

# Analysis Report

Prepared For: \_\_\_\_\_

Prepared By: \_\_\_\_\_

## Analytical method

Mobile Phase A: 0.1% Formic Acid in Water

Mobile Phase B: 0.1% Formic Acid in Acetonitrile

## Testing Site and Date

Testing Site: \_\_\_\_\_

Testing Date: 02/27/15

## Analyte

Product name: 202187-I

Name: 2--- Clomiphene Citrate

Condition while received: Well

Storage Condition after received: Room Temperature

There was no discrepancy when sample received.

## Analytical Instrument

Equipment: High-Performance Liquid Chromatography with Mass Spectrometric  
(MS/MS) Detection

ID Number: HPLC-023/MSMS-017

Software: MassLynx v 4.1

## Result (original \_\_\_\_\_ attachment):

Assay Percent % 97.5%

Analyst: \_\_\_\_\_

Date: 02/28/15

Auditor: \_\_\_\_\_

Date: 02/28/15

Clomiphene Citrate (ClmC)

Molecular weight:598.08

HPLC-023 Condition

Solvent A: 0.1% Formic Acid in Water

Solvent B: 0.1% Formic Acid in Acetonitrile

Mobile Phase: Solvent A:Solvent B (40:60, v/v)

Flow Rate (mL/min): 0.300

MSMS-017 Condition:

Cone (V)	10
Collision (eV)	20
Dwell Time (secs)	0.3
Delay Time (secs)	0.00
Ionization Mode	ES+
Source Temperature (°C)	130
Desolvation Temperature (°C)	350
Cone Gas (L/hr)	84
Desolvation Gas (L/hr)	805
Capillary (kV)	2.5
Hex 1 (V)	30
Aperture (V)	0.5
Hex 2 (V)	1.0
LM/HM Resolution 1	12.0
Ion Energy 1 (V)	1.5
LM/HM Resolution 2	12.0
Ion Energy 2 (V)	2.0
Entrance	-1.0
Exit	1.0
Multiplier (V)	650

Quantify Compound Summary Report MassLynx 4.1

Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 09:53:03 China Standard Time  
By

Method: 27 Feb 2015 15:07:47  
Calibration: 27 Feb 2015 16:03:00

Compound name: CLM

Correlation coefficient:  $r = 0.999068$ ,  $r^2 = 0.998137$   
Calibration curve:  $1.06292 * x + 9.66815$   
Response type: External Std, Area  
Curve type: Linear, Origin: Exclude, Weighting: Null, Axis trans: Ln

#	Sample Text	ID	Type	Area	Primary Flags	Conc.	%Dev	Factor1	RT	Response
1	ClmC Std 0.500 ng/mL	W1	Standard	7045	bb	0.468	-6.49	1.0	2.80	7045
2	ClmC Std 1.00 ng/mL	W2	Standard	16768	bb	1.06	5.72	1.0	2.76	16770
3	ClmC Std 2.00 ng/mL	W3	Standard	34676	bb	2.09	4.71	1.0	2.77	34680
4	ClmC Std 5.00 ng/mL	W4	Standard	87325	bb	4.99	-0.137	1.0	2.79	87330
5	ClmC Std 10.00 ng/mL	W5	Standard	176387	bb	9.67	-3.26	1.0	2.76	176400
6	ClmC Std 2.00 ng/mL		Analyte	31601	bb	1.92		1.0	2.77	31600
7	ClmC Std 2.00 ng/mL		Analyte	32083	bb	1.95		1.0	2.74	32080
8	ClmC Std 2.00 ng/mL		Analyte	32927	bb	1.99		1.0	2.75	32930

