

Instrument Report

Direct Amplification: Simplexa COVID-19 Direct_1 Segment Report

Assay Name	Simplexa COVID-19 Direct.2	Run Name	Run 12-09-2020 At 2140
Test By	ICS Administrator	Report By	ICS Administrator
Lot Number	9537N	Lot Expiration	03/2021
Instrument	1D0278	Software	2.1.0.4
Disc ID	B70410918	Test Date	12/9/2020 9:40:52 PM

Ct Values

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	QC Statement/Notes
1	7017127782	Unknown	0	0	31.2	
2	7017133267	Unknown	32.2	0	30.6	
3	7017134575	Unknown	0	0	30.8	
4	7017136074	Unknown	0	0	31.5	
5	7017136081	Unknown	0	32.7	0	
6	7017136078	Unknown	0	0	32.5	
7	7017136104	Unknown	0	0	31.2	
8	7017136087	Unknown	0	0	32.8	

Results

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	Interpretation	QC Statement / Notes
1	7017127782	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
2	7017133267	Unknown	S gene: Detected	ORF1ab: Not Detected	RNA IC: Valid	Positive	
3	7017134575	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
4	7017136074	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
5	7017136081	Unknown	S gene: Not Detected	ORF1ab: Detected	RNA IC: Valid	Positive	
6	7017136078	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
7	7017136104	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
8	7017136087	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	

Batch Report (strip map)

PCR Strip Map

Strip A wells 1-8	Strip B wells 9-16	Strip C wells 17-24
1	9 * Positive * (27.9, 28.7)	17
2	10 Negative	18
3	11 Negative	19
4	12 Negative	20
5	13 Negative	21
6	14 Negative	22
7	15 * Positive * (20.1, 20.2)	23
8	16 * Positive * (28.9, 29.6)	24

12-10-20

Direct Amplification: Simplexa COVID-19 Direct_1 Segment Report

Assay Name	Simplexa COVID-19 Direct 2	Run Name	Run 01-14-2021 At 2212
Test By	ICS Administrator	Report By	ICS Administrator
Lot Number	9545N	Lot Expiration	04/2021
Instrument	1D0278	Software	2.1.0.4
Disc ID	B70264815	Test Date	1/14/2021 10:12:35 PM

Ct Values

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	QC Statement/Notes
1	7017599742	Unknown	0	0	32.4	TR JH
2	7017601967	Unknown	0	0	31.7	TR JH
3	7017601959	Unknown	0	0	34.2	TR JH
4	7017601624	Unknown	0	0	32.3	TR JH
5	7017601563	Unknown	0	0	31.9	TR JH
6	7017597176	Unknown	22.5	23.4	31.5	TR JH
7	7017599325	Unknown	0	0	31.3	TR JH
8	7017597198	Unknown	0	0	31.1	TR JH

Primary Secondary Reviewer

Results

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	QC Statement / Notes
1	7017599742	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
2	7017601967	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
3	7017601959	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
4	7017601624	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
5	7017601563	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
6	7017597176	Unknown	S gene: Detected	ORF1ab: Detected	RNA IC: Valid	Positive
7	7017599325	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
8	7017597198	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative

Both Primary and Secondary Reviewers must initial on every patient test line indicating that they have reviewed each result and that result matches the Batch list and Epic result entry.

PCR Strip Map

Strip A wells 1-8	Strip B wells 9-16	Strip C wells 17
1 [Barcode] 20U-344SR0648 7017137515	9 * Positive * (27.9, 28.7)	17
2 [Barcode] 20U-344SR0646 7017137513	10 Negative	18
3 [Barcode] 20U-344SR0647 7017137514	11 Negative	19
4 [Barcode] 20U-344SR0616 7017136854	12 Negative	20
5 [Barcode] 20U-344SR0688 7017135738	13 Negative	21
6 [Barcode] 20U-344SR0618 7017136898	14 Negative	22
7 [Barcode] 20U-344SR0615 701713773	15 * Positive * (20.1, 20.2)	23
8 [Barcode] 20U-344SR0657 7017137767	16 * Positive * (28.9, 29.6)	24

