Australian Government
Department of Health
Therapeutic Goods Administration

Laboratories Branch

Operations	
Procedure	Assay for Lipids in vaccines by HPLC/CAD (Pfizer/BI)-BPC-Method-24) Worksheet
Written	[redacted]
Authorised	
Date issued	22/02/2021
Revision #	1

TGA SAMPLE No.2107002694 **SUBSTANCES ASSAYED: ALC-0159, Cholesterol,**

Lot number: FE3430 **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
2107002694	1	0.819	3.003	6.719	1.493
	2	0.793	2.968	6.628	1.507
	3	0.776	2.987	6.656	1.506
Average	-	0.80	2.99	6.67	1.50
% RSD [redacted]	-	2.7	0.6	0.7	0.5

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 Other ☐.....

refer 2107002629 w.s

REQUIREMENTS (Manuf.) [redacted]

Identification RT requirements met ? (RT ± 5% compared to SST) **(Y/N)**

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

RESULT **PASS** ☑ **FAIL** ☐

Signature of Analyst..... [redacted] .....Date..... 20/07/2021

Checked by Official Analyst..... [redacted] .....Date..... 20/7/21

WORKING STANDARD CURVE PREPARATION DETAILS

Date Stock solution prepared:22/06/2021 **Prepared by:** [redacted] **Within expiry Y/N** ✓

Attached ☐ or Refer to (TRIM Record number/Sample number) D21-2768402

	ALC-0159	Cholesterol	ALC-0315	DSPC [redacted] 20/07/2021
Concentration in stock solution (mg/mL)	0.30564	1.01220	2.58327	0.55992

Prepared by: [redacted] Date prepared 19/07/2021 POVA LIMS: 33270

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	0.01528
				Cholesterol	0.050	0.05061
				ALC-0315	0.120	0.12916
				DSPC	0.028	0.02800
2	100	900	10	ALC-0159	0.030	0.03056
				Cholesterol	0.100	0.10122
				ALC-0315	0.240	0.25833
				DSPC	0.056	0.05599
3	100	300	4	ALC-0159	0.075	0.07641
				Cholesterol	0.250	0.25305
				ALC-0315	0.600	0.64582
				DSPC	0.140	0.13998
4	200	200	2	ALC-0159	0.150	0.15282
				Cholesterol	0.500	0.50610
				ALC-0315	1.200	1.29163
				DSPC	0.280	0.27996
5	225	75	1.33	ALC-0159	0.225	0.22923
				Cholesterol	0.750	0.75915
				ALC-0315	1.800	1.93745
				DSPC	0.420	0.41994

ASSAY CONTROL PREPARATION DETAILS

Date control solution prepared: 22/06/2021 **Within expiry Y/N** ✓

Attached ☐ or Refer to (TRIM/ Record number/Sample number) D21-2768402

DP REFERENCE MATERIAL PREPARED Y/N ✓

LIMS number	Lot number/Expiry	Sample solution (uL)	MeOH (uL)	DF
2103001141	EE8493/ Aug 2021	50	950	20

Pova LIMS: 33270

SAMPLE PREPARATION DETAILS

Date prepared: 19/07/2021 **Prepared by:** [redacted] **POVA LIMS:** 33270

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.: 198913

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 ~~200~~100uL mixed lipid stock solution added to ~~200~~300uL methanol instead of 100uL stock solution added to 100uL methanol. (to increase amount of solution, concentration not changed) [redacted] 20/07/21

Level 4 dilution for standard curve ~~100~~200uL mixed lipid stock solution added to ~~300~~200uL methanol instead of 50uL stock solution added to 150uL methanol (to increase amount of solution, concentration not changed) [redacted] 20/07/21

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

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	4233	5.944	9.951	13.160	17.770
2	4235	5.901	9.958	13.193	17.775
3	4237	5.922	9.949	13.201	17.753
Mean		5.9	10.0	13.2	17.8
% RSD		0.37	0.05	0.16	0.06

Peak Results
Area Summarized by Name

	Result Id	ALC-0159 (µV*sec)	cholesterol (µV*sec)	ALC-0315 (µV*sec)	DSPC (µV*sec)
1	4233	913704	2002668	5772980	1274207
2	4235	933120	1954910	5588005	1260002
3	4237	922594	1979244	5721241	1265908
Mean		923139.4	1978940.7	5694075.1	1266705.6
% RSD		1.05	1.21	1.68	0.56

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	4241	5.895	9.963	13.453	17.809
2	4235	5.901	9.958	13.193	17.775
3	4237	5.922	9.949	13.201	17.753
4	4239	5.934	9.947	13.421	17.794
5	4233	5.944	9.951	13.160	17.770
Mean		5.9	10.0	13.3	17.8
% RSD		0.36	0.07	1.05	0.12

Peak Results
Area Summarized by Name

	Result Id	ALC-0159 (µV*sec)	cholesterol (µV*sec)	ALC-0315 (µV*sec)	DSPC (µV*sec)
1	4241	898525	1960667	5697758	1251026
2	4235	933120	1954910	5588005	1260002
3	4237	922594	1979244	5721241	1265908
4	4239	894475	1910021	5618269	1257173
5	4233	913704	2002668	5772980	1274207
Mean		912483.6	1961502.0	5679650.6	1261663.2
% RSD		1.77	1.75	1.33	0.70

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	4205	108.607	107.128	106.977	109.171
2	4203	103.390	107.390	107.144	109.862
Mean		***105.999***	***107.259***	***107.061***	***109.517***

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
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Vaccine System Suitability Report

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

Pass / Fail

Peak Results
RT_Dev Summarized by Name

	SampleName	Result Id	ALC-0159	cholesterol	ALC-0315	DSPC
1	2107002694 Prep 1	4207	99.132	100.053	102.946	100.095
2	2107002694 Prep 1	4209	99.132	100.053	102.946	100.095
3	2107002694 Prep 2	4211	99.132	100.053	102.946	100.095
4	2107002694 Prep 2	4213	99.132	100.053	102.946	100.095
5	2107002694 Prep 3	4215	99.132	100.053	102.946	100.095
6	2107002694 Prep 3	4217	99.132	100.053	102.946	100.095
Mean			99.1	100.1	102.9	100.1

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Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
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Vaccine System Suitability Report