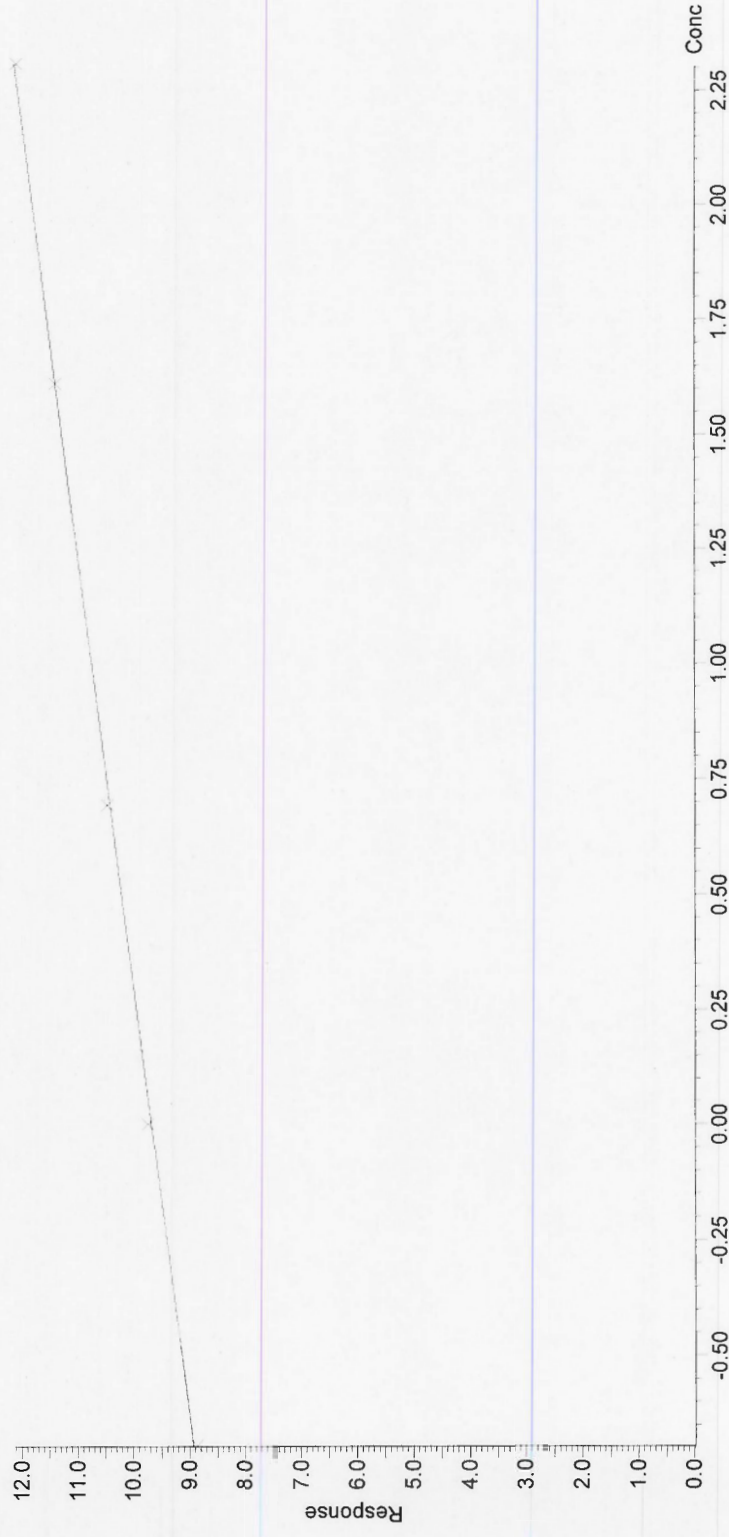
D Deleted. 02/28/15

Quantify Calibration Report MassLynx 4.1

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By   
Reason processing data  
Printed: At Saturday, February 28, 2015 09:53:03 China Standard Time  
By 

Method:  27 Feb 2015 15:07:47  
Calibration: 27 Feb 2015 16:03:00

Compound name: CLM  
Correlation coefficient:  $r = 0.999068, r^2 = 0.998137$   
Calibration curve:  $1.06292 * x + 9.66815$   
Response type: External Std, Area  
Curve type: Linear, Origin: Exclude, Weighting: Null, Axis trans: Ln





Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

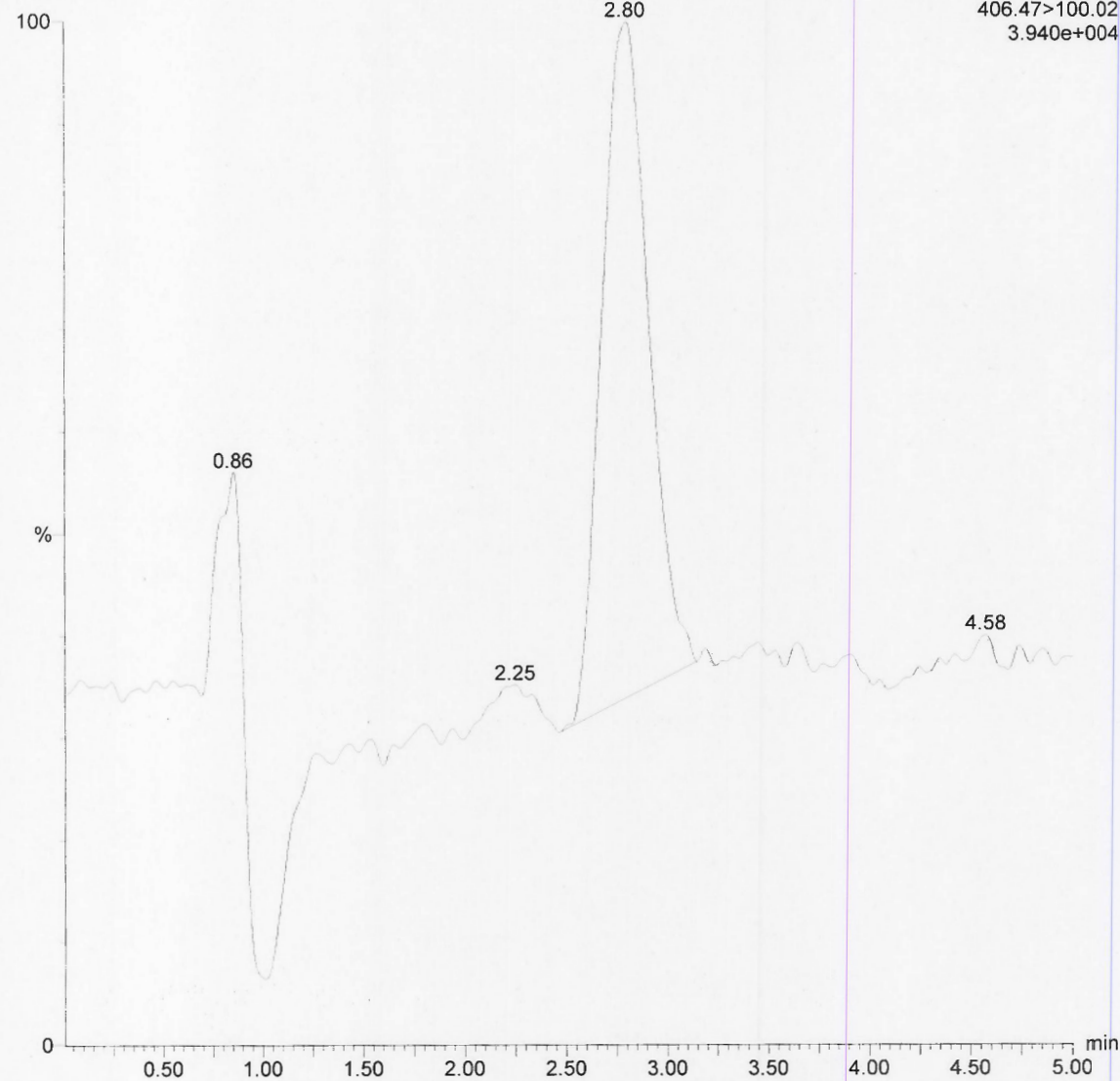
Method: 27 Feb 2015 15:07:47  
Calibration: 27 Feb 2015 16:03:00

