



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. 2110003744

SUBSTANCES ASSAYED: ALC-0159, Cholesterol,

Lot number: FL3560

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
2110003744	1	0.879	3.108	6.909	1.514
	2	0.869	3.104	6.862	1.511
	3	0.874	3.090	6.857	1.503
Average	-	0.87	3.10	6.88	1.51
% RSD [REDACTED]	-	0.6	0.3	0.4	0.3

ATTACHMENTS: Analysts Notes worksheets ☐ Result summary report ☒ System suitability report ☒
 Example chromatograms ☒ Run and method summary ☒ Calibration plots ☒
 MP preparation details ☒

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 20/10/2021

Checked by Official Analyst... Electronically signed by [REDACTED] Date 20/10/21

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 19 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	0.23730
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: 19 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 20/10/2021

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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	4609	6.099	10.339	13.883	18.494
2	4611	6.057	10.341	13.921	18.485
3	4613	6.099	10.326	13.905	18.480
Mean		6.085	10.335	13.903	18.486
% RSD		0.40	0.08	0.14	0.04

Peak Results Area Summarized by Name					
	Result Id	ALC-0159 (μV*sec)	cholesterol (μV*sec)	ALC-0315 (μV*sec)	DSPC (μV*sec)
1	4609	845233	2219601	5379141	1377159
2	4611	841545	2224934	5388614	1371759
3	4613	839168	2211194	5392533	1376833
Mean		841981.9	2218576.1	5386762.9	1375250.2
% RSD		0.36	0.31	0.13	0.22

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	4611	6.057	10.341	13.921	18.485
2	4613	6.099	10.326	13.905	18.480
3	4609	6.099	10.339	13.883	18.494
4	4615	6.101	10.337	14.167	18.487
5	4617	6.127	10.323	14.159	18.484
Mean		6.096	10.333	14.007	18.486
% RSD		0.41	0.08	1.02	0.03

Peak Results Area Summarized by Name					
	Result Id	ALC-0159 (μV*sec)	cholesterol (μV*sec)	ALC-0315 (μV*sec)	DSPC (μV*sec)
1	4611	841545	2224934	5388614	1371759
2	4613	839168	2211194	5392533	1376833
3	4609	845233	2219601	5379141	1377159
4	4615	857563	2260525	5525694	1397497
5	4617	868388	2263558	5529575	1425308
Mean		850379.2	2235962.3	5443111.6	1389711.1
% RSD		1.45	1.09	1.42	1.60

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	4579	100.302	100.492	99.649	101.480
2	4581	100.097	100.327	99.928	100.526
Mean		100.200	100.409	99.788	101.003

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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	2110003744 Prep 1	4583	96.471	100.053	102.451	100.095
2	2110003744 Prep 1	4585	96.471	100.053	102.451	100.095
3	2110003744 Prep 2	4587	96.471	100.053	102.451	100.095
4	2110003744 Prep 2	4589	96.471	100.053	102.451	100.095
5	2110003744 Prep 3	4591	96.471	100.053	102.451	100.095
6	2110003744 Prep 3	4593	96.471	100.053	102.451	100.095
Mean			96.5	100.1	102.5	100.1

Project Name: Chemistry\System20_2021_09 Lipids

Sample LIMS No. 2110003744

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Id: 4433

Sample Set Acquired By [REDACTED]

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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	186135.759811	0.014948	-1.850	No	No	0.999980
2	ALC-0159	Level 1	0.015230	188186.533811	0.015138	-0.607	No	No	0.999980
3	ALC-0159	Level 2	0.030460	355949.757597	0.030680	0.724	No	No	0.999980
4	ALC-0159	Level 2	0.030460	353994.988377	0.030499	0.127	No	No	0.999980
5	ALC-0159	Level 3	0.076140	838250.256420	0.076000	-0.183	No	No	0.999980
6	ALC-0159	Level 3	0.076140	845608.670959	0.076699	0.735	No	No	0.999980
7	ALC-0159	Level 4	0.152280	1629934.682438	0.152575	0.194	No	No	0.999980
8	ALC-0159	Level 4	0.152280	1619213.081461	0.151519	-0.500	No	No	0.999980
9	ALC-0159	Level 5	0.228410	2388268.744877	0.228723	0.137	No	No	0.999980
10	ALC-0159	Level 5	0.228410	2383725.527195	0.228258	-0.066	No	No	0.999980
Mean									1.0

Peak: cholesterol

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	cholesterol	Level 1	0.051230	440629.663221	0.051687	0.892	No	No	0.999927
2	cholesterol	Level 1	0.051230	439341.268295	0.051543	0.611	No	No	0.999927
3	cholesterol	Level 2	0.102470	883028.914591	0.101653	-0.797	No	No	0.999927
4	cholesterol	Level 2	0.102470	879382.413759	0.101237	-1.203	No	No	0.999927
5	cholesterol	Level 3	0.256170	2174815.994617	0.253643	-0.986	No	No	0.999927
6	cholesterol	Level 3	0.256170	2236407.127611	0.261137	1.939	No	No	0.999927
7	cholesterol	Level 4	0.512340	4194717.912873	0.513411	0.209	No	No	0.999927
8	cholesterol	Level 4	0.512340	4166432.961814	0.509550	-0.544	No	No	0.999927
9	cholesterol	Level 5	0.768500	5962205.190949	0.770789	0.298	No	No	0.999927
10	cholesterol	Level 5	0.768500	5936484.100781	0.766784	-0.223	No	No	0.999927
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	1232355.626462	0.115094	-2.997	No	No	0.999892
2	ALC-0315	Level 1	0.118650	1236495.985309	0.115559	-2.605	No	No	0.999892
3	ALC-0315	Level 2	0.237300	2335247.800773	0.239879	1.087	No	No	0.999892
4	ALC-0315	Level 2	0.237300	2309151.474946	0.236903	-0.167	No	No	0.999892
5	ALC-0315	Level 3	0.593250	5360298.041851	0.593296	0.008	No	No	0.999892
6	ALC-0315	Level 3	0.593250	5468960.132117	0.606316	2.202	No	No	0.999892
7	ALC-0315	Level 4	1.186500	10067412.095876	1.180901	-0.472	No	No	0.999892
8	ALC-0315	Level 4	1.186500	10050443.646673	1.178689	-0.658	No	No	0.999892
9	ALC-0315	Level 5	1.779750	14522647.380845	1.790149	0.584	No	No	0.999892
10	ALC-0315	Level 5	1.779750	14411276.201130	1.774163	-0.314	No	No	0.999892
Mean									1.0

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

Vaccine System Suitability Report

Peak: DSPC

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	DSPC	Level 1	0.027720	299856.797519	0.026873	-3.056	No	No	0.999884
2	DSPC	Level 1	0.027720	302475.453434	0.027135	-2.111	No	No	0.999884
3	DSPC	Level 2	0.055430	584482.150092	0.055659	0.413	No	No	0.999884
4	DSPC	Level 2	0.055430	580144.605917	0.055215	-0.387	No	No	0.999884
5	DSPC	Level 3	0.138580	1378839.028909	0.139722	0.824	No	No	0.999884
6	DSPC	Level 3	0.138580	1393775.953015	0.141361	2.007	No	No	0.999884
7	DSPC	Level 4	0.277160	2551431.080033	0.276178	-0.354	No	No	0.999884
8	DSPC	Level 4	0.277160	2535415.188407	0.274193	-1.070	No	No	0.999884
9	DSPC	Level 5	0.415740	3616887.757766	0.417998	0.543	No	No	0.999884
10	DSPC	Level 5	0.415740	3595647.856040	0.414952	-0.189	No	No	0.999884
Mean									1.0