The R2 values for the Cal Curves must be greater than 0.995 — Pass / Fail

Peak: DSPC

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	DSPC	Level 1	0.028000	288799.913756	0.026711	-4.604	No	No	0.999788
2	DSPC	Level 1	0.028000	280362.577831	0.025631	-8.461	No	No	0.999788
3	DSPC	Level 2	0.055990	527539.078213	0.057349	2.427	No	No	0.999788
4	DSPC	Level 2	0.055990	522778.607214	0.056736	1.333	No	No	0.999788
5	DSPC	Level 3	0.139980	1192458.320305	0.143584	2.575	No	No	0.999788
6	DSPC	Level 3	0.139980	1175296.026554	0.141341	0.972	No	No	0.999788
7	DSPC	Level 4	0.279960	2203043.673065	0.277320	-0.943	No	No	0.999788
8	DSPC	Level 4	0.279960	2203940.785154	0.277440	-0.900	No	No	0.999788
9	DSPC	Level 5	0.419940	3247040.888698	0.419093	-0.202	No	No	0.999788
10	DSPC	Level 5	0.419940	3272066.189919	0.422539	0.619	No	No	0.999788
Mean									1.0

Peak: ALC-0159

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0159	Level 1	0.015280	252332.824404	0.012029	-21.276	No	No	0.998760
2	ALC-0159	Level 1	0.015280	263349.103340	0.013189	-13.682	No	No	0.998760
3	ALC-0159	Level 2	0.030560	457200.983028	0.033686	10.228	No	No	0.998760
4	ALC-0159	Level 2	0.030560	463564.299977	0.034361	12.438	No	No	0.998760
5	ALC-0159	Level 3	0.076410	861239.207786	0.076884	0.621	No	No	0.998760
6	ALC-0159	Level 3	0.076410	844317.224871	0.075062	-1.764	No	No	0.998760
7	ALC-0159	Level 4	0.152820	1557769.515255	0.152952	0.087	No	No	0.998760
8	ALC-0159	Level 4	0.152820	1543728.938689	0.151398	-0.930	No	No	0.998760
9	ALC-0159	Level 5	0.229230	2202304.266872	0.225271	-1.727	No	No	0.998760
10	ALC-0159	Level 5	0.229230	2277018.101066	0.233781	1.986	No	No	0.998760
Mean									1.0

Peak: cholesterol

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	cholesterol	Level 1	0.050610	414350.758303	0.051220	1.205	No	No	0.999953
2	cholesterol	Level 1	0.050610	404426.470919	0.049792	-1.616	No	No	0.999953
3	cholesterol	Level 2	0.101220	773931.777553	0.102894	1.654	No	No	0.999953
4	cholesterol	Level 2	0.101220	740513.393754	0.098096	-3.086	No	No	0.999953
5	cholesterol	Level 3	0.253050	1849699.607970	0.256871	1.510	No	No	0.999953
6	cholesterol	Level 3	0.253050	1820784.905437	0.252744	-0.121	No	No	0.999953
7	cholesterol	Level 4	0.506100	3590204.239431	0.504063	-0.403	No	No	0.999953
8	cholesterol	Level 4	0.506100	3600050.326300	0.505455	-0.128	No	No	0.999953
9	cholesterol	Level 5	0.759150	5409578.113153	0.759970	0.108	No	No	0.999953
10	cholesterol	Level 5	0.759150	5403744.416946	0.759154	0.000	No	No	0.999953
Mean									1.0

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

Vaccine System Suitability Report

Peak: ALC-0315

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0315	Level 1	0.129160	1328091.114263	0.125661	-2.709	No	No	0.999867
2	ALC-0315	Level 1	0.129160	1290673.923224	0.120708	-6.544	No	No	0.999867
3	ALC-0315	Level 2	0.258330	2380313.944709	0.265247	2.678	No	No	0.999867
4	ALC-0315	Level 2	0.258330	2317513.058021	0.256899	-0.554	No	No	0.999867
5	ALC-0315	Level 3	0.645820	5316388.987690	0.658089	1.900	No	No	0.999867
6	ALC-0315	Level 3	0.645820	5275830.815066	0.652628	1.054	No	No	0.999867
7	ALC-0315	Level 4	1.291630	9902121.785778	1.281880	-0.755	No	No	0.999867
8	ALC-0315	Level 4	1.291630	9906109.760646	1.282428	-0.712	No	No	0.999867
9	ALC-0315	Level 5	1.937450	14598740.006484	1.934411	-0.157	No	No	0.999867
10	ALC-0315	Level 5	1.937450	14687204.939254	1.946841	0.485	No	No	0.999867
Mean									1.0

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
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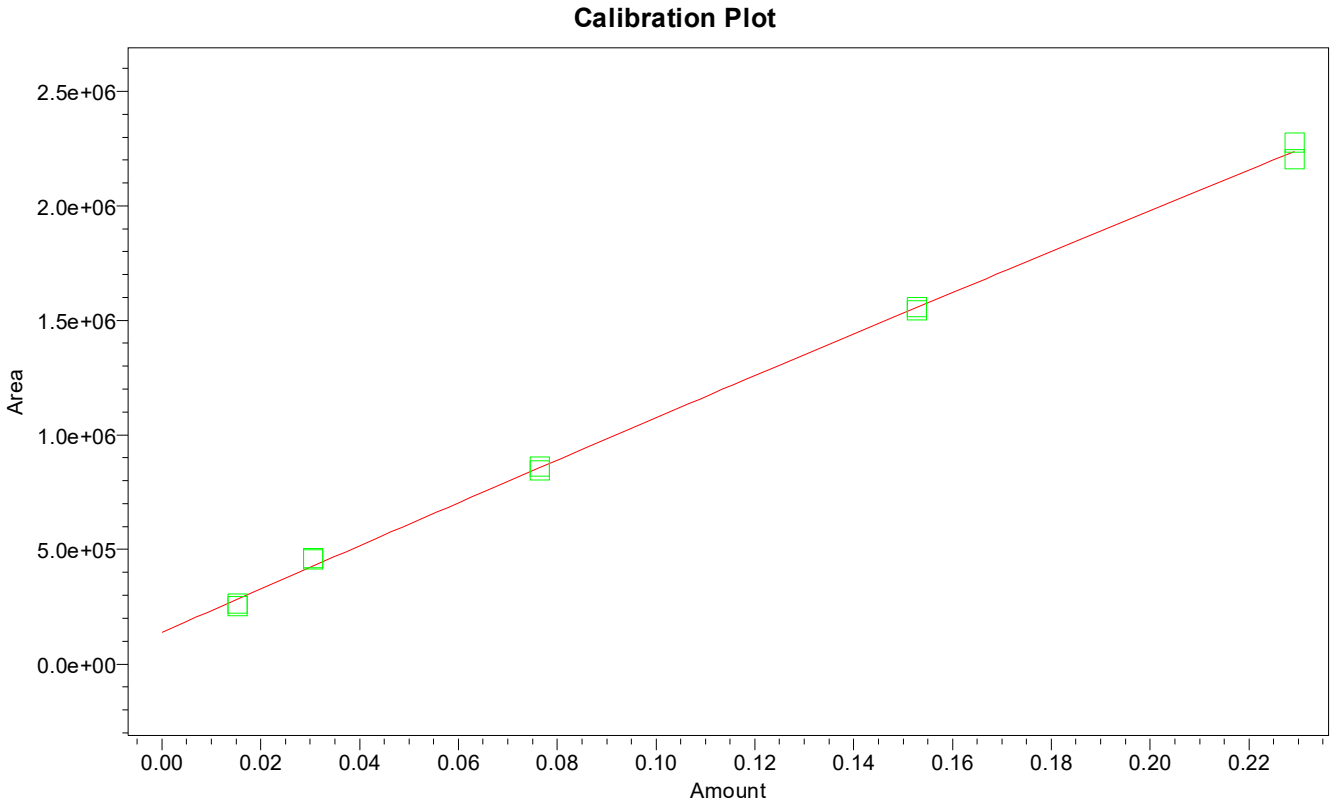
Cal Curve Report



