXXXXXX

LIMS Number:

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

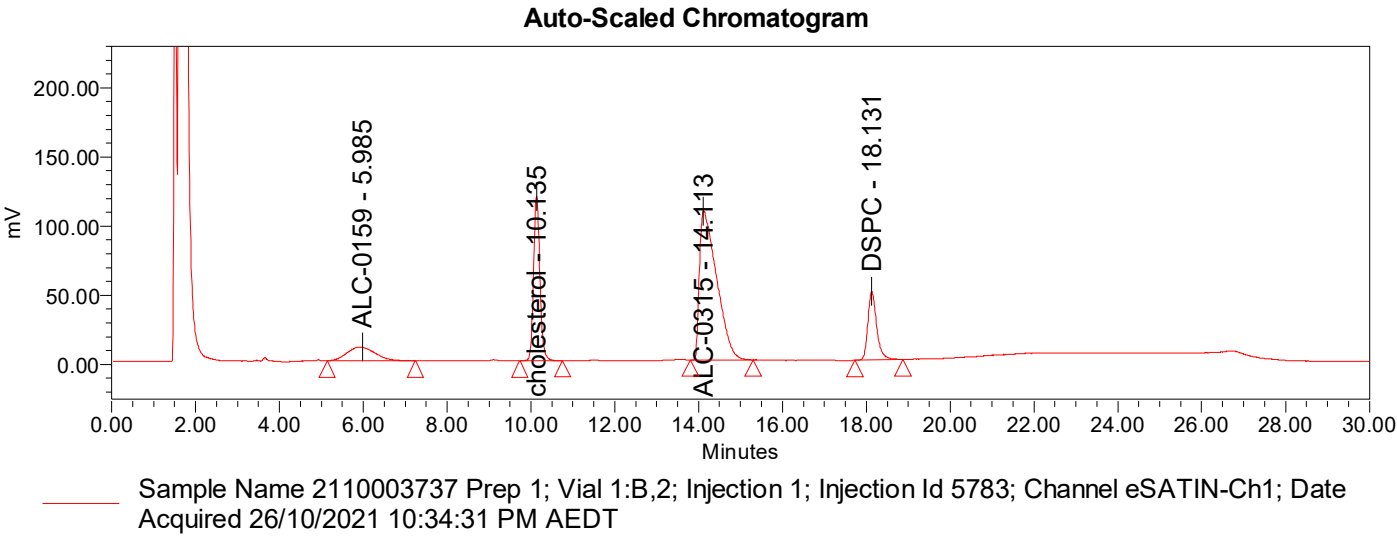