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

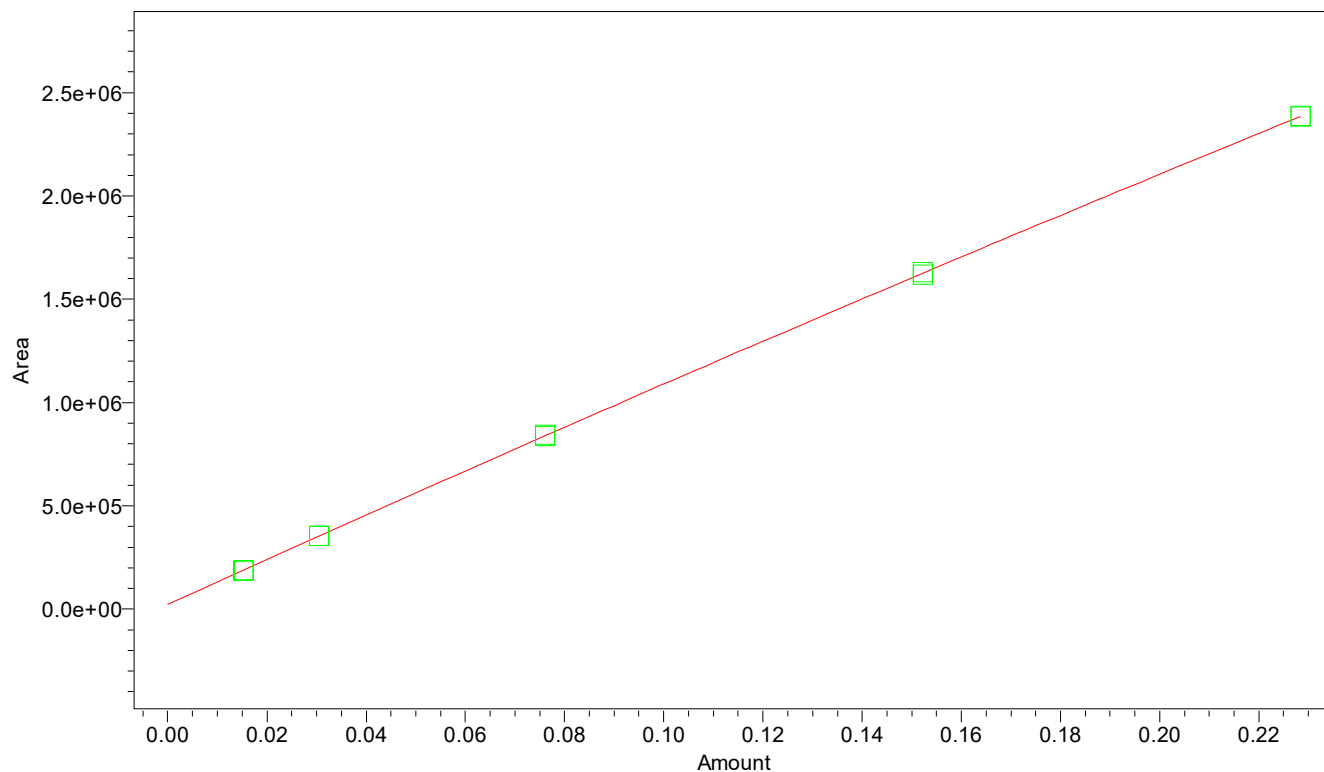
Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

Cal Curve Report

Calibration Plot



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

Cal Curve Id: 4544; A: 2.364212e+04; B: 1.090762e+07; C: -2.488841e+06; D: 0.000000e+00; R^2: 0.999980

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

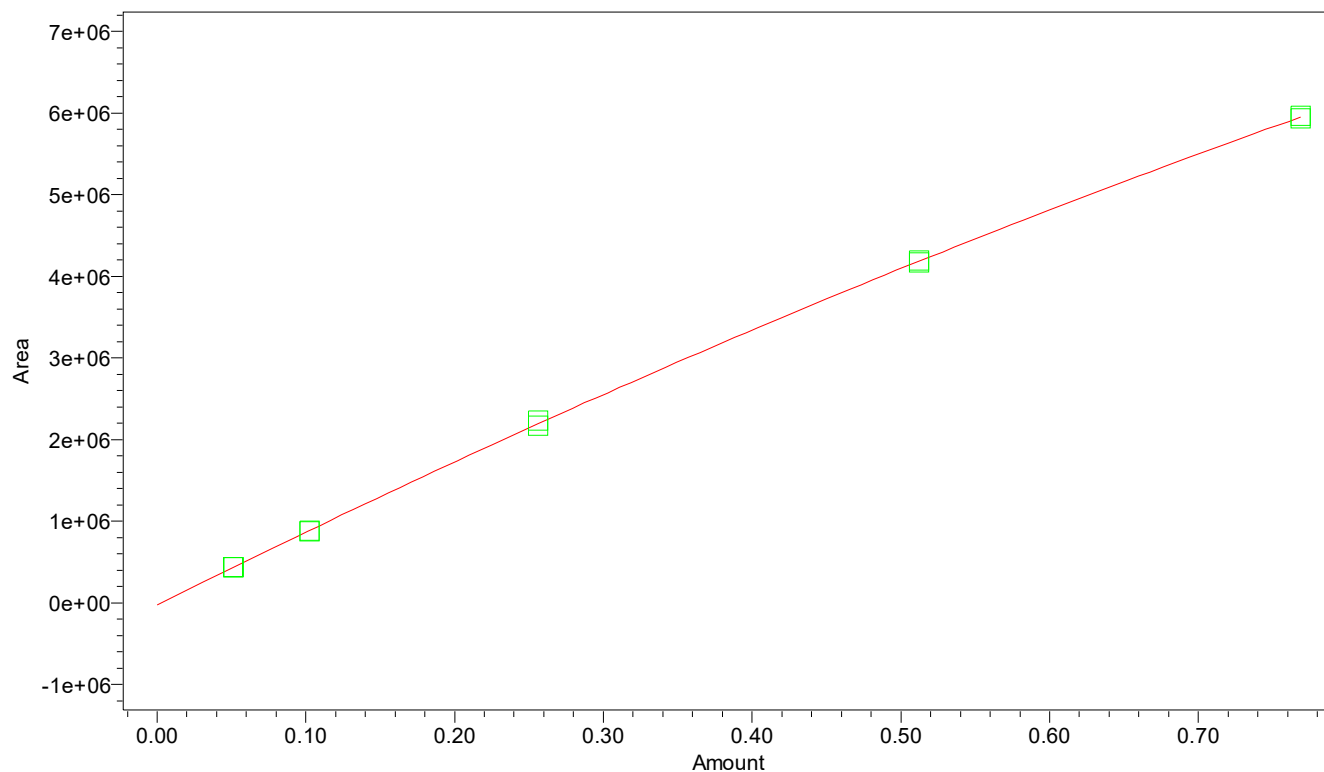
Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

