DATA PROOF POINT
SALIVA vs. SWAB

SDNA -1000 SALIVA COLLECTION DEVICE

SPECTRUM™
SOLUTIONS

EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

RUCDR Infinite Biologics COVID-19 QPCR Testing

SPECTRUM SDNA -1000 SALIVA COLLECTION DEVICE

Swab vs. Saliva Biosamples

EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

SPECTRUM™ SOLUTIONS

STUDY DESIGN

- 50 Subjects with KNOWN COVID-19 status (Positive and Negative)
- Independently verified clinical status
- All in-patients across 3 hospitals
- Swab collection in Universal Transfer Media
- Saliva collection in Spectrum self-collection device

Sampled at same time

- All samples processed within 72hrs of collection
- Same volume of UTM and saliva input for nucleic acid extraction (300ul)
- Same volume of extraction product (5ul) used for QPCR detection

EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

EUA FDA & STATE CERTIFICATIONS

EUA#200090
EUA#200091

- EUA submission for both swab and saliva collection
  - Copan/Puritan/Hologic swabs
  - **Spectrum SDNA-1000 saliva collection device**
  - Automated Chemagen Viral DNA/RNA bead-based extraction chemistry
  - ThermoFisher TaqPath COVID-19 detection kit (20ul)
  - Perkin Elmer Coronavirus nucleic acid detection kit qPCR (20ul)
  - Thermo QuantStudio (384), Via7 (384) cyclers
- NJ DOH approval received
- NY DOH approval received
- *Testing initiated across hospitals, telehealth, healthcare networks*

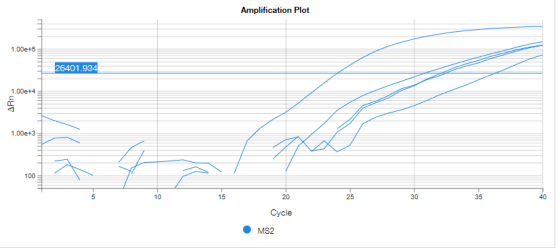
EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