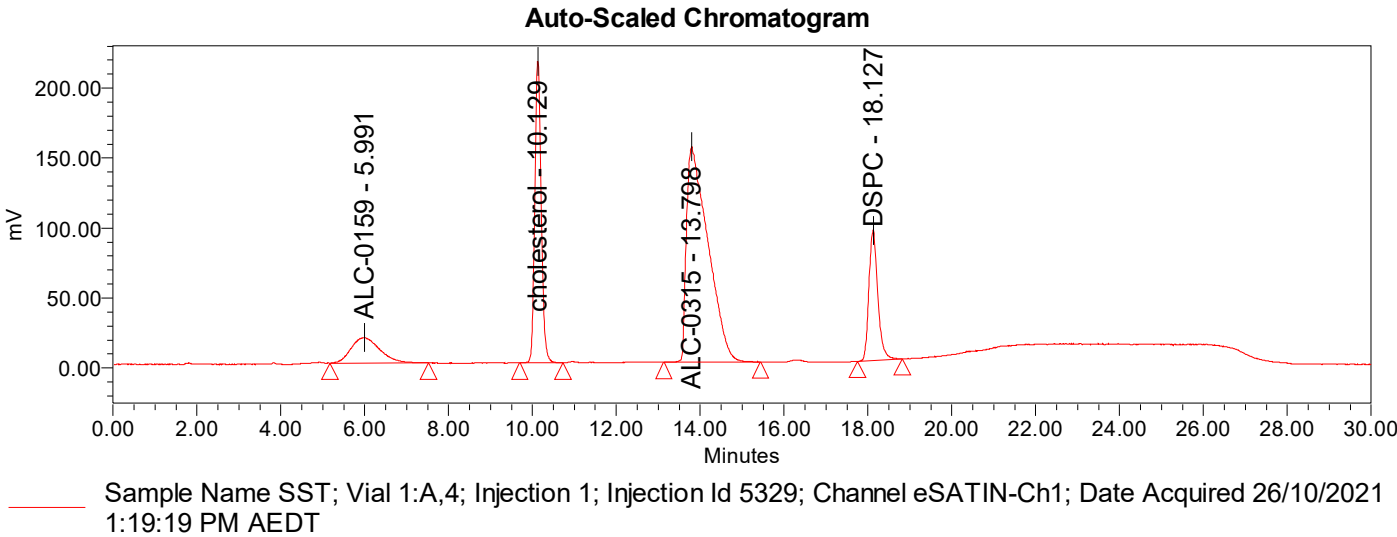
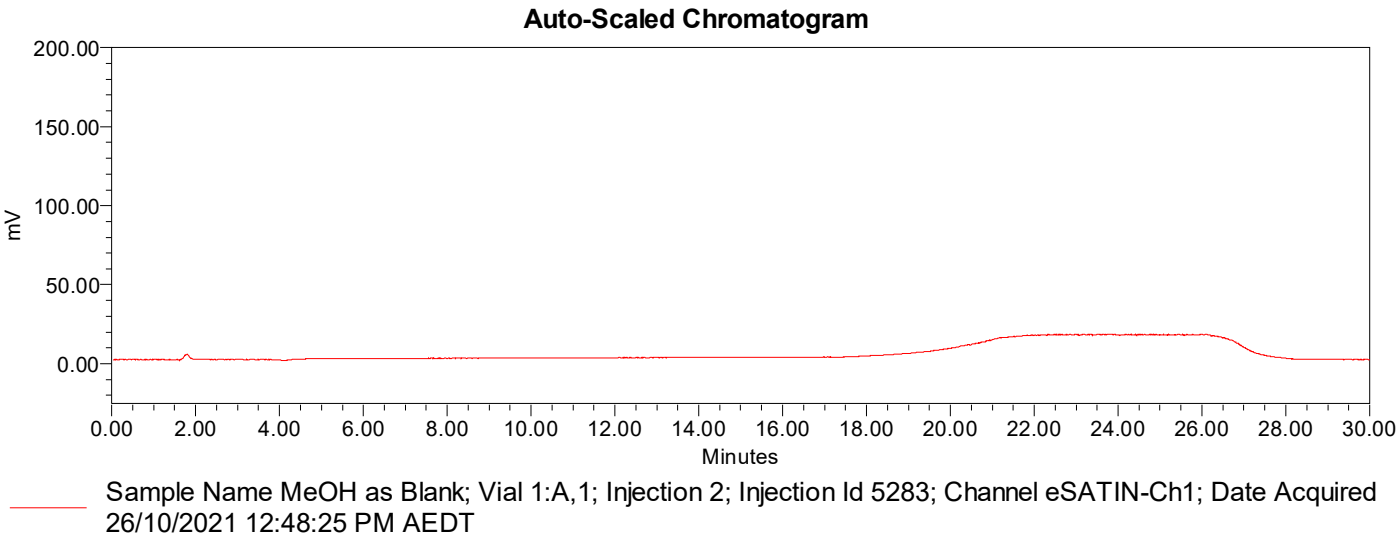
Results Summary Report