Cal Curve Report

Calibration Plot



Name: cholesterol; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order);
Cal Curve Id: 4545; A: -2.623459e+04; B: 9.123334e+06; C: -1.756771e+06; D: 0.000000e+00;
R^2: 0.999927

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003744

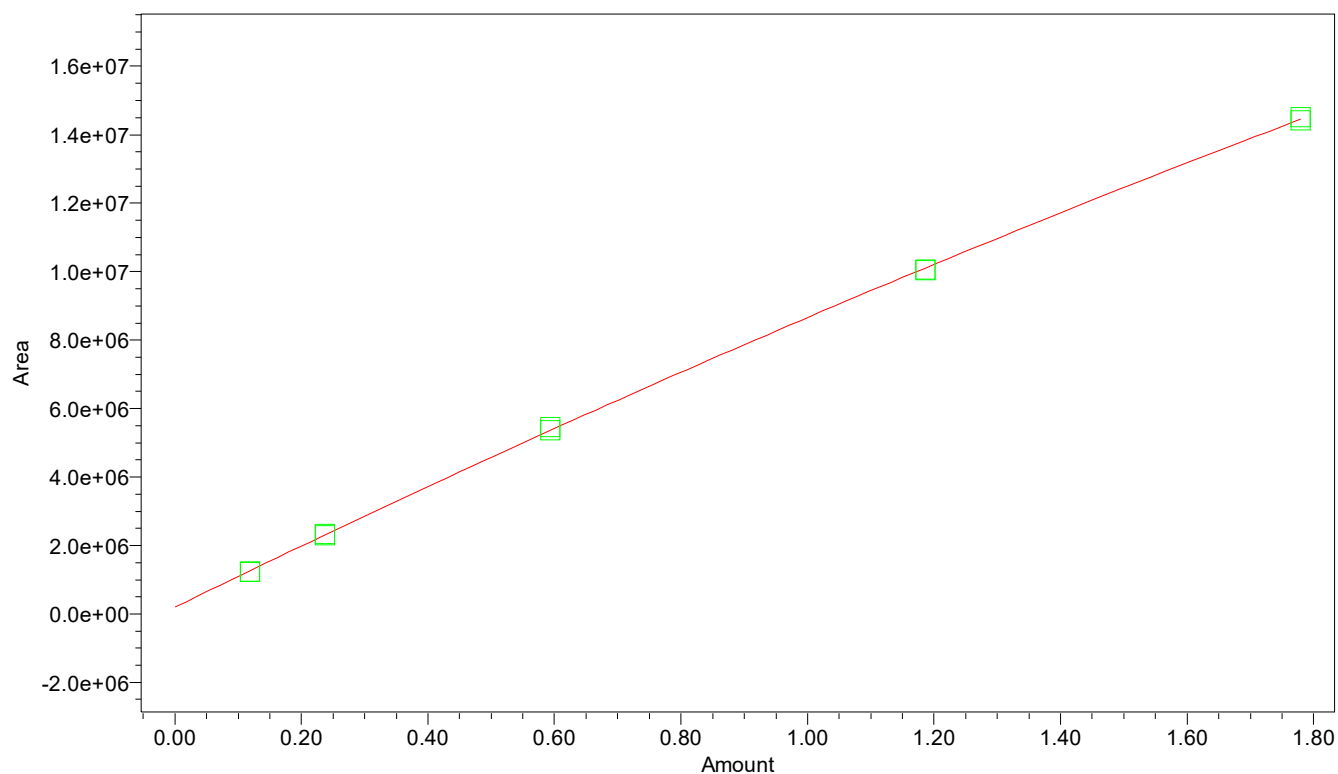
Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

Cal Curve Report

Calibration Plot



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

Cal Curve Id: 4546; A: 1.990123e+05; B: 9.045348e+06; C: -5.831815e+05; D: 0.000000e+00; R²: 0.999892

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003744

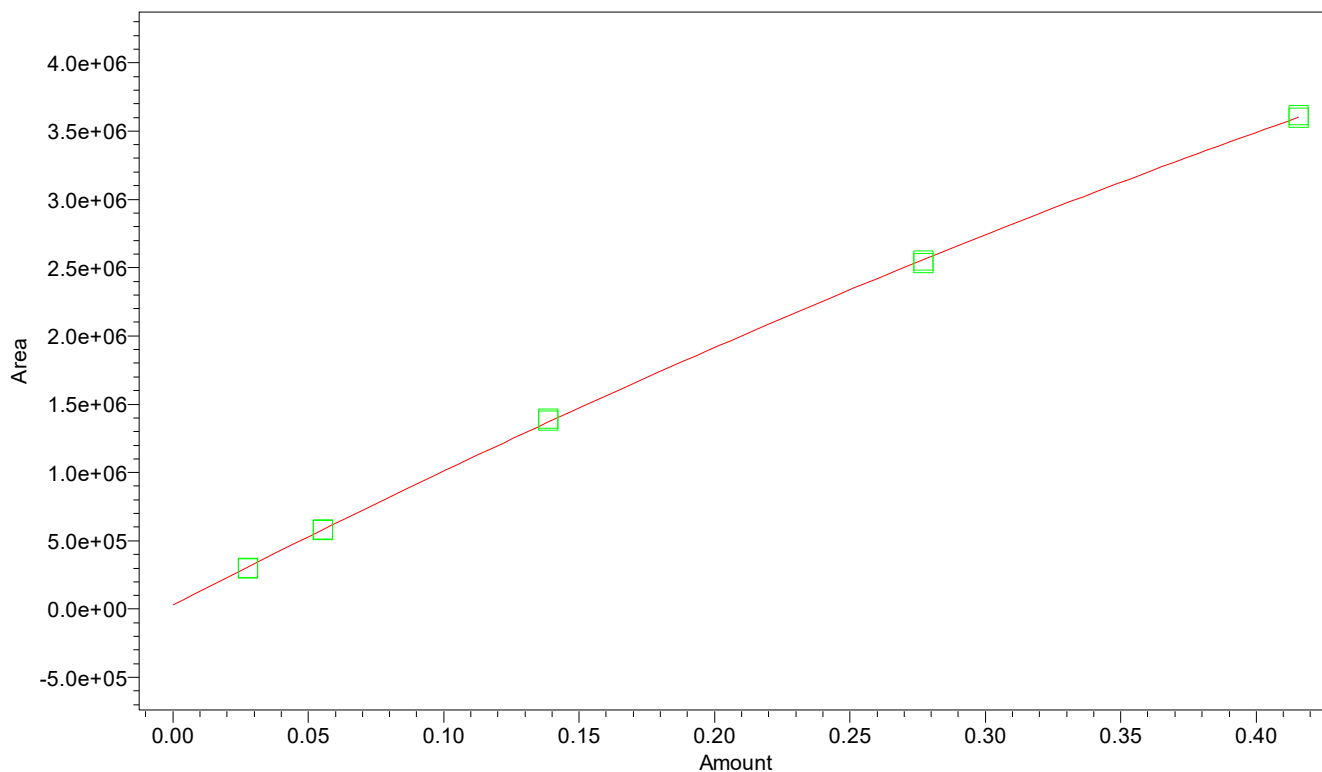
Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