Name: AR17001, Date: 27-Feb-2015, Time: 15:09:19, ID: W1, Description: ClmC Std 0.500 ng/mL

CLM

AR17001

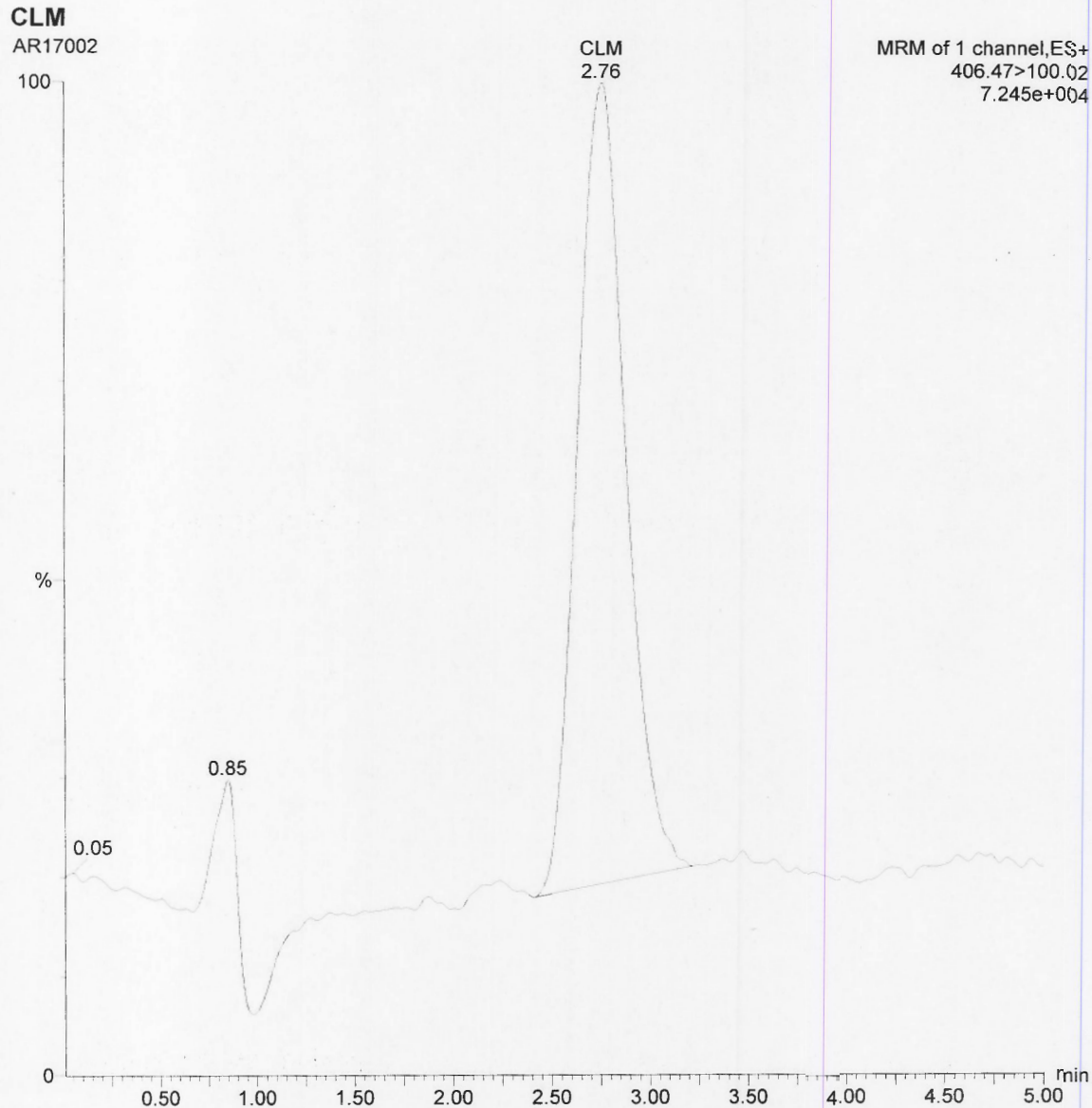
MRM of 1 channel, ES+  
406.47>100.02  
3.940e+004