Name: ALC-0159; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order); Cal Curve Id: 4173; A: 1.378734e+05; B: 9.535072e+06; C: -1.646333e+06; D: 0.000000e+00; R^2: 0.998760

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
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Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
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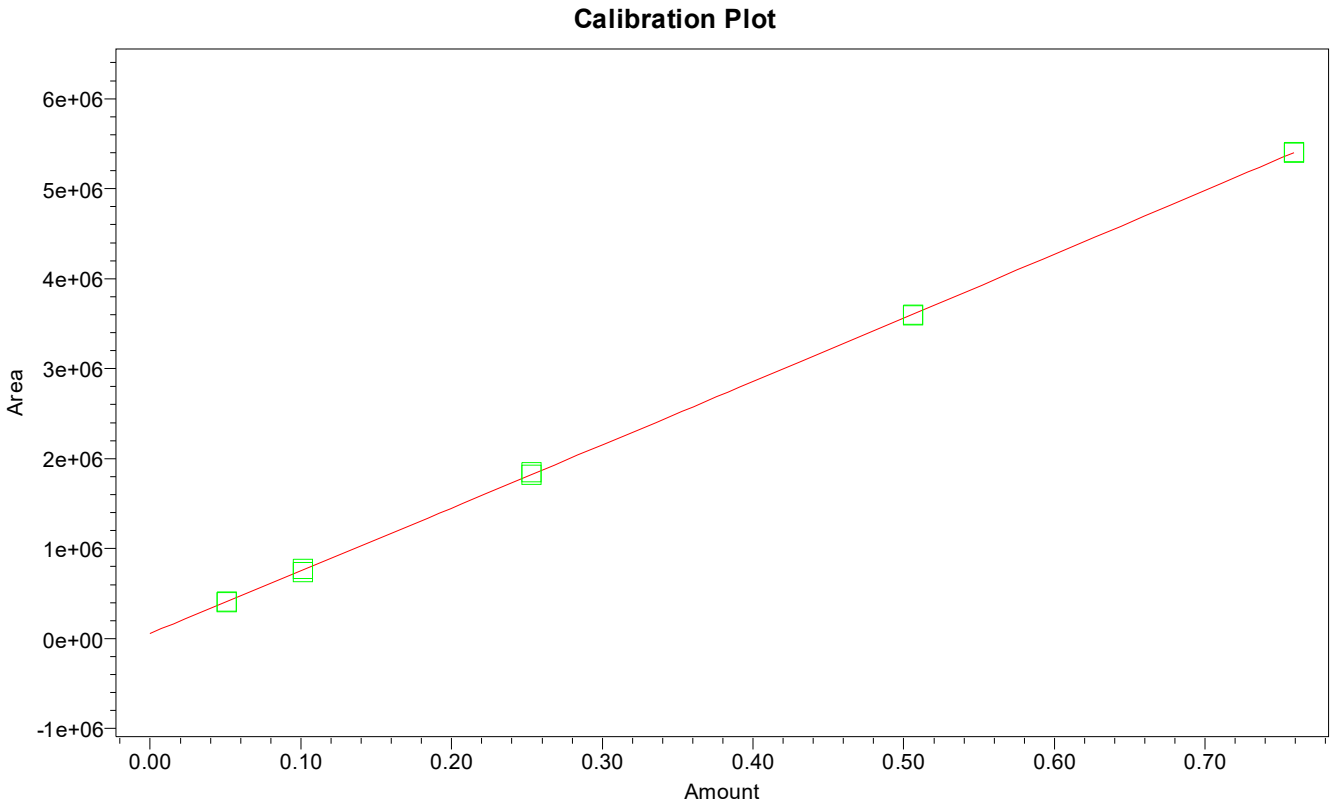
Cal Curve Report



Name: cholesterol; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order); Cal Curve Id: 4174; A: 5.864737e+04; B: 6.937653e+06; C: 1.359563e+05; D: 0.000000e+00; R^2: 0.999953