Cal Curve Report

Calibration Plot



Name: DSPC; Processing Method: Lipid Linearity_Quadratic_3; Fit Type: Quadratic (2nd Order); Cal Curve Id: 4547; A: 2.833799e+04; B: 1.020814e+07; C: -3.882915e+06; D: 0.000000e+00; R^2: 0.999884

Peak: ALC-0159

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0159	Level 1	0.015230	186135.759811	0.014948	-1.850	No	No	0.999980
2	ALC-0159	Level 1	0.015230	188186.533811	0.015138	-0.607	No	No	0.999980
3	ALC-0159	Level 2	0.030460	355949.757597	0.030680	0.724	No	No	0.999980
4	ALC-0159	Level 2	0.030460	353994.988377	0.030499	0.127	No	No	0.999980
5	ALC-0159	Level 3	0.076140	838250.256420	0.076000	-0.183	No	No	0.999980
6	ALC-0159	Level 3	0.076140	845608.670959	0.076699	0.735	No	No	0.999980
7	ALC-0159	Level 4	0.152280	1629934.682438	0.152575	0.194	No	No	0.999980
8	ALC-0159	Level 4	0.152280	1619213.081461	0.151519	-0.500	No	No	0.999980
9	ALC-0159	Level 5	0.228410	2388268.744877	0.228723	0.137	No	No	0.999980
10	ALC-0159	Level 5	0.228410	2383725.527195	0.228258	-0.066	No	No	0.999980

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

Cal Curve Report

Peak: cholesterol

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	cholesterol	Level 1	0.051230	440629.663221	0.051687	0.892	No	No	0.999927
2	cholesterol	Level 1	0.051230	439341.268295	0.051543	0.611	No	No	0.999927
3	cholesterol	Level 2	0.102470	883028.914591	0.101653	-0.797	No	No	0.999927
4	cholesterol	Level 2	0.102470	879382.413759	0.101237	-1.203	No	No	0.999927
5	cholesterol	Level 3	0.256170	2174815.994617	0.253643	-0.986	No	No	0.999927
6	cholesterol	Level 3	0.256170	2236407.127611	0.261137	1.939	No	No	0.999927
7	cholesterol	Level 4	0.512340	4194717.912873	0.513411	0.209	No	No	0.999927
8	cholesterol	Level 4	0.512340	4166432.961814	0.509550	-0.544	No	No	0.999927
9	cholesterol	Level 5	0.768500	5962205.190949	0.770789	0.298	No	No	0.999927
10	cholesterol	Level 5	0.768500	5936484.100781	0.766784	-0.223	No	No	0.999927

Peak: ALC-0315

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	ALC-0315	Level 1	0.118650	1232355.626462	0.115094	-2.997	No	No	0.999892
2	ALC-0315	Level 1	0.118650	1236495.985309	0.115559	-2.605	No	No	0.999892
3	ALC-0315	Level 2	0.237300	2335247.800773	0.239879	1.087	No	No	0.999892
4	ALC-0315	Level 2	0.237300	2309151.474946	0.236903	-0.167	No	No	0.999892
5	ALC-0315	Level 3	0.593250	5360298.041851	0.593296	0.008	No	No	0.999892
6	ALC-0315	Level 3	0.593250	5468960.132117	0.606316	2.202	No	No	0.999892
7	ALC-0315	Level 4	1.186500	10067412.095876	1.180901	-0.472	No	No	0.999892
8	ALC-0315	Level 4	1.186500	10050443.646673	1.178689	-0.658	No	No	0.999892
9	ALC-0315	Level 5	1.779750	14522647.380845	1.790149	0.584	No	No	0.999892
10	ALC-0315	Level 5	1.779750	14411276.201130	1.774163	-0.314	No	No	0.999892

Peak: DSPC

	Name	Level	X Value	Response	Calc. Value	% Deviation	Manual	Ignore	R^2
1	DSPC	Level 1	0.027720	299856.797519	0.026873	-3.056	No	No	0.999884
2	DSPC	Level 1	0.027720	302475.453434	0.027135	-2.111	No	No	0.999884
3	DSPC	Level 2	0.055430	584482.150092	0.055659	0.413	No	No	0.999884
4	DSPC	Level 2	0.055430	580144.605917	0.055215	-0.387	No	No	0.999884
5	DSPC	Level 3	0.138580	1378839.028909	0.139722	0.824	No	No	0.999884
6	DSPC	Level 3	0.138580	1393775.953015	0.141361	2.007	No	No	0.999884
7	DSPC	Level 4	0.277160	2551431.080033	0.276178	-0.354	No	No	0.999884
8	DSPC	Level 4	0.277160	2535415.188407	0.274193	-1.070	No	No	0.999884
9	DSPC	Level 5	0.415740	3616887.757766	0.417998	0.543	No	No	0.999884
10	DSPC	Level 5	0.415740	3595647.856040	0.414952	-0.189	No	No	0.999884

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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	4506	4583	2110003744 Prep 1	0.879	3.108	6.909	1.514
2	4513	4587	2110003744 Prep 2	0.869	3.104	6.862	1.511
3	4520	4591	2110003744 Prep 3	0.874	3.090	6.857	1.503
Mean				0.87	3.10	6.88	1.51
Std. Dev.				0.00	0.01	0.03	0.01
% RSD				0.6	0.3	0.4	0.3

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	4506	4583	2110003744 Prep 1	0.893	3.121	6.915	1.518
2	4509	4585	2110003744 Prep 1	0.865	3.095	6.903	1.510
3	4513	4587	2110003744 Prep 2	0.873	3.116	6.887	1.508
4	4516	4589	2110003744 Prep 2	0.865	3.092	6.837	1.514
5	4520	4591	2110003744 Prep 3	0.876	3.092	6.880	1.499
6	4523	4593	2110003744 Prep 3	0.871	3.087	6.833	1.508
Mean				0.87	3.10	6.88	1.51

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	4488	4595	2103001141 Ref Material	0.831	3.004	6.803	1.481
2	4491	4597	2103001141 Ref Material	0.826	3.012	6.807	1.485
Mean				0.829	3.008	6.805	1.483

Result Summary Table (peak area)
Amount Summarized by Name

	Inj Id	Result Id	Sample Name	ALC-0159	cholesterol	ALC-0315	DSPC
1	4495	4579	Assay control	0.075	0.248	0.625	0.141
2	4498	4581	Assay control	0.075	0.248	0.627	0.140
Mean				0.075	0.248	0.626	0.140

Results Summary Report

Calibration Data Table
Peak: ALC-0159

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	4453	4559	ALC-0159	0.015230	186136	4544
2	4456	4561	ALC-0159	0.015230	188187	4544
3	4460	4563	ALC-0159	0.030460	355950	4544
4	4463	4565	ALC-0159	0.030460	353995	4544
5	4467	4567	ALC-0159	0.076140	838250	4544
6	4470	4569	ALC-0159	0.076140	845609	4544
7	4474	4571	ALC-0159	0.152280	1629935	4544
8	4477	4573	ALC-0159	0.152280	1619213	4544
9	4481	4575	ALC-0159	0.228410	2388269	4544
10	4484	4577	ALC-0159	0.228410	2383726	4544