#	Name	Area	Conc.	RT.	Response	Primary Flags
1	CLM	7045	0.5	2.80	7045	bb

Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

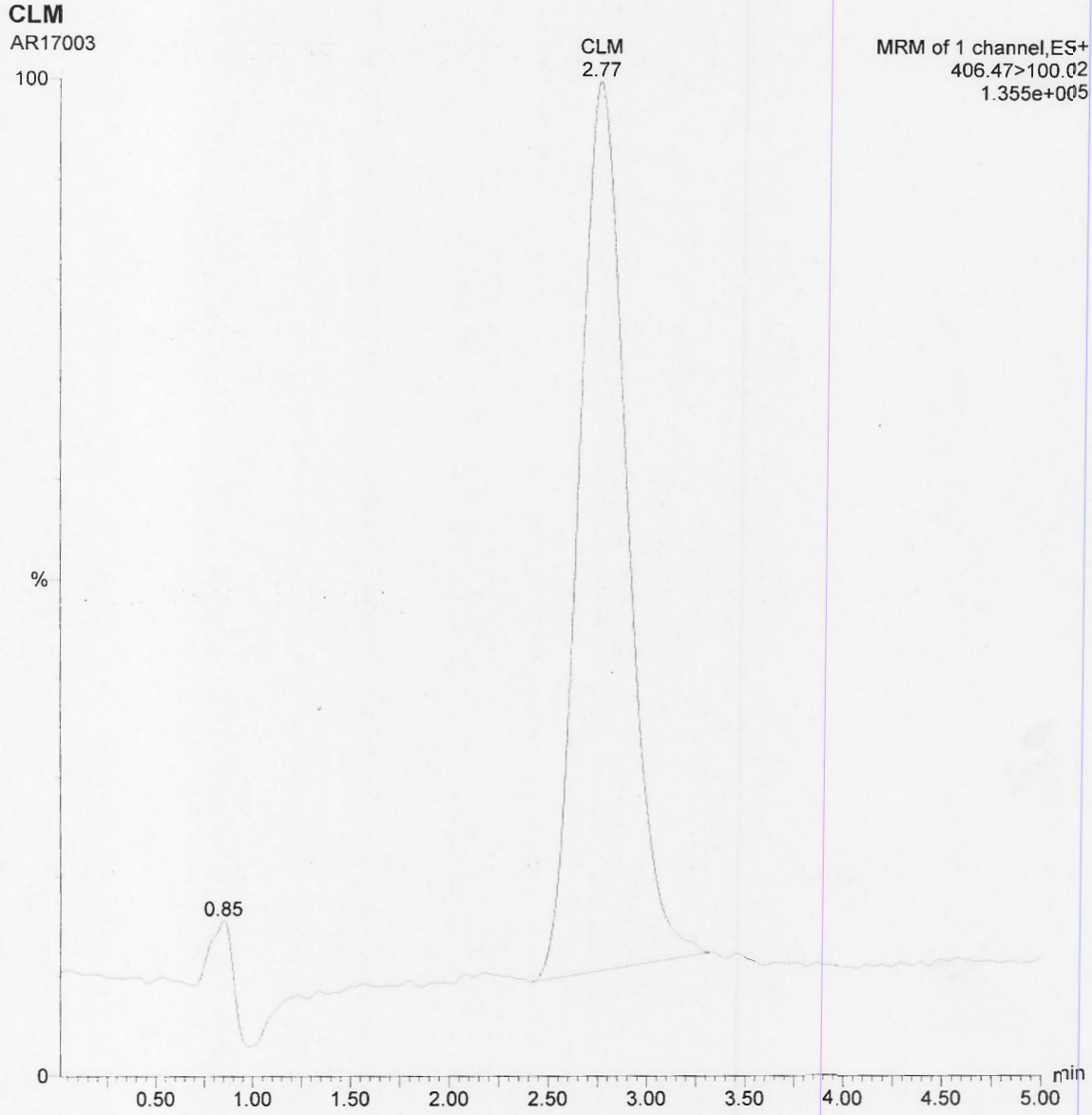
Name: AR17002, Date: 27-Feb-2015, Time: 15:15:59, ID: W2, Description: ClmC Std 1.00 ng/mL