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
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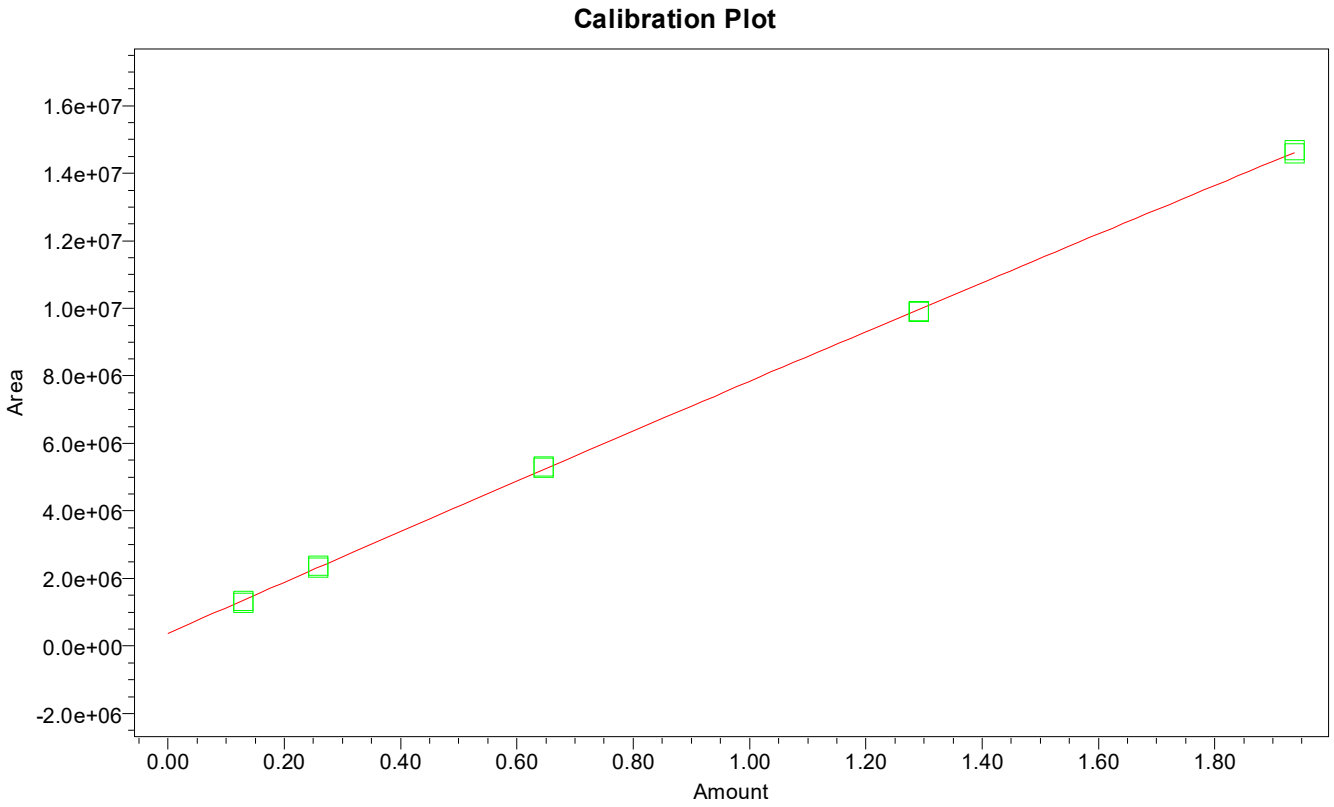
Cal Curve Report



Name: ALC-0315; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order); Cal Curve Id: 4175; A: 3.768270e+05; B: 7.585256e+06; C: -1.205500e+05; D: 0.000000e+00; R^2: 0.999867

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
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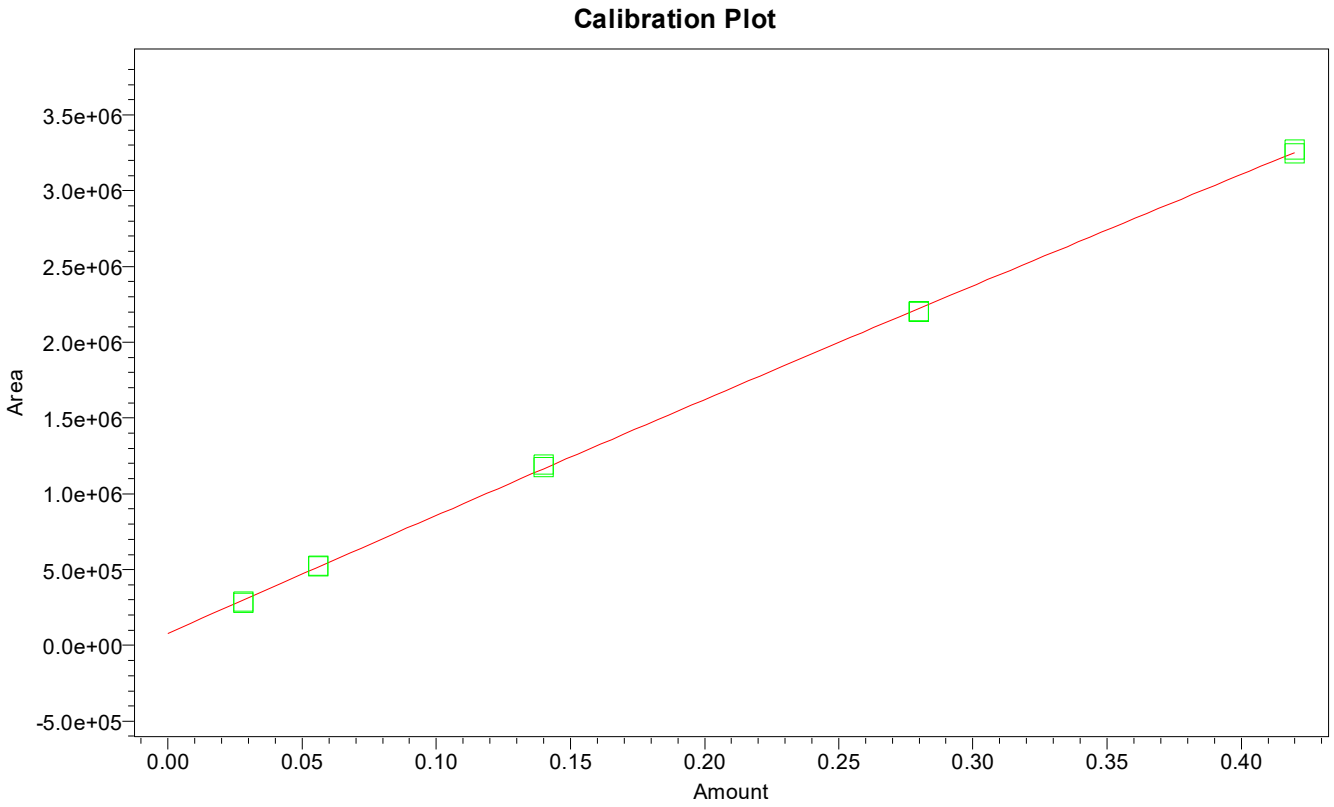
Cal Curve Report