Result Summary Table (peak area)

Peak Name: cholesterol

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	5329	5964	SST	10.129	2293501	215729	0.264
2	5463	5966	SST	10.124	2259887	210858	0.260
3	5599	5968	SST	10.117	2254296	210135	0.259
4	5603	5914	Level 1	10.117	431456	42474	0.051
5	5732	5916	Level 1	10.144	418877	40529	0.051
6	5736	5918	Level 2	10.135	894389	86528	0.102
7	5739	5920	Level 2	10.130	886732	85558	0.102
8	5743	5922	Level 3	10.134	2250163	211268	0.256
9	5747	5924	Level 3	10.138	2249301	211964	0.256
10	5751	5926	Level 4	10.136	4162122	373629	0.512
11	5754	5928	Level 4	10.136	4182732	379262	0.512
12	5758	5930	Level 5	10.138	5952093	529588	0.769
13	5761	5932	Level 5	10.142	5735460	514341	0.769
14	5765	5950	2103001141 Ref Material	10.144	1262030	122466	2.867
15	5768	5952	2103001141 Ref Material	10.143	1275557	123447	2.898
16	5772	5934	Assay control	10.136	2106105	198379	0.242
17	5775	5936	Assay control	10.132	2098354	196734	0.241
18	5783	5938	2110003737 Prep 1	10.135	1247326	119106	2.834
19	5786	5940	2110003737 Prep 1	10.136	1247396	120940	2.834
20	5790	5942	2110003737 Prep 2	10.134	1241841	120108	2.821
21	5793	5944	2110003737 Prep 2	10.135	1243509	119226	2.825
22	5797	5946	2110003737 Prep 3	10.146	1243239	119905	2.824
23	5800	5948	2110003737 Prep 3	10.166	1245829	118526	2.830
24	5808	5970	SST	10.145	2271031	214944	0.261
25	5811	5972	SST	10.155	2238208	208720	0.258

Example Chromatograms



Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003737

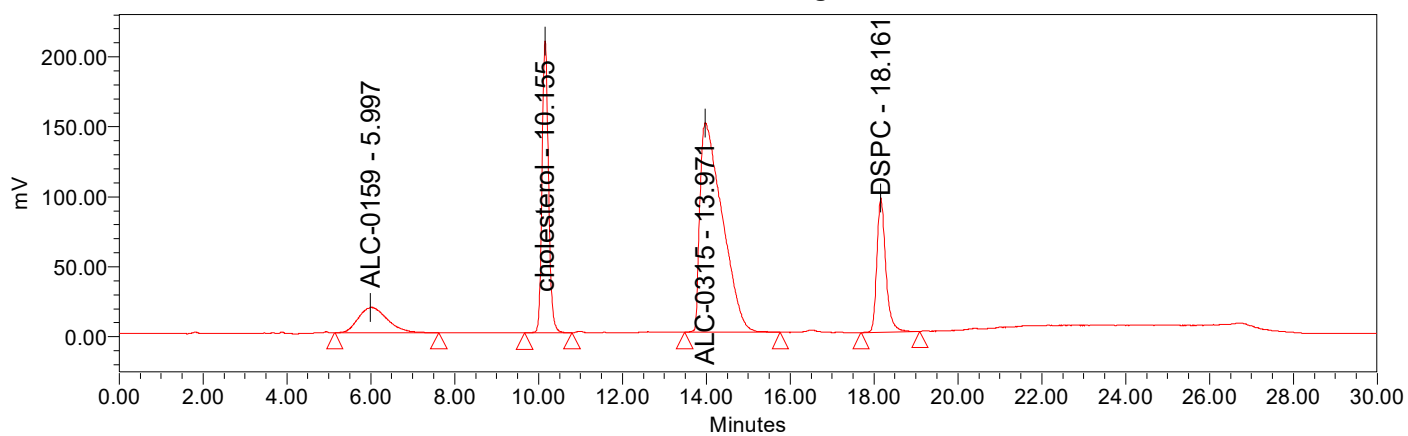
Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Example Chromatograms

Auto-Scaled Chromatogram



Sample Name SST; Vial 1:A,4; Injection 2; Injection Id 5811; Channel eSATIN-Ch1; Date Acquired 27/10/2021 2:41:16 AM AEDT

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Run and Method Summary Report