#	Name	Area	Conc.	RT.	Response	Primary Flags
1	CLM	16768	1.1	2.76	16770	bb

Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

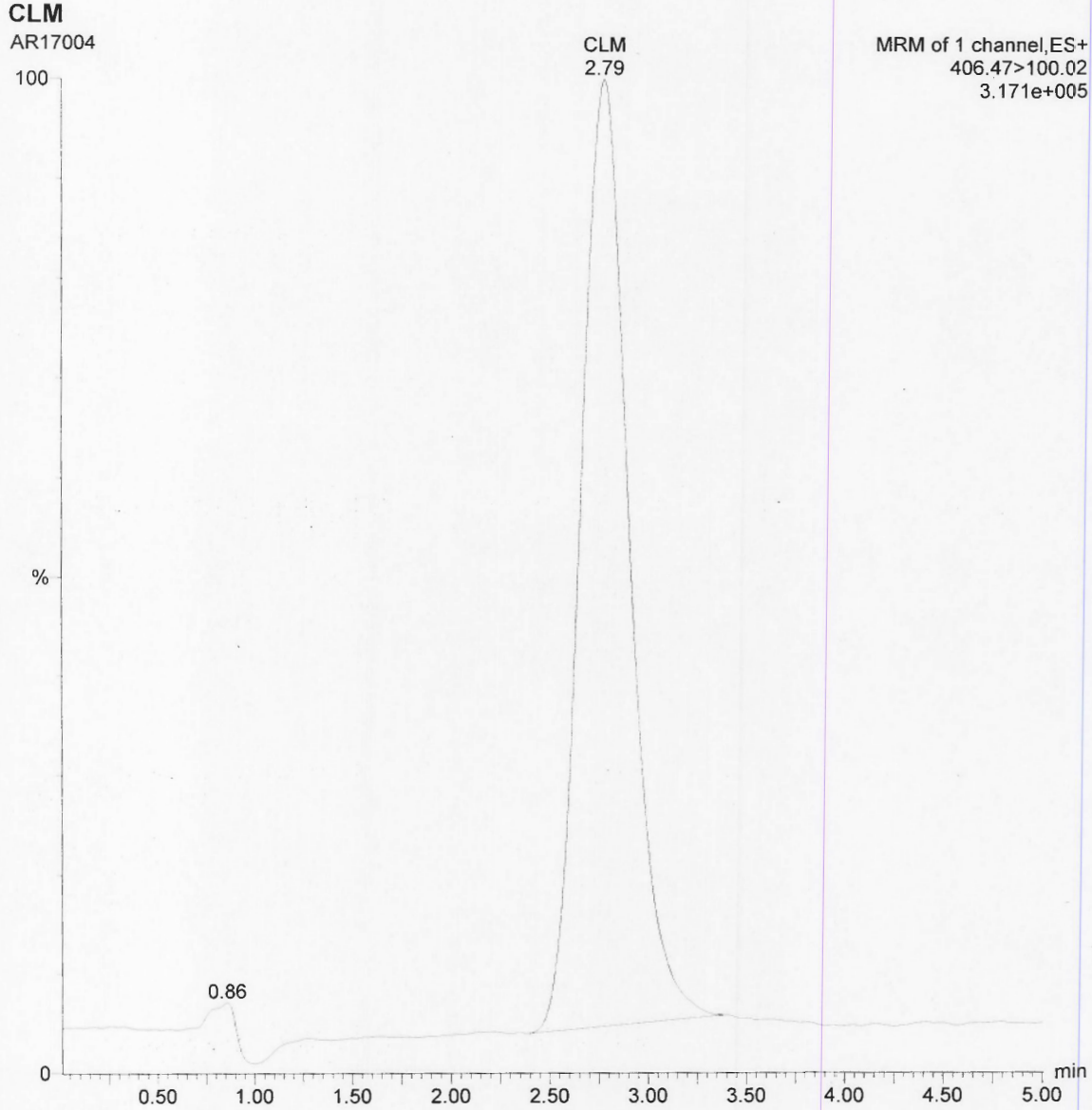
Name: AR17003, Date: 27-Feb-2015, Time: 15:22:38, ID: W3, Description: CLM Std 2.00 ng/mL



#	Name	Area	Conc.	RT.	Response	Primary Flags
1	CLM	34676	2.1	2.77	34680	bb

Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

Name: AR17004, Date: 27-Feb-2015, Time: 15:29:18, ID: W4, Description: ClmC Std 5.00 ng/mL