Name: DSPC; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order); Cal Curve Id: 4176; A: 7.959040e+04; B: 7.851095e+06; C: -6.996828e+05; D: 0.000000e+00; R^2: 0.999788

Peak: DSPC

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	DSPC	Level 1	0.028000	288799.913756	0.026711	-4.604	No	No	0.999788
2	DSPC	Level 1	0.028000	280362.577831	0.025631	-8.461	No	No	0.999788
3	DSPC	Level 2	0.055990	527539.078213	0.057349	2.427	No	No	0.999788
4	DSPC	Level 2	0.055990	522778.607214	0.056736	1.333	No	No	0.999788
5	DSPC	Level 3	0.139980	1192458.320305	0.143584	2.575	No	No	0.999788
6	DSPC	Level 3	0.139980	1175296.026554	0.141341	0.972	No	No	0.999788
7	DSPC	Level 4	0.279960	2203043.673065	0.277320	-0.943	No	No	0.999788
8	DSPC	Level 4	0.279960	2203940.785154	0.277440	-0.900	No	No	0.999788
9	DSPC	Level 5	0.419940	3247040.888698	0.419093	-0.202	No	No	0.999788
10	DSPC	Level 5	0.419940	3272066.189919	0.422539	0.619	No	No	0.999788

Project Name: Chemistry\System20_2021_05_Lipids
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Print Date: 20/07/2021

Cal Curve Report

Peak: ALC-0159

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0159	Level 1	0.015280	252332.824404	0.012029	-21.276	No	No	0.998760
2	ALC-0159	Level 1	0.015280	263349.103340	0.013189	-13.682	No	No	0.998760
3	ALC-0159	Level 2	0.030560	457200.983028	0.033686	10.228	No	No	0.998760
4	ALC-0159	Level 2	0.030560	463564.299977	0.034361	12.438	No	No	0.998760
5	ALC-0159	Level 3	0.076410	861239.207786	0.076884	0.621	No	No	0.998760
6	ALC-0159	Level 3	0.076410	844317.224871	0.075062	-1.764	No	No	0.998760
7	ALC-0159	Level 4	0.152820	1557769.515255	0.152952	0.087	No	No	0.998760
8	ALC-0159	Level 4	0.152820	1543728.938689	0.151398	-0.930	No	No	0.998760
9	ALC-0159	Level 5	0.229230	2202304.266872	0.225271	-1.727	No	No	0.998760
10	ALC-0159	Level 5	0.229230	2277018.101066	0.233781	1.986	No	No	0.998760

Peak: cholesterol

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	cholesterol	Level 1	0.050610	414350.758303	0.051220	1.205	No	No	0.999953
2	cholesterol	Level 1	0.050610	404426.470919	0.049792	-1.616	No	No	0.999953
3	cholesterol	Level 2	0.101220	773931.777553	0.102894	1.654	No	No	0.999953
4	cholesterol	Level 2	0.101220	740513.393754	0.098096	-3.086	No	No	0.999953
5	cholesterol	Level 3	0.253050	1849699.607970	0.256871	1.510	No	No	0.999953
6	cholesterol	Level 3	0.253050	1820784.905437	0.252744	-0.121	No	No	0.999953
7	cholesterol	Level 4	0.506100	3590204.239431	0.504063	-0.403	No	No	0.999953
8	cholesterol	Level 4	0.506100	3600050.326300	0.505455	-0.128	No	No	0.999953
9	cholesterol	Level 5	0.759150	5409578.113153	0.759970	0.108	No	No	0.999953
10	cholesterol	Level 5	0.759150	5403744.416946	0.759154	0.000	No	No	0.999953

Peak: ALC-0315

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0315	Level 1	0.129160	1328091.114263	0.125661	-2.709	No	No	0.999867
2	ALC-0315	Level 1	0.129160	1290673.923224	0.120708	-6.544	No	No	0.999867
3	ALC-0315	Level 2	0.258330	2380313.944709	0.265247	2.678	No	No	0.999867
4	ALC-0315	Level 2	0.258330	2317513.058021	0.256899	-0.554	No	No	0.999867
5	ALC-0315	Level 3	0.645820	5316388.987690	0.658089	1.900	No	No	0.999867
6	ALC-0315	Level 3	0.645820	5275830.815066	0.652628	1.054	No	No	0.999867
7	ALC-0315	Level 4	1.291630	9902121.785778	1.281880	-0.755	No	No	0.999867
8	ALC-0315	Level 4	1.291630	9906109.760646	1.282428	-0.712	No	No	0.999867
9	ALC-0315	Level 5	1.937450	14598740.006484	1.934411	-0.157	No	No	0.999867
10	ALC-0315	Level 5	1.937450	14687204.939254	1.946841	0.485	No	No	0.999867

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

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	3945	4207	2107002694 Prep 1	0.819	3.003	6.719	1.493
2	3952	4211	2107002694 Prep 2	0.793	2.968	6.628	1.507
3	3959	4215	2107002694 Prep 3	0.776	2.987	6.656	1.506
Mean				0.80	2.99	6.67	1.50
Std. Dev.				0.02	0.02	0.05	0.01
% RSD				2.7	0.6	0.7	0.5

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	3945	4207	2107002694 Prep 1	0.812	3.008	6.725	1.501
2	3948	4209	2107002694 Prep 1	0.825	2.998	6.714	1.486
3	3952	4211	2107002694 Prep 2	0.767	2.979	6.695	1.525
4	3955	4213	2107002694 Prep 2	0.819	2.957	6.561	1.489
5	3959	4215	2107002694 Prep 3	0.780	3.000	6.700	1.508
6	3962	4217	2107002694 Prep 3	0.771	2.974	6.612	1.503
Mean				0.80	2.99	6.67	1.50

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	3934	4203	Assay control	0.078	0.270	0.673	0.155
2	3937	4205	Assay control	0.082	0.270	0.672	0.154
Mean				0.080	0.270	0.673	0.155