SPECTRUM™ SOLUTIONS

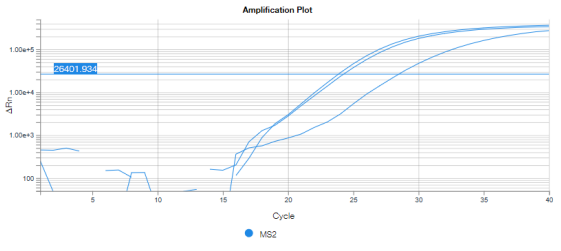
SALIVA

Internal Control Spike

MS2 - Positive

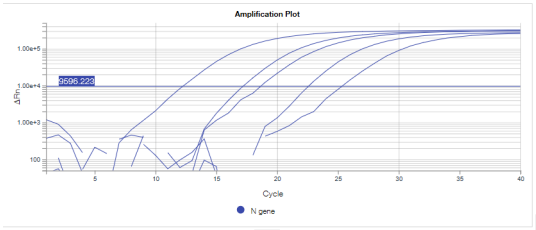


MS2 - Negative

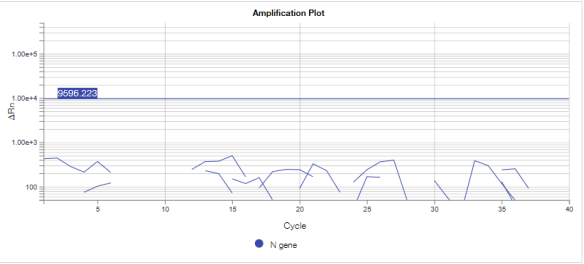


N Gene

N- Positive

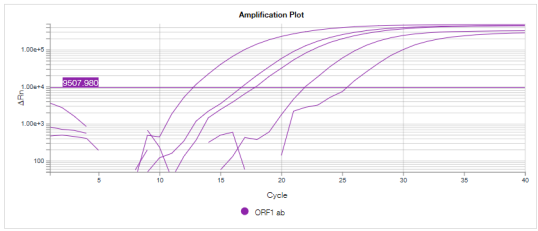


N- Negative

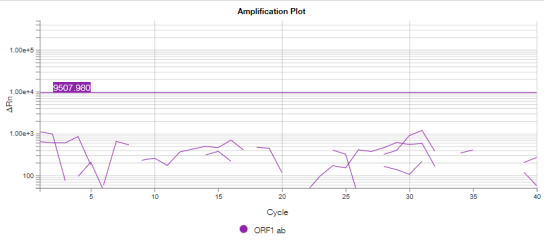


ORF1ab

ORF1 ab Positive

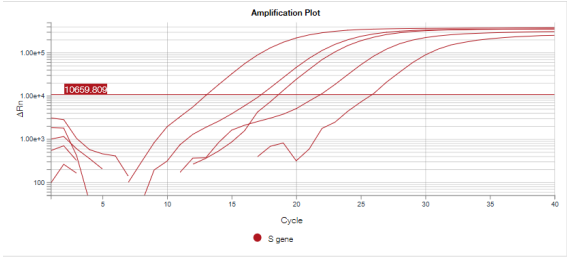


ORF1 ab Negative

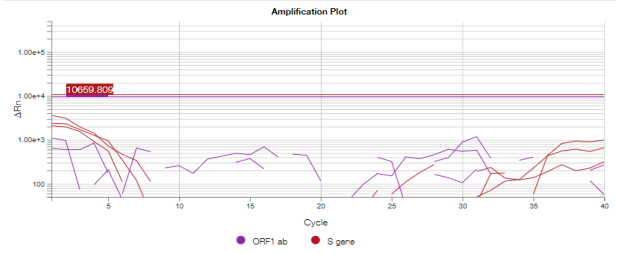


S Gene

S - Positive



S-Negative



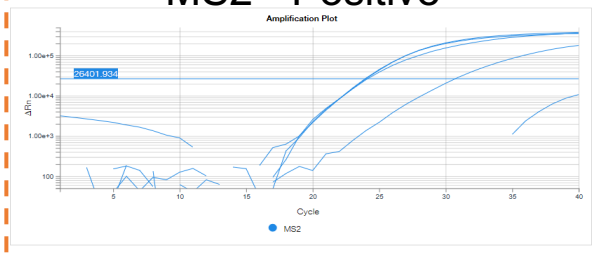
EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