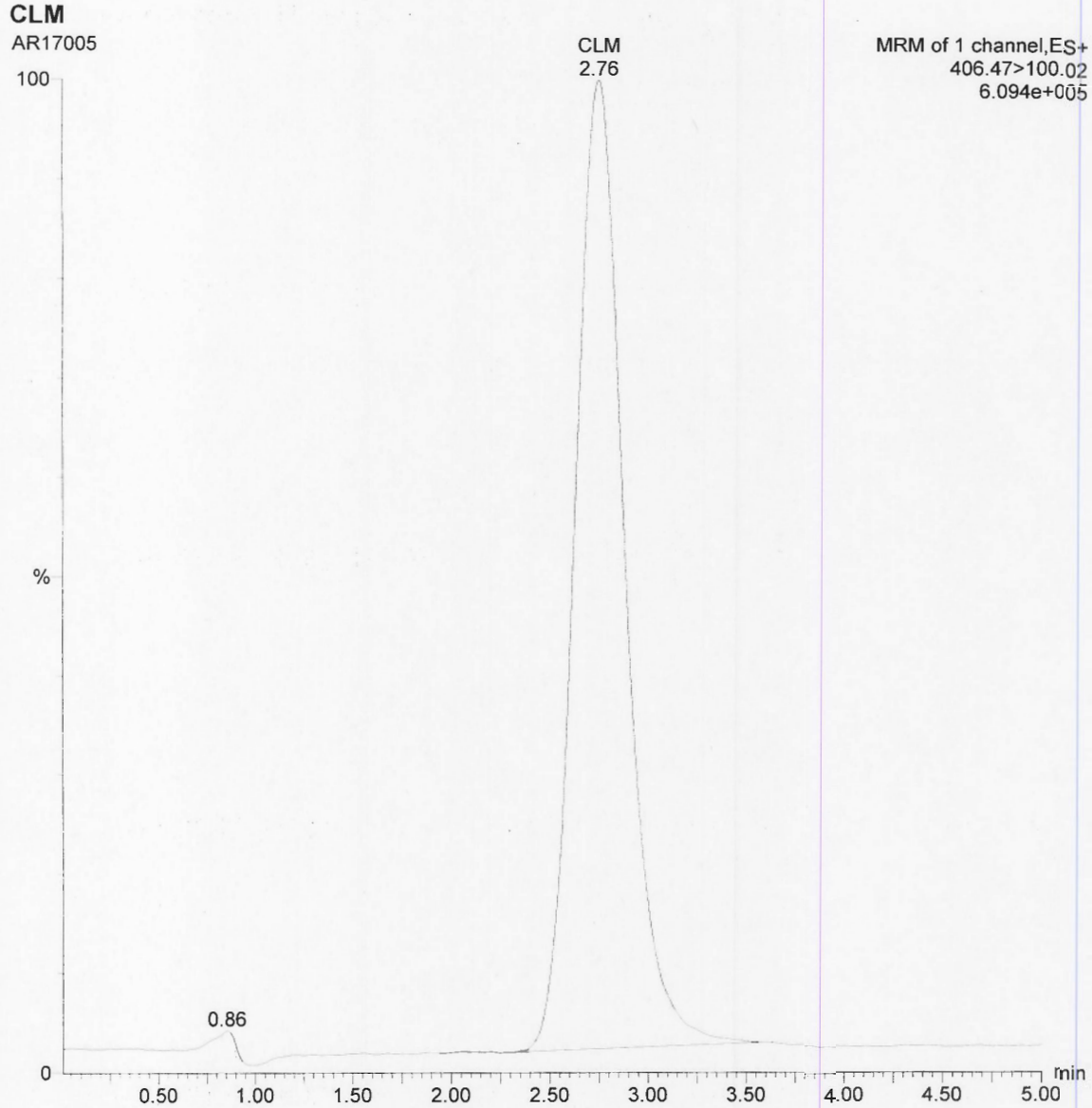


#	Name	Area	Conc.	RT.	Response	Primary Flags
1	CLM	87325	5.0	2.79	87330	bb



Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

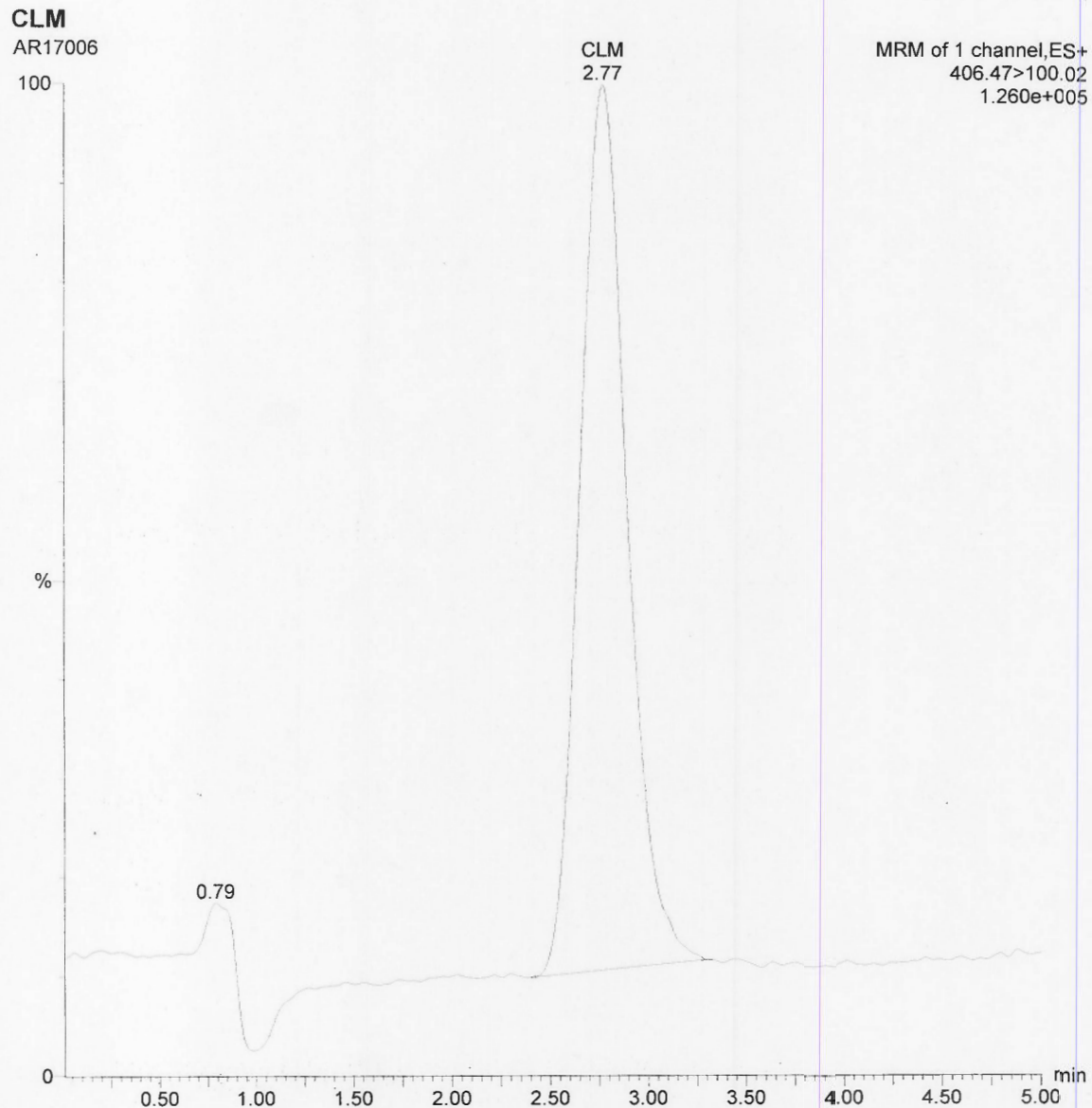
Name: AR17005, Date: 27-Feb-2015, Time: 15:35:58, ID: W5, Description: ClmC Std 10.00 ng/mL