Calibration Data Table
Peak: DSPC

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	3892	4183	DSPC	0.028000	288800	4176
2	3895	4185	DSPC	0.028000	280363	4176
3	3899	4187	DSPC	0.055990	527539	4176
4	3902	4189	DSPC	0.055990	522779	4176
5	3906	4191	DSPC	0.139980	1192458	4176
6	3909	4193	DSPC	0.139980	1175296	4176
7	3913	4195	DSPC	0.279960	2203044	4176
8	3916	4197	DSPC	0.279960	2203941	4176
9	3920	4199	DSPC	0.419940	3247041	4176
10	3923	4201	DSPC	0.419940	3272066	4176

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

Results Summary Report

Calibration Data Table
Peak: ALC-0159

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	3892	4183	ALC-0159	0.015280	252333	4173
2	3895	4185	ALC-0159	0.015280	263349	4173
3	3899	4187	ALC-0159	0.030560	457201	4173
4	3902	4189	ALC-0159	0.030560	463564	4173
5	3906	4191	ALC-0159	0.076410	861239	4173
6	3909	4193	ALC-0159	0.076410	844317	4173
7	3913	4195	ALC-0159	0.152820	1557770	4173
8	3916	4197	ALC-0159	0.152820	1543729	4173
9	3920	4199	ALC-0159	0.229230	2202304	4173
10	3923	4201	ALC-0159	0.229230	2277018	4173

Calibration Data Table
Peak: cholesterol

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	3892	4183	cholesterol	0.050610	414351	4174
2	3895	4185	cholesterol	0.050610	404426	4174
3	3899	4187	cholesterol	0.101220	773932	4174
4	3902	4189	cholesterol	0.101220	740513	4174
5	3906	4191	cholesterol	0.253050	1849700	4174
6	3909	4193	cholesterol	0.253050	1820785	4174
7	3913	4195	cholesterol	0.506100	3590204	4174
8	3916	4197	cholesterol	0.506100	3600050	4174
9	3920	4199	cholesterol	0.759150	5409578	4174
10	3923	4201	cholesterol	0.759150	5403744	4174

Calibration Data Table
Peak: ALC-0315

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	3892	4183	ALC-0315	0.129160	1328091	4175
2	3895	4185	ALC-0315	0.129160	1290674	4175
3	3899	4187	ALC-0315	0.258330	2380314	4175
4	3902	4189	ALC-0315	0.258330	2317513	4175
5	3906	4191	ALC-0315	0.645820	5316389	4175
6	3909	4193	ALC-0315	0.645820	5275831	4175
7	3913	4195	ALC-0315	1.291630	9902122	4175
8	3916	4197	ALC-0315	1.291630	9906110	4175
9	3920	4199	ALC-0315	1.937450	14598740	4175
10	3923	4201	ALC-0315	1.937450	14687205	4175

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

Results Summary Report

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

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	3934	4203	Assay control	5.925	871376	16542	0.078
2	3937	4205	Assay control	5.916	907860	16923	0.082
3	3945	4207	2107002694 Prep 1	5.878	522381	9974	0.812
4	3948	4209	2107002694 Prep 1	5.871	528507	10017	0.825
5	3952	4211	2107002694 Prep 2	5.839	501305	9803	0.767
6	3955	4213	2107002694 Prep 2	5.855	525686	10092	0.819
7	3959	4215	2107002694 Prep 3	5.862	507187	10034	0.780
8	3962	4217	2107002694 Prep 3	5.902	503238	9661	0.771

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

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	3934	4203	Assay control	13.404	5429358	152689	0.673
2	3937	4205	Assay control	13.405	5421585	152363	0.672
3	3945	4207	2107002694 Prep 1	13.675	2913646	104166	6.725
4	3948	4209	2107002694 Prep 1	13.684	2909535	105476	6.714
5	3952	4211	2107002694 Prep 2	13.675	2902333	105277	6.695
6	3955	4213	2107002694 Prep 2	13.675	2852088	102266	6.561
7	3959	4215	2107002694 Prep 3	13.682	2904391	103554	6.700
8	3962	4217	2107002694 Prep 3	13.669	2871187	103211	6.612

Result Summary Table (peak area)
Peak Name: DSPC

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	3934	4203	Assay control	17.801	1282332	83254	0.155
2	3937	4205	Assay control	17.790	1274876	80709	0.154
3	3945	4207	2107002694 Prep 1	17.803	664701	43136	1.501
4	3948	4209	2107002694 Prep 1	17.803	659033	43618	1.486
5	3952	4211	2107002694 Prep 2	17.795	674337	43174	1.525
6	3955	4213	2107002694 Prep 2	17.789	660258	42516	1.489
7	3959	4215	2107002694 Prep 3	17.807	667665	43680	1.508
8	3962	4217	2107002694 Prep 3	17.786	665642	42789	1.503

Result Summary Table (peak area)
Peak Name: cholesterol

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	3934	4203	Assay control	9.963	1944284	181845	0.270
2	3937	4205	Assay control	9.966	1939658	179888	0.270
3	3945	4207	2107002694 Prep 1	9.965	1105176	103336	3.008
4	3948	4209	2107002694 Prep 1	9.966	1101702	102819	2.998
5	3952	4211	2107002694 Prep 2	9.960	1094877	102482	2.979
6	3955	4213	2107002694 Prep 2	9.951	1087490	102446	2.957
7	3959	4215	2107002694 Prep 3	9.956	1102398	104497	3.000
8	3962	4217	2107002694 Prep 3	9.953	1093353	102854	2.974

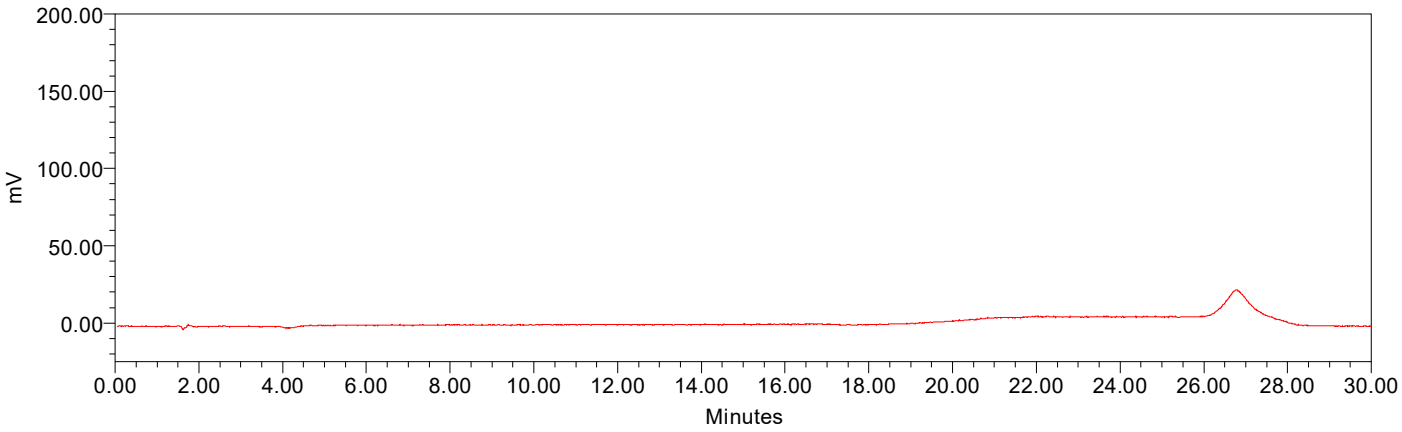
Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