SPECTRUM™ SOLUTIONS

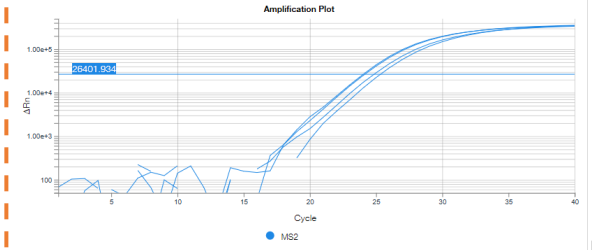
SWABS

Internal Control Spike

MS2 - Positive

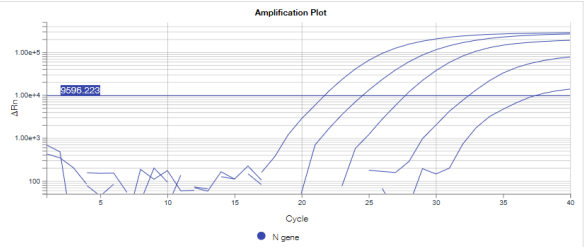


MS2 - Negative

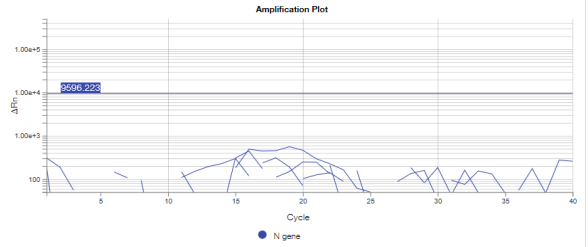


N Gene

N- Positive

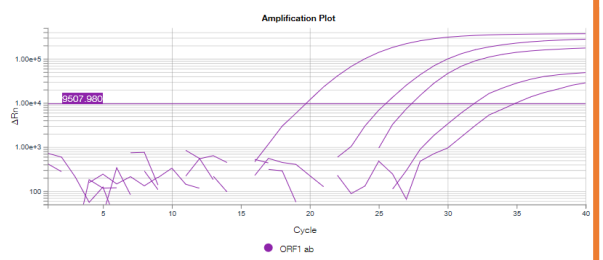


N- Negative

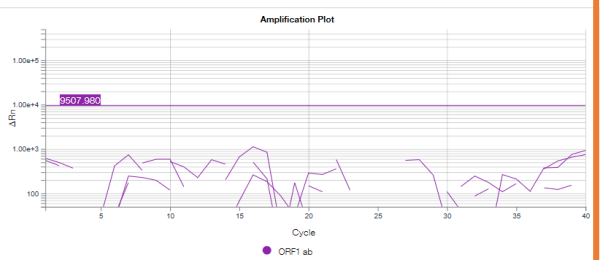


ORF1ab

ORF1 ab Positive

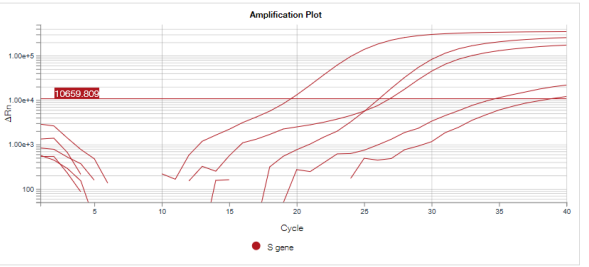


ORF1 ab Negative

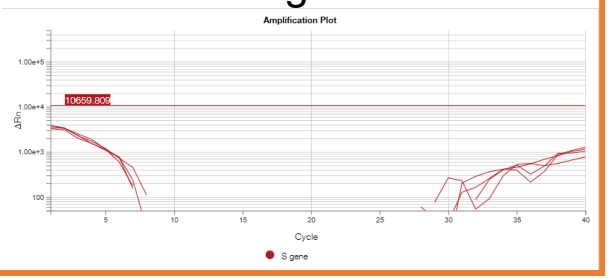


S Gene

S - Positive



S-Negative

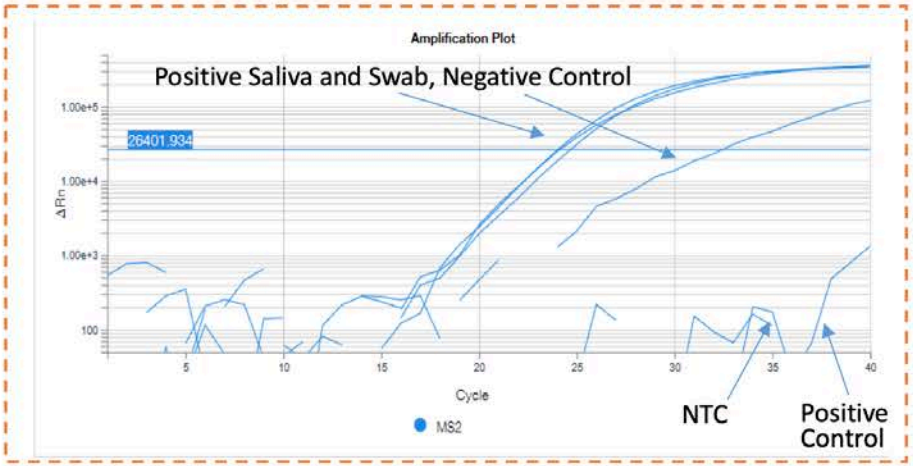


EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

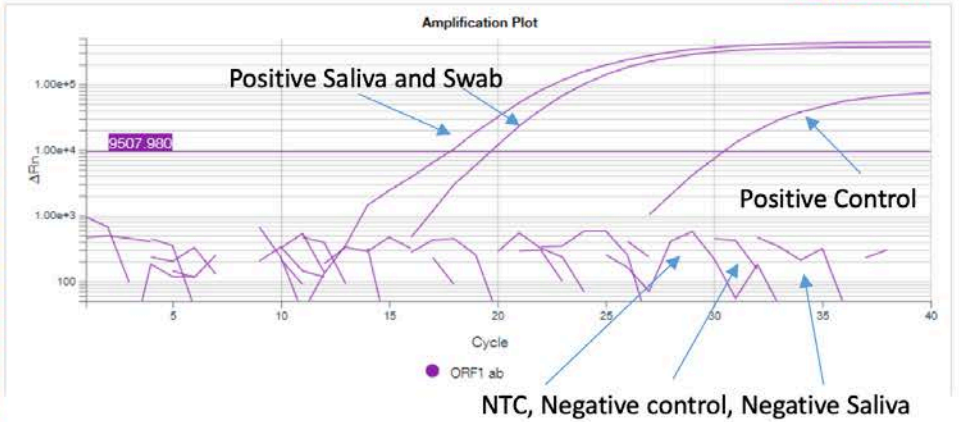
SPECTRUM™ SOLUTIONS

POSITIVE & NEGATIVE SALIVA, POSITIVE SWAB, POSITIVE CONTROL, NEGATIVE CONTROL, NTC