	Sample Name	Sample Type	Label	Vial	Inj #	Injection Id	Inj. Vol. (ul)	Dilution	Run Time (Minutes)	Level	Acquisition Method Set
1	MeOH as Blank	Unknown	B101	1:A,1	1	5280	10	1	30		Pfizer Vaccine
2	MeOH as Blank	Unknown	B101	1:A,1	2	5283	10	1	30		Pfizer Vaccine
3	SST	Control	Y101	1:A,4	1	5329	10	1	30		Pfizer Vaccine
4	SST	Control	Y101	1:A,4	2	5463	10	1	30		Pfizer Vaccine
5	SST	Control	Y101	1:A,4	3	5599	10	1	30		Pfizer Vaccine
6	Level 1	Standard	S101	1:A,2	1	5603	10	1	30	Level 1	Pfizer Vaccine
7	Level 1	Standard	S101	1:A,2	2	5732	10	1	30	Level 1	Pfizer Vaccine
8	Level 2	Standard	S102	1:A,3	1	5736	10	1	30	Level 2	Pfizer Vaccine
9	Level 2	Standard	S102	1:A,3	2	5739	10	1	30	Level 2	Pfizer Vaccine
10	Level 3	Standard	S103	1:A,4	1	5743	10	1	30	Level 3	Pfizer Vaccine
11	Level 3	Standard	S103	1:A,4	2	5747	10	1	30	Level 3	Pfizer Vaccine
12	Level 4	Standard	S104	1:A,5	1	5751	10	1	30	Level 4	Pfizer Vaccine
13	Level 4	Standard	S104	1:A,5	2	5754	10	1	30	Level 4	Pfizer Vaccine
14	Level 5	Standard	S105	1:A,6	1	5758	10	1	30	Level 5	Pfizer Vaccine
15	Level 5	Standard	S105	1:A,6	2	5761	10	1	30	Level 5	Pfizer Vaccine
16	2103001141 Ref Material	Unknown	C101	1:B,1	1	5765	10	20	30		Pfizer Vaccine
17	2103001141 Ref Material	Unknown	C101	1:B,1	2	5768	10	20	30		Pfizer Vaccine
18	Assay control	Unknown	U001	1:A,7	1	5772	10	1	30		Pfizer Vaccine
19	Assay control	Unknown	U001	1:A,7	2	5775	10	1	30		Pfizer Vaccine
20	MeOH as Blank	Unknown	B102	1:A,1	1	5779	10	1	30		Pfizer Vaccine
21	2110003737 Prep 1	Unknown	U101	1:B,2	1	5783	10	20	30		Pfizer Vaccine
22	2110003737 Prep 1	Unknown	U101	1:B,2	2	5786	10	20	30		Pfizer Vaccine
23	2110003737 Prep 2	Unknown	U102	1:B,3	1	5790	10	20	30		Pfizer Vaccine
24	2110003737 Prep 2	Unknown	U102	1:B,3	2	5793	10	20	30		Pfizer Vaccine
25	2110003737 Prep 3	Unknown	U103	1:B,4	1	5797	10	20	30		Pfizer Vaccine
26	2110003737 Prep 3	Unknown	U103	1:B,4	2	5800	10	20	30		Pfizer Vaccine
27	MeOH as Blank	Unknown	B103	1:A,1	1	5804	10	1	30		Pfizer Vaccine
28	SST	Control	Y102	1:A,4	1	5808	10	1	30		Pfizer Vaccine
29	SST	Control	Y102	1:A,4	2	5811	10	1	30		Pfizer Vaccine
30	MeOH as Blank	Unknown	B104	1:A,1	1	5815	10	1	30		Pfizer Vaccine

Column used for analysis: XSelect CSH C18, 3.5µm, 4.6 ×150 mm, S/N: 01533030924070.

Instrument Method: Pfizer Vaccine

Stored: 24/09/2021 5:25:11 PM AEST

Method Information

Method Comments Sampling rate 2, Range 500, Scaling factor 1000, Evop temp 50C
 Method Modified User chemist

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Run and Method Summary Report

Method Locked No
Method Id 1137
Old Id
Method Version 1
Method Edit User
Source S/W Info Empower 3 Software Build 3471 SPs Installed: Service Release 5 DB ID: 3107713112

eSATIN Instrument Setup

eSATIN General Information

Environment: 50(Hz)
Enable BCD: Off
BCD Polarity: Positive(+)

Channel 1 Information

Rate: 2.0(Pts/Sec.)
Description: Channel 1
Scale Factor: 1000.0
Units: mV

Channel 2 Information

eSATIN Events Information

Relay Initial State: Off
TTL1 Initial State: Off
TTL2 Initial State: Off
Relay Mode: Standard