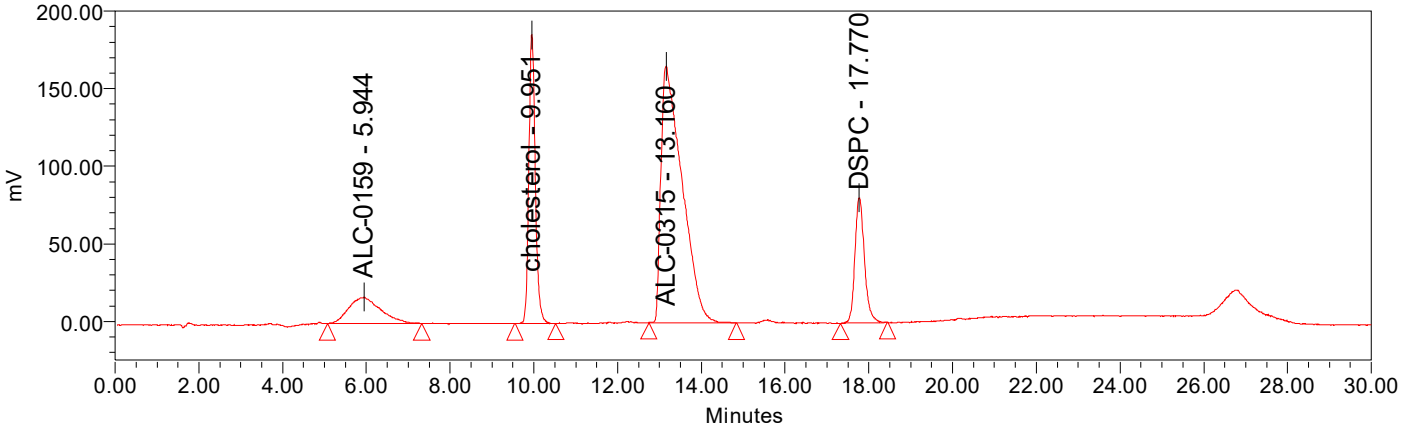
Example Chromatograms

Auto-Scaled Chromatogram



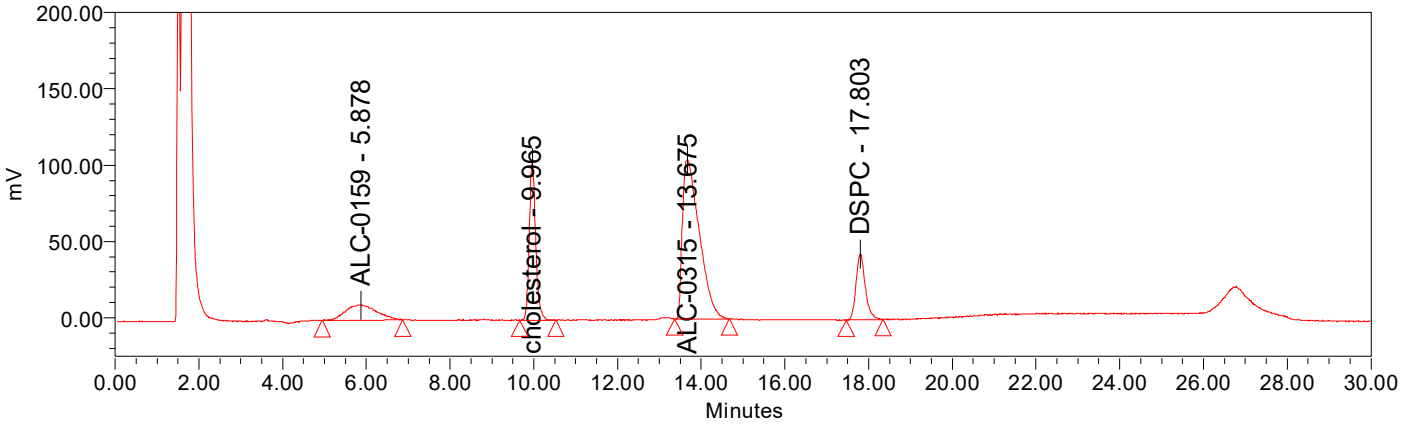
Sample Name MeOH as Blank; Vial 1:A,1; Injection 2; Injection Id 3878; Channel eSATIN-Ch1; Date Acquired 19/07/2021 5:35:49 PM AEST

Auto-Scaled Chromatogram



Sample Name SST; Vial 1:A,4; Injection 1; Injection Id 3882; Channel eSATIN-Ch1; Date Acquired 19/07/2021 6:06:41 PM AEST