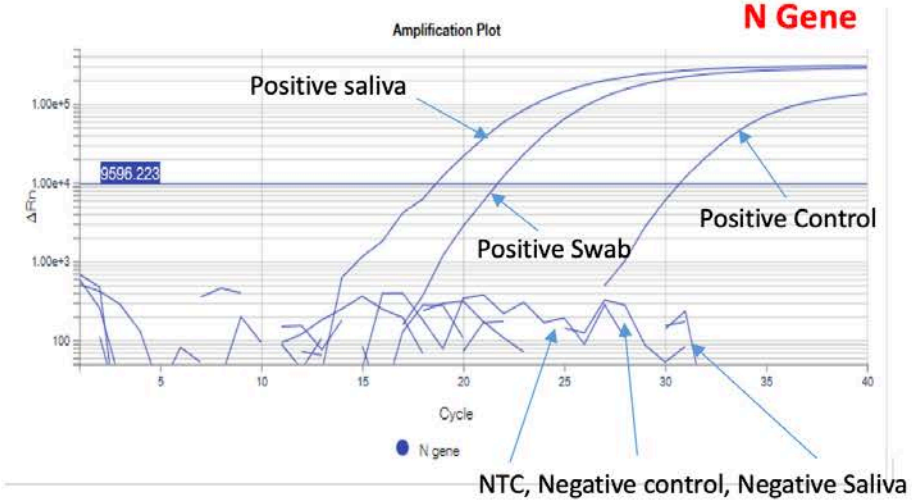
Internal Control Spike



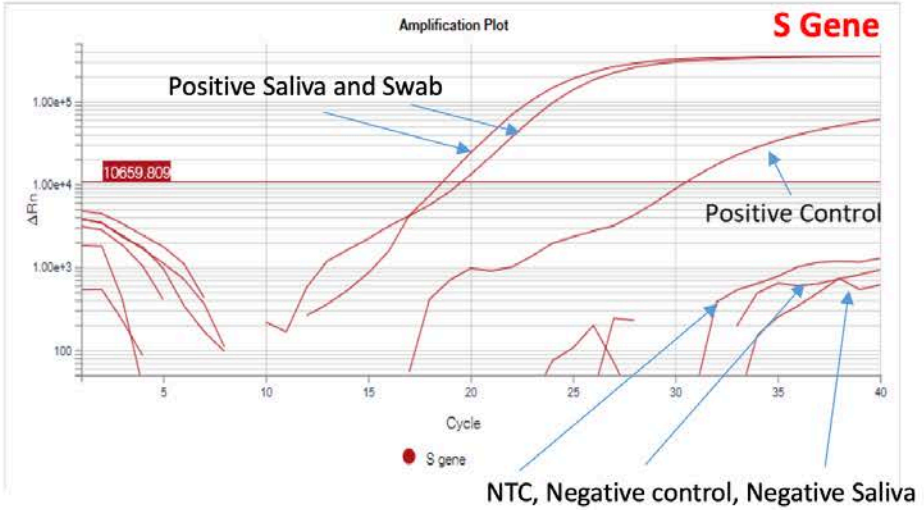
ORF1ab



N Gene



S Gene

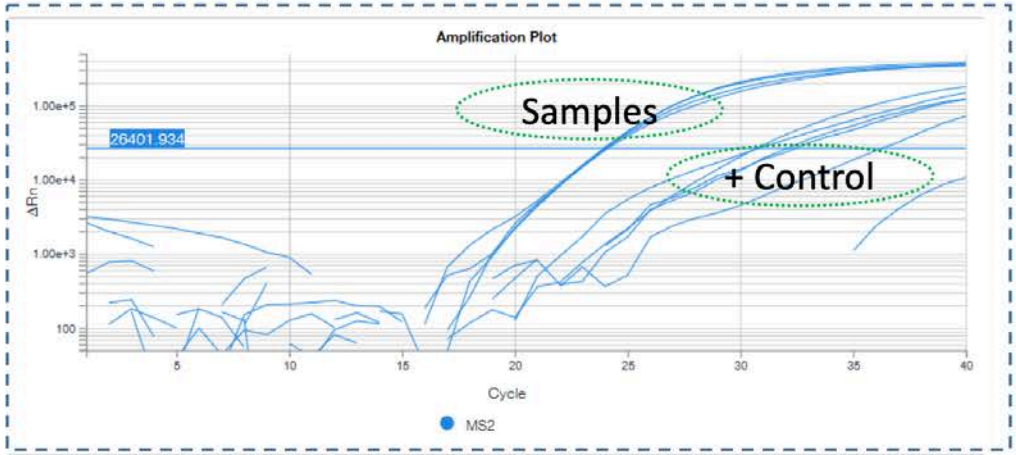


EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

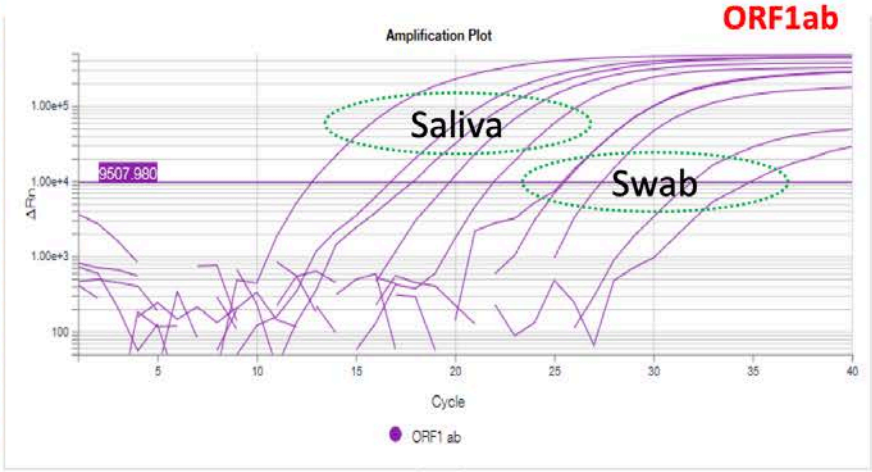
SPECTRUM™ SOLUTIONS

POSITIVE SALIVA & SWAB

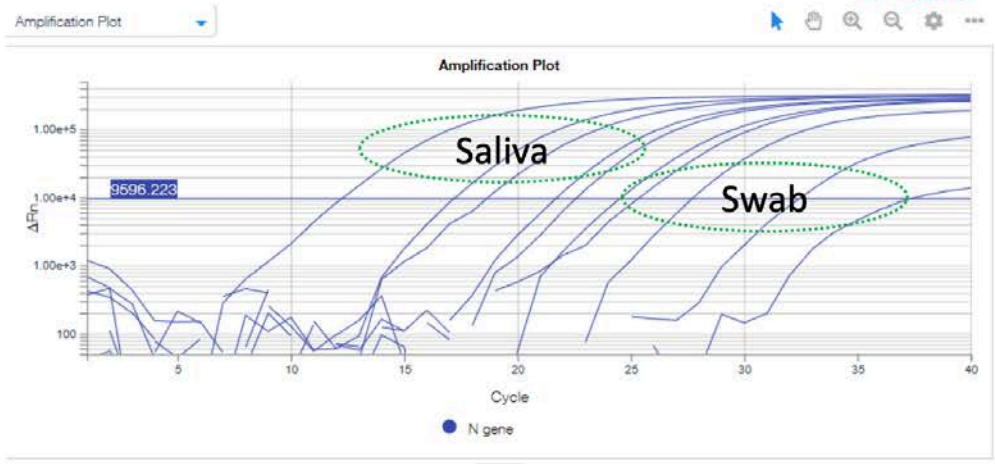
Internal Control Spike



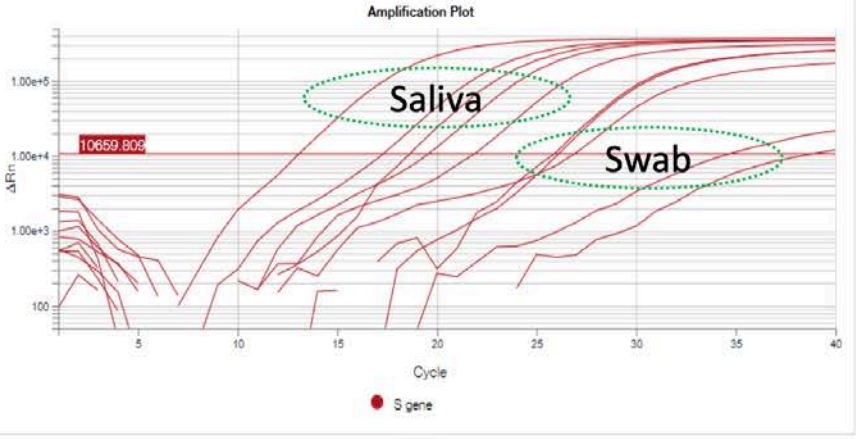
ORF1ab



N Gene



S Gene



EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

SPECTRUM™ SOLUTIONS

DATA SUMMARY

- 100% Positive and Negative agreement for contrived samples
- 100% Positive agreement for 1-2x LoD (4 copies/ml)
- 100% Agreement on all clinical samples