ACQ-FTN Instrument Setup

Comment	
Load Ahead	Disabled
Loop Offline	Disabled
Wash Solvent Name	50% MeOH
Pre-Inject Wash Time	0.0(sec)
Post-Inject Wash Time	6.0(sec)
Purge Solvent Name	Water
Dilution	Disabled
Dilution Volume	0(uL)
Delay Time	0(min)
Dilution Needle Placement	4(mm)
Target Column Temperature	40.0(°C)
Column Temperature Alarm Band	Disabled
Target Sample Temperature	12.0(°C)
Sample Temperature Alarm Band	Disabled
Syringe Draw Rate	Automatic
Needle Placement	Automatic
Pre-Aspirate Air Gap	Automatic
Post-Aspirate Air Gap	Automatic
Column Temperature Data Channel	No
Room Temperature Data Channel	No
Sample Temperature Data Channel	No
Sample Organizer Temperature Data Channel	No
Sample Pressure Data Channel	No

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Run and Method Summary Report

Preheater Temperature Data Channel	No
Seal Force Data Channel	No
No Injection Mode Enabled	No
Autoaddition Mix Stroke Cycles	Automatic
Autoaddition Mix Stroke Volume	Automatic(uL)
Active Preheater	Disabled
Run Events	No

ACQ-QSM Instrument Setup

Solvent A Name 5 mM AA pH 4.2
Solvent B Name 5mM AA:IPA:Acetonitrile 5:62:33
Solvent C Name
Solvent D Name
Low Pressure Limit 0(psi)
High Pressure Limit 15000(psi)
Seal Wash Period 5.00(min)

Gradient Table

	Time (min)	Flow Rate (mL/min)	%A	%B	%C	%D	Curve
1	Initial	0.900	15.0	85.0	0.0	0.0	Initial
2	2.00	0.900	15.0	85.0	0.0	0.0	6
3	2.10	0.900	11.0	89.0	0.0	0.0	6
4	15.00	0.900	8.0	92.0	0.0	0.0	6
5	19.00	0.900	0.0	100.0	0.0	0.0	6
6	24.00	0.900	0.0	100.0	0.0	0.0	6
7	26.00	0.900	15.0	85.0	0.0	0.0	6
8	30.00	0.900	15.0	85.0	0.0	0.0	6

Comment

Flow Ramp Rate 0.45(min)
D Solvent Selection (if supported) No Change
System Pressure Data Channel No
Flow Rate Data Channel No
%A Data Channel No
%B Data Channel No
%C Data Channel No
%D Data Channel No
Primary Data Channel No
Accumulator Data Channel No
Degasser Data Channel No
Gradient Start At Injection
Gradient Start Volume 0(uL)
Gradient Start Time 0.00(min)
Participate in pre-analysis No

ACQ-TUV Instrument Setup

Wavelength Mode Single Wavelength
Lamp On On

Channel A

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211026 Pfizer vaccine testin

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003737

Sample Set Id: 5819

Sample Set Start Date: 26/10/2021 12:16:46 PM AEDT

Print Date: 27/10/2021

Run and Method Summary Report

Comment
Wavelength 210(nm)
Sampling Rate 20(points/sec)
Data Mode Absorbance
Time Constant 0.1(sec)
Autozero On Wavelength Change Maintain Baseline
Autozero On Inject Start Yes

Analog 1

Sensitivity 2.0000(AUFS)
Chart Polarity Positive (+)
Voltage Offset 0(mV)
Enable Chart Mark Yes

Run Events Yes

Pulse Width 1.0(sec)
Rect Wave Period 0.2(sec)

Revision History

Version 1 24/09/2021 5:25:11 PM AEST User [REDACTED] Method
(\Empower3_FR5.health.gov.au\Chemistry\System20_2021_05_Lipids : 1138) copied into project. (from Full Audit Trail project)

Version 1 11/05/2021 11:51:04 AM AEST User System Method
(\Empower3_FR5.health.gov.au\Chemistry\System20_2021_01 Lipids : 2501) copied into project. (from Full Audit Trail project)

Version 1 16/02/2021 11:12:05 AM AEDT User chemist Created method 'Pfizer Vaccine'.

Method Version Summaries

	Method Name	Method Type	Method Comments
1	Pfizer Vaccine	Instrument	Sampling rate 2, Range 500, Scaling factor 1000, Evop temp 50C

Method Version Summaries

	Method Date	Method Modified User	Method Locked	Method Id	Old Id	Method Version
1	24/09/2021 5:25:11 PM AEST	chemist	No	1137		1

Method Version Summaries

	Source S/W Info
1	Empower 3 Software Build 3471 SPs Installed: Service Release 5 DB ID: 3107713112