Auto-Scaled Chromatogram



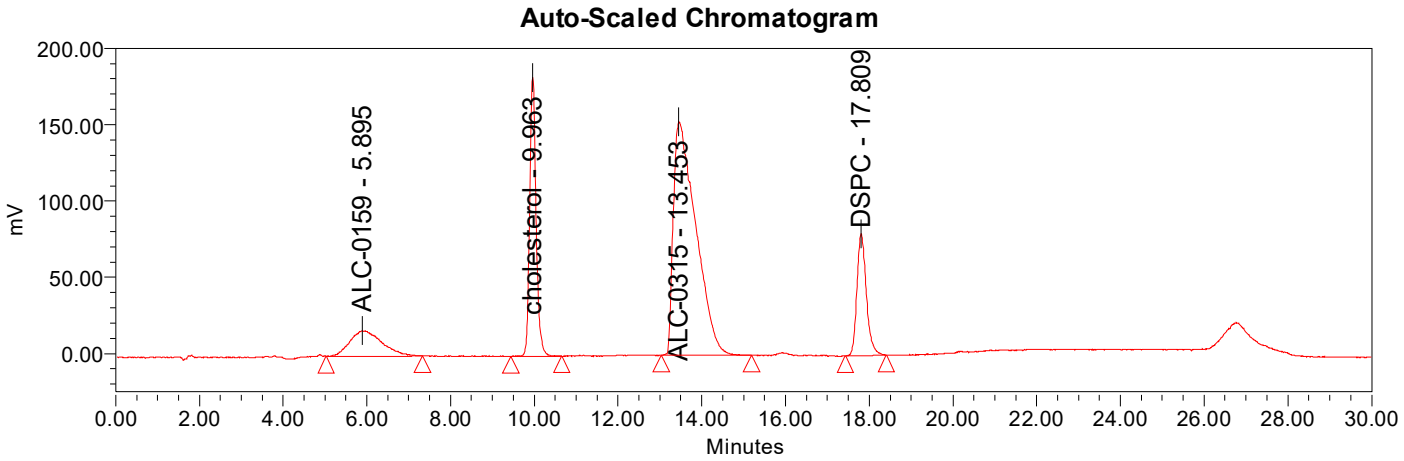
Sample Name 2107002694 Prep 1; Vial 1:B,2; Injection 1; Injection Id 3945; Channel eSATIN-Ch1; Date Acquired 20/07/2021 3:22:37 AM AEST

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

Example Chromatograms



Sample Name SST; Vial 1:A,4; Injection 2; Injection Id 3973; Channel eSATIN-Ch1; Date Acquired 20/07/2021 7:29:50 AM AEST

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

Run and Method Summary Report

Analyst: Shyam Konda

	Sample Name	Sample Type	Label	Vial	Inj #	Injection Id	Inj. Vol. (ul)	Dilution	Run Time (Minutes)	Level	Acquistion Method Set
1	MeOH as Blank	Unknown	B101	1:A,1	1	3874	10	1	30		Pfizer Vaccine
2	MeOH as Blank	Unknown	B101	1:A,1	2	3878	10	1	30		Pfizer Vaccine
3	SST	Control	Y101	1:A,4	1	3882	10	1	30		Pfizer Vaccine
4	SST	Control	Y101	1:A,4	2	3885	10	1	30		Pfizer Vaccine
5	SST	Control	Y101	1:A,4	3	3888	10	1	30		Pfizer Vaccine
6	Level 1	Standard	S101	1:A,2	1	3892	10	1	30	Level 1	Pfizer Vaccine
7	Level 1	Standard	S101	1:A,2	2	3895	10	1	30	Level 1	Pfizer Vaccine
8	Level 2	Standard	S102	1:A,3	1	3899	10	1	30	Level 2	Pfizer Vaccine
9	Level 2	Standard	S102	1:A,3	2	3902	10	1	30	Level 2	Pfizer Vaccine
10	Level 3	Standard	S103	1:A,4	1	3906	10	1	30	Level 3	Pfizer Vaccine
11	Level 3	Standard	S103	1:A,4	2	3909	10	1	30	Level 3	Pfizer Vaccine
12	Level 4	Standard	S104	1:A,5	1	3913	10	1	30	Level 4	Pfizer Vaccine
13	Level 4	Standard	S104	1:A,5	2	3916	10	1	30	Level 4	Pfizer Vaccine
14	Level 5	Standard	S105	1:A,6	1	3920	10	1	30	Level 5	Pfizer Vaccine
15	Level 5	Standard	S105	1:A,6	2	3923	10	1	30	Level 5	Pfizer Vaccine
16	2103001141 Ref Material	Unknown	C101	1:B,1	1	3927	10	1	30		Pfizer Vaccine
17	2103001141 Ref Material	Unknown	C101	1:B,1	2	3930	10	1	30		Pfizer Vaccine
18	Assay control	Unknown	U001	1:A,7	1	3934	10	1	30		Pfizer Vaccine
19	Assay control	Unknown	U001	1:A,7	2	3937	10	1	30		Pfizer Vaccine
20	MeOH as Blank	Unknown	B102	1:A,1	1	3941	10	1	30		Pfizer Vaccine
21	2107002694 Prep 1	Unknown	U101	1:B,2	1	3945	10	20	30		Pfizer Vaccine
22	2107002694 Prep 1	Unknown	U101	1:B,2	2	3948	10	20	30		Pfizer Vaccine
23	2107002694 Prep 2	Unknown	U102	1:B,3	1	3952	10	20	30		Pfizer Vaccine
24	2107002694 Prep 2	Unknown	U102	1:B,3	2	3955	10	20	30		Pfizer Vaccine
25	2107002694 Prep 3	Unknown	U103	1:B,4	1	3959	10	20	30		Pfizer Vaccine
26	2107002694 Prep 3	Unknown	U103	1:B,4	2	3962	10	20	30		Pfizer Vaccine
27	MeOH as Blank	Unknown	B103	1:A,1	1	3966	10	1	30		Pfizer Vaccine
28	SST	Control	Y102	1:A,4	1	3970	10	1	30		Pfizer Vaccine
29	SST	Control	Y102	1:A,4	2	3973	10	1	30		Pfizer Vaccine
30	MeOH as Blank	Unknown	B104	1:A,1	1	3977	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: 11/05/2021 11:51:04 AM AEST

Project Name: Chemistry\System20_2021_05_Lipids
Sample Set Name: 20210719 Vaccine testing

Sample Set Acquired By [redacted]

Sample LIMS No. 2106002526
Sample Set Id: 3872
Sample Set Start Date: 19/07/2021 5:04:11 PM AEST
Print Date: 20/07/2021

Run and Method Summary Report

Method Information

Method Comments	Sampling rate 2, Range 500, Scaling factor 1000, Evop temp 50C
Method Modified User	chemist
Method Locked	No
Method Id	1138
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

Run and Method Summary Report

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
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)

Run and Method Summary Report

Participate in pre-analysis No

ACQ-TUV Instrument Setup

Wavelength Mode Single Wavelength
Lamp On On

Channel A

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 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	11/05/2021 11:51:04 AM AEST	chemist	No	1138		1

Method Version Summaries

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