Calibration Data Table
Peak: cholesterol

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	4453	4559	cholesterol	0.051230	440630	4545
2	4456	4561	cholesterol	0.051230	439341	4545
3	4460	4563	cholesterol	0.102470	883029	4545
4	4463	4565	cholesterol	0.102470	879382	4545
5	4467	4567	cholesterol	0.256170	2174816	4545
6	4470	4569	cholesterol	0.256170	2236407	4545
7	4474	4571	cholesterol	0.512340	4194718	4545
8	4477	4573	cholesterol	0.512340	4166433	4545
9	4481	4575	cholesterol	0.768500	5962205	4545
10	4484	4577	cholesterol	0.768500	5936484	4545

Calibration Data Table
Peak: ALC-0315

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	4453	4559	ALC-0315	0.118650	1232356	4546
2	4456	4561	ALC-0315	0.118650	1236496	4546
3	4460	4563	ALC-0315	0.237300	2335248	4546
4	4463	4565	ALC-0315	0.237300	2309151	4546
5	4467	4567	ALC-0315	0.593250	5360298	4546
6	4470	4569	ALC-0315	0.593250	5468960	4546
7	4474	4571	ALC-0315	1.186500	10067412	4546
8	4477	4573	ALC-0315	1.186500	10050444	4546
9	4481	4575	ALC-0315	1.779750	14522647	4546
10	4484	4577	ALC-0315	1.779750	14411276	4546

Results Summary Report

Calibration Data Table
Peak: DSPC

	Inj Id	Result Id	Name	Concentration	Response	Cal Curve Id
1	4453	4559	DSPC	0.027720	299857	4547
2	4456	4561	DSPC	0.027720	302475	4547
3	4460	4563	DSPC	0.055430	584482	4547
4	4463	4565	DSPC	0.055430	580145	4547
5	4467	4567	DSPC	0.138580	1378839	4547
6	4470	4569	DSPC	0.138580	1393776	4547
7	4474	4571	DSPC	0.277160	2551431	4547
8	4477	4573	DSPC	0.277160	2535415	4547
9	4481	4575	DSPC	0.415740	3616888	4547
10	4484	4577	DSPC	0.415740	3595648	4547

Project Name: Chemistry\System20_2021_09 Lipids
Sample Set Name: 20211019 Pfizer vaccin testing

LIMS Number:
Sample Set Id: 4433
Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT
Print Date: 20/10/2021

Analyst XXXXXXXXXX

Results Summary Report

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

	Inj Id	Result Id	Sample Name	RT	Area ($\mu V \cdot \text{sec}$)	Height (μV)	Lipid Content
1	4443	4609	SST	6.099	845233	17536	0.077
2	4446	4611	SST	6.057	841545	17240	0.076
3	4449	4613	SST	6.099	839168	17148	0.076
4	4453	4559	Level 1	6.111	186136	3784	0.015
5	4456	4561	Level 1	6.045	188187	3753	0.015
6	4460	4563	Level 2	6.120	355950	7177	0.030
7	4463	4565	Level 2	6.090	353995	7203	0.030
8	4467	4567	Level 3	6.081	838250	17203	0.076
9	4470	4569	Level 3	6.058	845609	17358	0.076
10	4474	4571	Level 4	6.085	1629935	33856	0.152
11	4477	4573	Level 4	6.095	1619213	33151	0.152
12	4481	4575	Level 5	6.085	2388269	48963	0.228
13	4484	4577	Level 5	6.104	2383726	48867	0.228
14	4488	4595	2103001141 Ref Material	6.160	472499	9272	0.831
15	4491	4597	2103001141 Ref Material	6.156	470006	9063	0.826
16	4495	4579	Assay control	6.107	829362	17031	0.075
17	4498	4581	Assay control	6.130	827745	16869	0.075
18	4506	4583	2110003744 Prep 1	5.857	505889	11634	0.893
19	4509	4585	2110003744 Prep 1	5.852	490570	11469	0.865
20	4513	4587	2110003744 Prep 2	5.911	495245	11462	0.873
21	4516	4589	2110003744 Prep 2	5.879	490650	11380	0.865
22	4520	4591	2110003744 Prep 3	5.914	496537	11618	0.876
23	4523	4593	2110003744 Prep 3	5.874	494065	11398	0.871
24	4531	4615	SST	6.101	857563	17696	0.078
25	4534	4617	SST	6.127	868388	17863	0.079

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

	Inj Id	Result Id	Sample Name	RT	Area ($\mu V \cdot \text{sec}$)	Height (μV)	Lipid Content
1	4443	4609	SST	13.883	5379141	157843	0.596
2	4446	4611	SST	13.921	5388614	156143	0.597
3	4449	4613	SST	13.905	5392533	154679	0.597
4	4453	4559	Level 1	14.414	1232356	59616	0.119
5	4456	4561	Level 1	14.441	1236496	59504	0.119
6	4460	4563	Level 2	14.320	2335248	92117	0.237
7	4463	4565	Level 2	14.340	2309151	91939	0.237
8	4467	4567	Level 3	14.030	5360298	155625	0.593
9	4470	4569	Level 3	14.050	5468960	154104	0.593
10	4474	4571	Level 4	13.735	10067412	219879	1.187
11	4477	4573	Level 4	13.745	10050444	219337	1.187
12	4481	4575	Level 5	13.519	14522647	269751	1.780
13	4484	4577	Level 5	13.492	14411276	270468	1.780

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Analyst XXXXXXXXXX

LIMS Number:

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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	4488	4595	2103001141 Ref Material	14.288	3208442	112667	6.803
15	4491	4597	2103001141 Ref Material	14.321	3210198	113294	6.807
16	4495	4579	Assay control	14.110	5626792	156535	0.625
17	4498	4581	Assay control	14.098	5641313	157356	0.627
18	4506	4583	2110003744 Prep 1	14.311	3256851	114299	6.915
19	4509	4585	2110003744 Prep 1	14.344	3251367	114124	6.903
20	4513	4587	2110003744 Prep 2	14.345	3244653	114723	6.887
21	4516	4589	2110003744 Prep 2	14.353	3222863	111789	6.837
22	4520	4591	2110003744 Prep 3	14.371	3241410	113740	6.880
23	4523	4593	2110003744 Prep 3	14.380	3221483	112570	6.833
24	4531	4615	SST	14.167	5525694	153866	0.613
25	4534	4617	SST	14.159	5529575	154786	0.614

Result Summary Table (peak area)