# Name	Area	Conc.	RT.	Response	Primary Flags
1 CLM	176387	9.7	2.76	176400	cb

Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

Name: AR17006, Date: 27-Feb-2015, Time: 15:42:39, ID: , Description: CLM Std 2.00 ng/mL

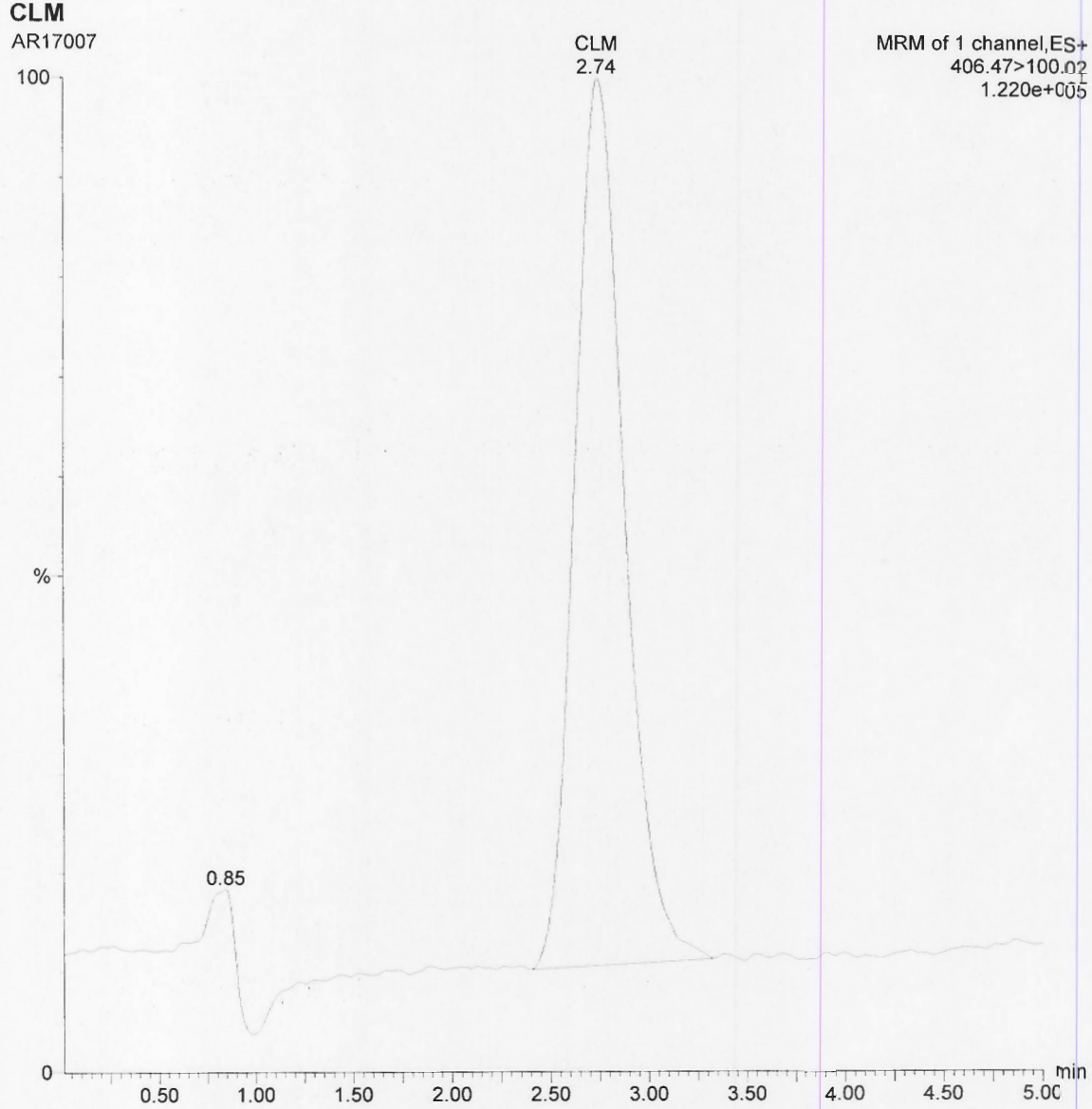


MRM of 1 channel, ES+  
406.47>100.02  
1.260e+005

# Name	Area	Conc.	RT.	Response	Primary Flags
1 CLM	31601	1.9	2.77	31600	tb

Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

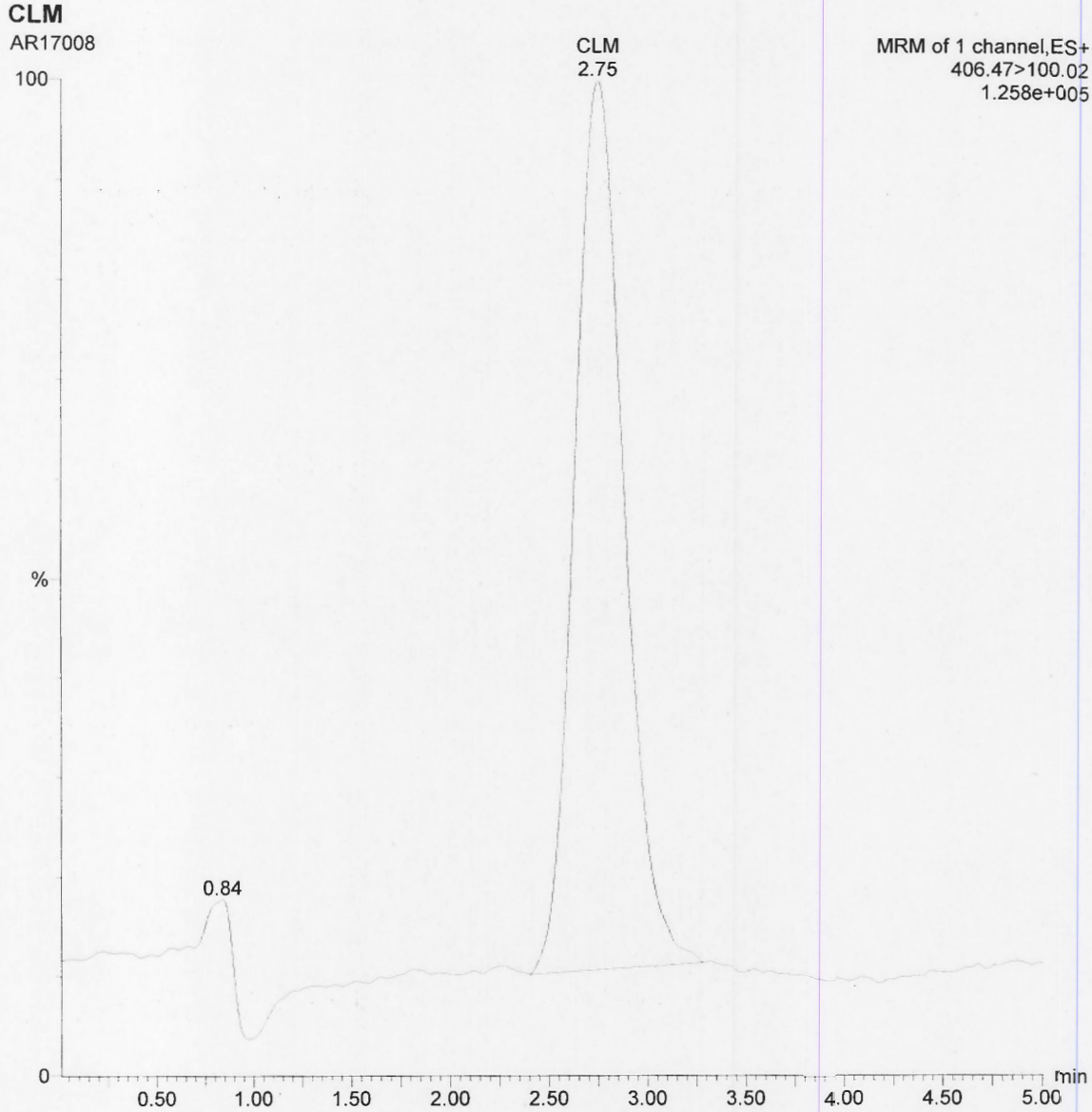
Name: AR17007, Date: 27-Feb-2015, Time: 15:49:18, ID: , Description: ClmC-Std 2.00 ng/mL



# Name	Area	Conc.	RT	Response	Primary Flags
1 CLM	32083	1.9	2.74	32080	bb

Dataset:   
Signature: At Friday, February 27, 2015 16:04:08 China Standard Time  
By   
Reason processing data  
Printed: At Saturday, February 28, 2015 10:13:49 China Standard Time  
By

Name: AR17008, Date: 27-Feb-2015, Time: 15:55:57, ID: , Description: ClmC Std 2.00 ng/mL



MRM of 1 channel, ES+  
406.47>100.02  
1.258e+005

# Name	Area	Conc.	RT.	Response	Primary Flags
1 CLM	32927	2.0	2.75	32930	bb



AR17 Clomiphene Citrate

HPLC Condition

Solvent A: 0.1%FA in Water

Solvent B: 0.1%FA in Acetonitrile

Mobile Phase: Solvent A:Solvent B (40:60, v/v)

Flow Rate (mL/min): 0.300

Column: Waters Atlantis dC18, 100 × 2.1 mm, 5 μm, Column

	Calculated Conc.(ng/mL)	Mean Actual Conc.(ng/mL)	Theoretical Conc.(ng/mL)	Assay Percent %
S1-1	1.92	1.95	2.00	97.5
S1-2	1.95			
S1-3	1.99			