Instrument 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	870410918	Test Date	12/9/2020 9:40:52 PM

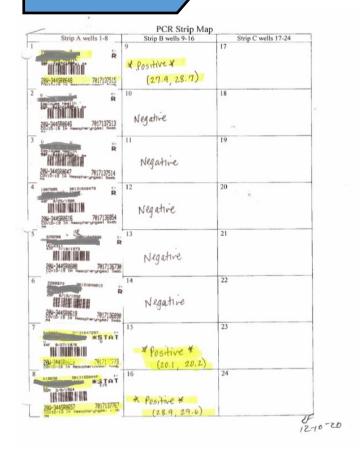
Ct Values

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	a
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	70171277 82	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
2	70171332 67	Unknown	S gene: Detected	ORF1ab: Not Detected	RNA IC: Valid	Positive	
3	70171345 75	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
4	70171360 74	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
5	70171360 81	Unknown	S gene: Not Detected	ORF1ab Detected	RNA IC: Valid	Positive	
6	70171360 78	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
7	70171361 04	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
8	70171360 87	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	

Batch Report (strip map)



Direct Amplification: Simplexa COVID-19 Direct_1 Segment Report

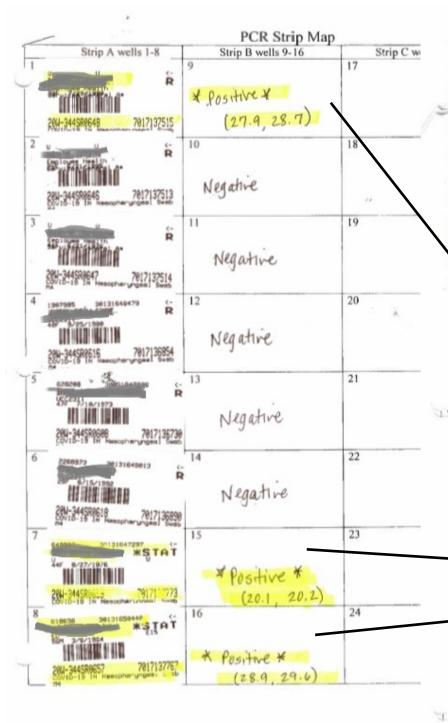
.ssay Name	Simplexa COVID-19 Direct 2	Run Name	Run 01-14-2021 At 2212	
Test By	ICS Administrator	Report By	ICS Administrator	
Lot Number	9545N -	Lot Expiration	04/2021	
Instrument	1D0278	Software	2.1.0.4	
Disc ID	B70264815	Test Date	1/14/2021 10:12:35 PM	

Ct Values

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	QC Stater	nent/Notes	
1	7017599742	Unknown	0	0	32.4	R	Lut	
2	7017601967	Unknown	0	0	31.7	TE	du	
3	7017601959	Unknown	0	0	34.2	TR	2H	
4	7017601624	Unknown	0	0	32 3	TR	ZH	
5	7017601563	Unknown	0	0	31.9	TR	ZH	
6	7017597176	Unknown	22.5	23.4	31.5	TR	th	
7	7017599325	Unknown	0	0	31.3	TR	dH	
8	7017597198	Unknown	0	0	31.1	TR	2H	
Result	S				Р	rimary	Seconda	ry Review

1.00	100 C					
Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	QC Statement Interpretation / Notes
1	70175997 42	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
2	70176019 67	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
3	701 76019 59	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
4	70176016 24	Unknown	S gene Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
5	70176015 63	Unknown	S gene Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
6	70175971 76	Unknown	S gene: Detected	ORF1ab Detected	RNA IC: Valid	Positive
7	70175993 25	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
8	70175971 98	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.



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	870421908	Test Date	12/10/2020 12:30:08 AM	

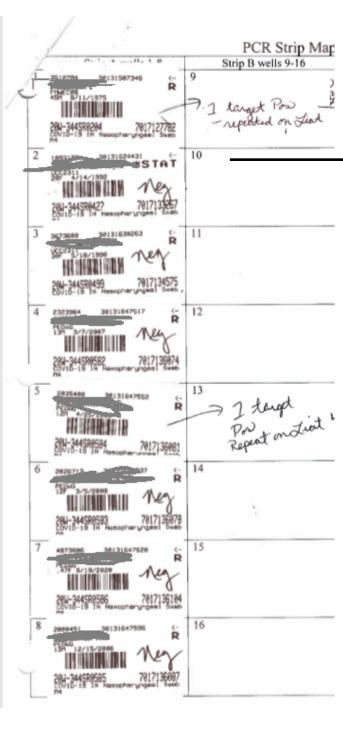
Ct Values

Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	OC 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	70171377.3	Unknown	20.1	20.2	35.9	
8	7017137767	Unknown	28.9	29.6	31,3	

Results

Wedge	Sample	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	Interpretation	QC Statement / Notes
1	70171375 15	Unknown	Sigene: Detected	ORF1ab. Detected	RNA IC: Valid	Positive	
2	70171375 13	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
3	70171375 14	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
4	70171368 54	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
5	70171367 30	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
6	70171368 90	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative	
7	70171377 73	Unknown	S gene: Detected	ORF1ab Detected	RNA IC: Valid	Positive	
8	70171377 67	Unknown	S gene Detected	ORF1ab Detected	RNA IC: Valid	Positive	

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



ssay Name	Simplexa 0	OVID-19 Direct.	2		Run Name	Run 12-09-2020 At 2140
t By	ICS Admin	istrator			Report By	ICS Administrator
ot Number	9537N				Lot Expiration	03/2021
rument	1D0278				Rothunso	2104
Disc ID	87041091	B70410918 Resulted				rectly,
Ct Values	3		m	ixed p	atients	i
Wedge S	Sample Id	Sample Typ	e (es
1 70	017127782	Unknown	0	0	31.2	
2 70	017133267	Unknown	32.2	0	30.6	
3 7	017134575	Unknown	0	0	30.8	
4 7	017136074	Unknown	0	0	31.5	
5 7	017136081	Unknown	0	32.7	0	0
6 7	017136078	Unknown	0	0	32.5	à.
7 7	017136104	Unknown	0	0	31.2	
	017136087	Unknown	0	0	32.8	

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Wedge	Sample Id	Sample Type	S gene (FAM)	ORF1ab (JOE)	RNA IC (Q670)	QC Statemen Interpretation / Notes
1	70171277 82	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
2	70171332 67	Unknown	S gene: Detected	ORF1ab: Not Detected	RNA IC: Valid	Positive
3	70171345 75	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
4	70171360 74	Unknown	S gene: Not Detected	ORE1ab: Not Detected	RNA.IC. Valid	Negative
5	70171360 81	Unknown	S gene: Not Detected	ORF1ab Detected	RNA IC: Valid	Positive
6	70171360 78	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
7	70171361 04	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative
8	70171360 87	Unknown	S gene: Not Detected	ORF1ab: Not Detected	RNA IC: Valid	Negative