Peak Name: DSPC

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	4443	4609	SST	18.494	1377159	102950	0.140
2	4446	4611	SST	18.485	1371759	102461	0.139
3	4449	4613	SST	18.480	1376833	103304	0.140
4	4453	4559	Level 1	18.503	299857	23302	0.028
5	4456	4561	Level 1	18.513	302475	23439	0.028
6	4460	4563	Level 2	18.503	584482	45043	0.055
7	4463	4565	Level 2	18.526	580145	44691	0.055
8	4467	4567	Level 3	18.502	1378839	102652	0.139
9	4470	4569	Level 3	18.504	1393776	104621	0.139
10	4474	4571	Level 4	18.524	2551431	187028	0.277
11	4477	4573	Level 4	18.514	2535415	186506	0.277
12	4481	4575	Level 5	18.517	3616888	263926	0.416
13	4484	4577	Level 5	18.500	3595648	258460	0.416
14	4488	4595	2103001141 Ref Material	18.503	763044	57282	1.481
15	4491	4597	2103001141 Ref Material	18.522	765013	57737	1.485
16	4495	4579	Assay control	18.517	1389710	104836	0.141
17	4498	4581	Assay control	18.502	1377630	102436	0.140
18	4506	4583	2110003744 Prep 1	18.492	780548	59257	1.518
19	4509	4585	2110003744 Prep 1	18.512	776679	59395	1.510
20	4513	4587	2110003744 Prep 2	18.500	775717	58257	1.508
21	4516	4589	2110003744 Prep 2	18.502	778667	58468	1.514
22	4520	4591	2110003744 Prep 3	18.508	771653	58057	1.499
23	4523	4593	2110003744 Prep 3	18.508	775892	58319	1.508
24	4531	4615	SST	18.487	1397497	104314	0.142
25	4534	4617	SST	18.484	1425308	105840	0.145

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Analyst

LIMS Number:

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

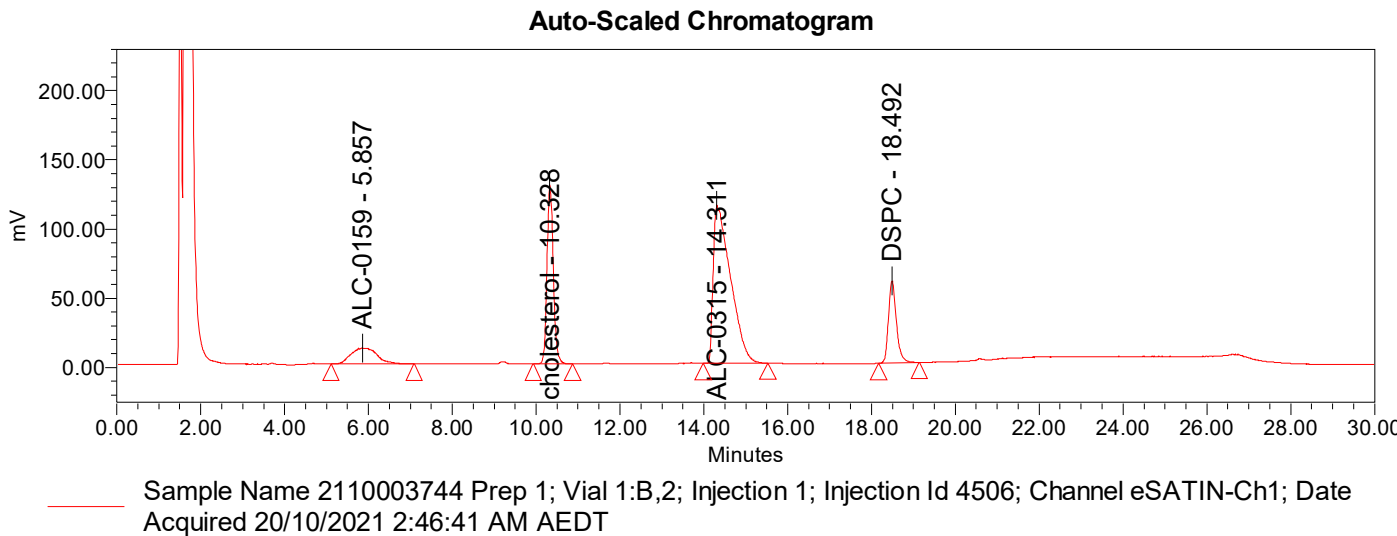
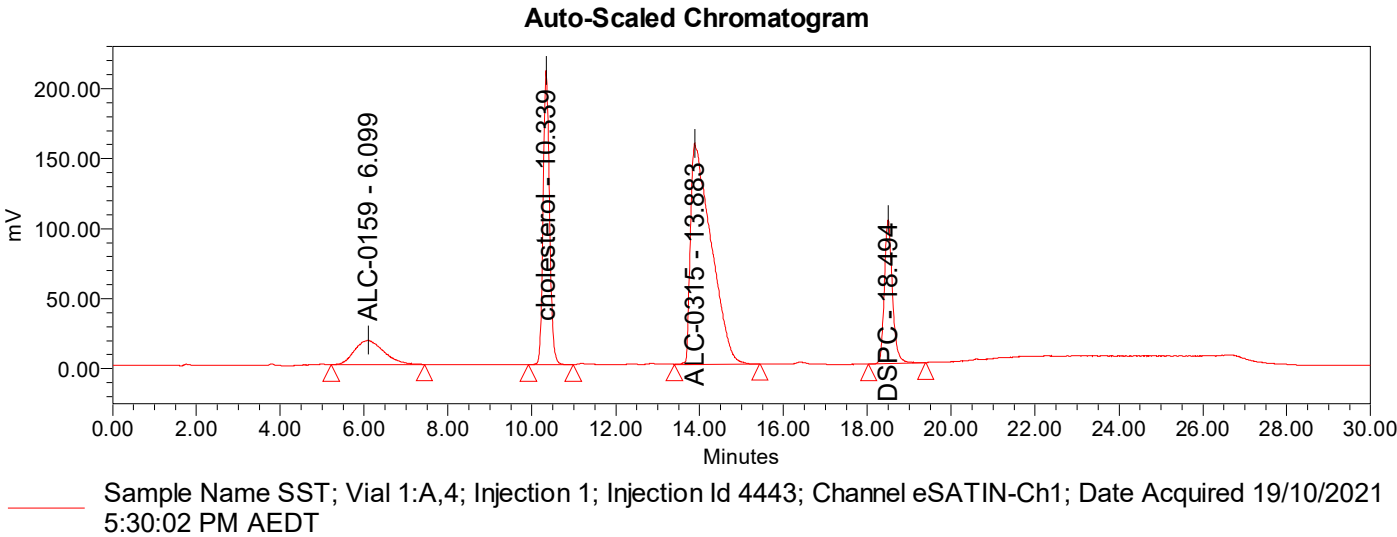
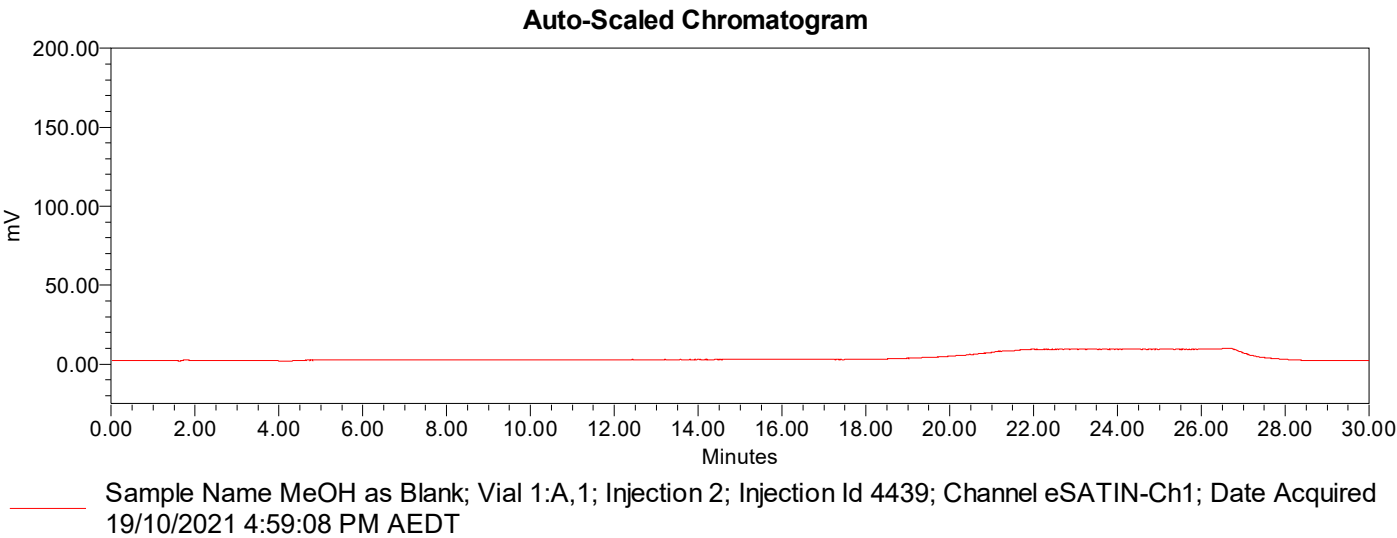
Results Summary Report