Direct Amplification: Simplexa COVID-19 Direct_1 Segment Report

Assay Name	Simplexa COVID-19 Direct.2	Run Name	Run 12-10-2020 At 0029
Test By	ICS Administrator	Report By	ICS Administrator
Lot Number	9566N	Lot Expiration	04/2021
Instrument	1D0278	Software	2.1.0.4
Disc ID	B70421908	Test Date	12/10/2020 12:30:08 AM

Ct Values

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	QC Statement/Notes
1	7017137515	Unknown	27.9	28.7	30.4	
2	7017137513	Unknown	0	0	29.9	
3	7017137514	Unknown	0	0	32.1	
4	7017136854	Unknown	0	0	30.5	
5	7017136730	Unknown	0	0	30.9	
6	7017136890	Unknown	0	0	31.4	
7	701713773	Unknown	20.1	20.2	35.9	
8	7017137767	Unknown	28.9	29.6	31.3	

Results

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	Interpretation	QC Statement / Notes
1	7017137515	Unknown	S gene: Detected	ORF1ab: Detected	RNA IC: Valid	Positive	
2	7017137513	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
3	7017137514	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
4	7017136854	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
5	7017136730	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
6	7017136890	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
7	701713773	Unknown	S gene: Detected	ORF1ab: Detected	RNA IC: Valid	Positive	
8	7017137767	Unknown	S gene: Detected	ORF1ab: Detected	RNA IC: Valid	Positive	

Printed Result page should match the results on the Batch Page (strip map).

PCR Strip Map

Strip B wells 9-16

9	<p>20112778 30131507346 481 5/11/1975 201-344SR0204 7017127782 COVID-19 IN Nasopharyngeal Swab</p> <p><i>1 target Pos - reported on lead</i></p>
10	<p>20113327 30131024431 267 4/14/1992 201-344SR0427 7017133267 COVID-19 IN Nasopharyngeal Swab</p> <p><i>neg</i></p>
11	<p>20113457 30131030203 367 3/18/1990 201-344SR0495 7017134575 COVID-19 IN Nasopharyngeal Swab</p> <p><i>neg</i></p>
12	<p>20113607 30131047517 131 3/7/2007 201-344SR0502 7017136074 COVID-19 IN Nasopharyngeal Swab</p> <p><i>neg</i></p>
13	<p>20113608 30131047502 131 4/20/1990 201-344SR0504 7017136081 COVID-19 IN Nasopharyngeal Swab</p> <p><i>1 target Pos Repeat on patient</i></p>
14	<p>20113609 30131047537 131 3/5/2008 201-344SR0503 7017136078 COVID-19 IN Nasopharyngeal Swab</p> <p><i>neg</i></p>
15	<p>20113610 30131047520 131 5/19/2020 201-344SR0506 7017136104 COVID-19 IN Nasopharyngeal Swab</p> <p><i>neg</i></p>
16	<p>20113611 30131047506 131 12/15/2006 201-344SR0505 7017136087 COVID-19 IN Nasopharyngeal Swab</p> <p><i>neg</i></p>

Direct Amplification: Simplexa COVID-19 Direct_1 Segment Report

Assay Name	Simplexa COVID-19 Direct.2	Run Name	Run 12-09-2020 At 2140
By	ICS Administrator	Report By	ICS Administrator
Lot Number	9537N	Lot Expiration	03/2021
Instrument	1D0278	Software	2.1.0.1
Disc ID	B70410918		

Wedge	Sample Id	Sample Type	S	O	IC
1	7017127782	Unknown	0	0	31.2
2	7017133267	Unknown	32.2	0	30.6
3	7017134575	Unknown	0	0	30.8
4	7017136074	Unknown	0	0	31.5
5	7017136081	Unknown	0	32.7	0
6	7017136078	Unknown	0	0	32.5
7	7017136104	Unknown	0	0	31.2
8	7017136087	Unknown	0	0	32.8

Resulted incorrectly, mixed patients.

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	Interpretation	QC Statement / Notes
1	7017127782	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
2	7017133267	Unknown	S gene: Detected	ORF1ab: Not Detected	RNA IC: Valid	Positive	
3	7017134575	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
4	7017136074	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
5	7017136081	Unknown	S gene: Not Detected	ORF1ab: Detected	RNA IC: Valid	Positive	
6	7017136078	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
7	7017136104	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
8	7017136087	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	