Result Summary Table (peak area)

Peak Name: cholesterol

	Inj Id	Result Id	Sample Name	RT	Area (µV*sec)	Height (µV)	Lipid Content
1	4443	4609	SST	10.339	2219601	210564	0.259
2	4446	4611	SST	10.341	2224934	208385	0.260
3	4449	4613	SST	10.326	2211194	209881	0.258
4	4453	4559	Level 1	10.341	440630	42820	0.051
5	4456	4561	Level 1	10.336	439341	42912	0.051
6	4460	4563	Level 2	10.348	883029	85286	0.102
7	4463	4565	Level 2	10.356	879382	85436	0.102
8	4467	4567	Level 3	10.336	2174816	207114	0.256
9	4470	4569	Level 3	10.342	2236407	208991	0.256
10	4474	4571	Level 4	10.356	4194718	379713	0.512
11	4477	4573	Level 4	10.348	4166433	375327	0.512
12	4481	4575	Level 5	10.348	5962205	527920	0.769
13	4484	4577	Level 5	10.341	5936484	525196	0.769
14	4488	4595	2103001141 Ref Material	10.344	1304603	124222	3.004
15	4491	4597	2103001141 Ref Material	10.349	1307869	124378	3.012
16	4495	4579	Assay control	10.347	2130656	200241	0.248
17	4498	4581	Assay control	10.347	2127294	199280	0.248
18	4506	4583	2110003744 Prep 1	10.328	1354793	129403	3.121
19	4509	4585	2110003744 Prep 1	10.342	1343486	127857	3.095
20	4513	4587	2110003744 Prep 2	10.339	1352420	130168	3.116
21	4516	4589	2110003744 Prep 2	10.338	1342397	127831	3.092
22	4520	4591	2110003744 Prep 3	10.342	1342427	128037	3.092
23	4523	4593	2110003744 Prep 3	10.343	1340025	128677	3.087
24	4531	4615	SST	10.337	2260525	212001	0.264
25	4534	4617	SST	10.323	2263558	209595	0.264

Example Chromatograms



Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003744

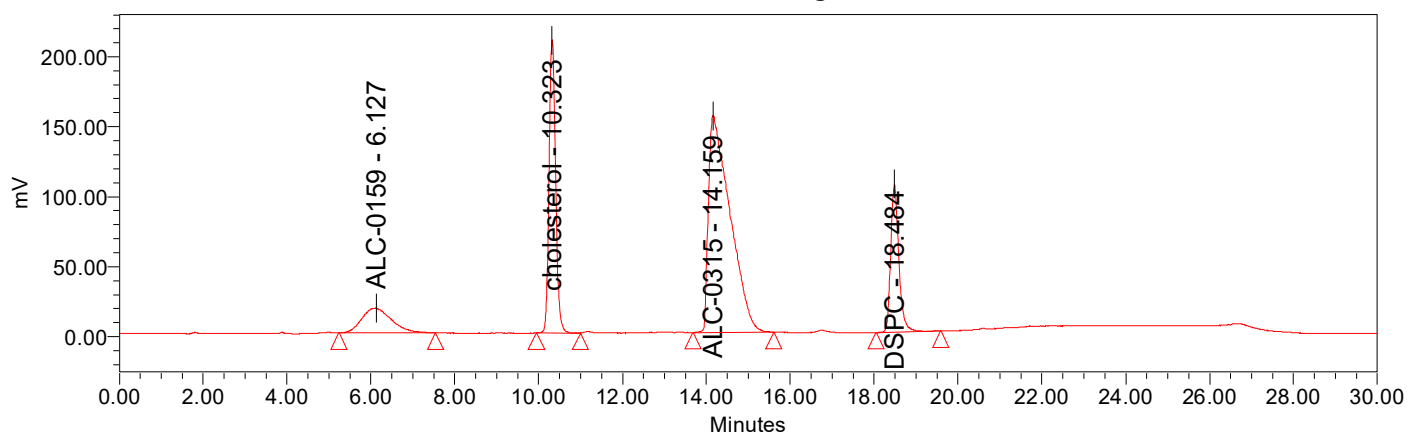
Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

Example Chromatograms

Auto-Scaled Chromatogram



Sample Name SST; Vial 1:A,4; Injection 2; Injection Id 4534; Channel eSATIN-Ch1; Date Acquired 20/10/2021 6:53:55 AM AEDT

Project Name: Chemistry\System20_2021_09 Lipids

Sample Set Name: 20211019 Pfizer vaccin testing

Sample Set Acquired By

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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	4435	10	1	30		Pfizer Vaccine
2	MeOH as Blank	Unknown	B101	1:A,1	2	4439	10	1	30		Pfizer Vaccine
3	SST	Control	Y101	1:A,4	1	4443	10	1	30		Pfizer Vaccine
4	SST	Control	Y101	1:A,4	2	4446	10	1	30		Pfizer Vaccine
5	SST	Control	Y101	1:A,4	3	4449	10	1	30		Pfizer Vaccine
6	Level 1	Standard	S101	1:A,2	1	4453	10	1	30	Level 1	Pfizer Vaccine
7	Level 1	Standard	S101	1:A,2	2	4456	10	1	30	Level 1	Pfizer Vaccine
8	Level 2	Standard	S102	1:A,3	1	4460	10	1	30	Level 2	Pfizer Vaccine
9	Level 2	Standard	S102	1:A,3	2	4463	10	1	30	Level 2	Pfizer Vaccine
10	Level 3	Standard	S103	1:A,4	1	4467	10	1	30	Level 3	Pfizer Vaccine
11	Level 3	Standard	S103	1:A,4	2	4470	10	1	30	Level 3	Pfizer Vaccine
12	Level 4	Standard	S104	1:A,5	1	4474	10	1	30	Level 4	Pfizer Vaccine
13	Level 4	Standard	S104	1:A,5	2	4477	10	1	30	Level 4	Pfizer Vaccine
14	Level 5	Standard	S105	1:A,6	1	4481	10	1	30	Level 5	Pfizer Vaccine
15	Level 5	Standard	S105	1:A,6	2	4484	10	1	30	Level 5	Pfizer Vaccine
16	2103001141 Ref Material	Unknown	C101	1:B,1	1	4488	10	20	30		Pfizer Vaccine
17	2103001141 Ref Material	Unknown	C101	1:B,1	2	4491	10	20	30		Pfizer Vaccine
18	Assay control	Unknown	U001	1:A,7	1	4495	10	1	30		Pfizer Vaccine
19	Assay control	Unknown	U001	1:A,7	2	4498	10	1	30		Pfizer Vaccine
20	MeOH as Blank	Unknown	B102	1:A,1	1	4502	10	1	30		Pfizer Vaccine
21	2110003744 Prep 1	Unknown	U101	1:B,2	1	4506	10	20	30		Pfizer Vaccine
22	2110003744 Prep 1	Unknown	U101	1:B,2	2	4509	10	20	30		Pfizer Vaccine
23	2110003744 Prep 2	Unknown	U102	1:B,3	1	4513	10	20	30		Pfizer Vaccine
24	2110003744 Prep 2	Unknown	U102	1:B,3	2	4516	10	20	30		Pfizer Vaccine
25	2110003744 Prep 3	Unknown	U103	1:B,4	1	4520	10	20	30		Pfizer Vaccine
26	2110003744 Prep 3	Unknown	U103	1:B,4	2	4523	10	20	30		Pfizer Vaccine
27	MeOH as Blank	Unknown	B103	1:A,1	1	4527	10	1	30		Pfizer Vaccine
28	SST	Control	Y102	1:A,4	1	4531	10	1	30		Pfizer Vaccine
29	SST	Control	Y102	1:A,4	2	4534	10	1	30		Pfizer Vaccine
30	MeOH as Blank	Unknown	B104	1:A,1	1	4538	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: 20211019 Pfizer vaccin testing

Sample Set Acquired By: [REDACTED]

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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: 20211019 Pfizer vaccin testing

Sample Set Acquired By

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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: 20211019 Pfizer vaccin testing

Sample Set Acquired By [REDACTED]

Sample LIMS No. 2110003744

Sample Set Id: 4433

Sample Set Start Date: 19/10/2021 4:27:28 PM AEDT

Print Date: 20/10/2021

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

OFFICIAL



Australian Government

Department of Health

Therapeutic Goods Administration

Laboratories Branch

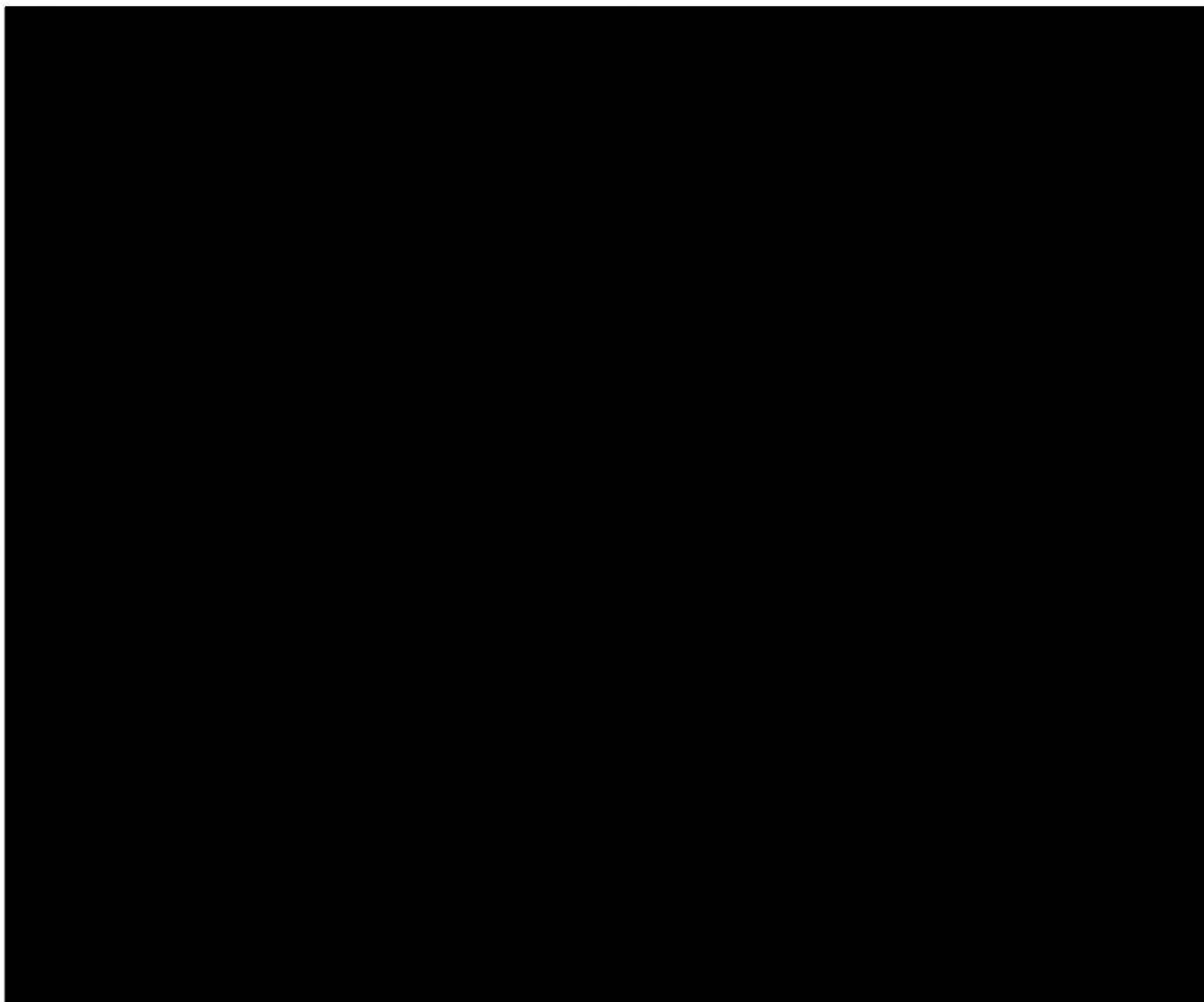
Owner: [REDACTED]	Number: Chem-Form-6
Author: [REDACTED]	Version: 1
Active: 27/06/2021	Review: <QPulse_DocReviewDate>
Title: Analysts notes - Worksheet	

ANALYSTS' NOTES

Sample Name: COMIRNATY

TGA Sample No. 2110003744

Mobile phase preparation:



Signature of Analyst Electronically signed by [REDACTED] Date: 20 Oct 2021

Checked by Official Analyst... Electronically signed by [REDACTED] Date: 20/10/21