- 100% Agreement on swab vs. saliva results in clinical samples

Sample Test Interpretation				
IC/MS2: JUN	**N Gene /VIC (Ct)**	**ORF1ab Gene/FAM (Ct)**	**S Gene/ABY (Ct)**	**Result**
<37	Undetermined	Undetermined	Undetermined	Negative
<37	Two or Three targets are <37			Positive
<37	One Target is <37			Re-Test; If re-test is the same, then Inconclusive
Undetermined	Undetermined	Undetermined	Undetermined	Re-Test; If re-test is the same, then Inconclusive

Control Requirements				
	IC/MS2: JUN	**N Gene /VIC (Ct)**	**ORF1ab Gene/FAM (Ct)**	**S Gene/ABY (Ct)**
Negative Control	≤40	Undetermined	Undetermined	Undetermined
Positive Control	Undetermined	Three targets are <37		
NTC	Undetermined	Undetermined	Undetermined	Undetermined

EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

SPECTRUM™ SOLUTIONS

DATA SUMMARY

Contrived Sample Validation

ThermoFisher COVID-19 TaqPath Kit			
Observed Result	Expected Result		
	Positive	Negative	Total
Positive	30	0	30
Negative	0	30	30
Total			60
95% Confidence Interval			
Positive % Agreement for 1-2x LoD			100%
Positive % Agreement for other concentrations			100%
Negative % Agreement			100%

Clinical Sample Validation

ThermoFisher New Coronavirus Nucleic Acid Detection Kit			
Observed Result	Expected Result		
	Positive (NP/Sal)	Negative (NP/Sal)	Total
Positive	30/30	0/0	30/30
Negative	0/0	30/30	30/30
Total			120
95% Confidence Interval			
Positive % Agreement for Clinical Patient NP vs Saliva			100%
Negative % Agreement			100%

EUA#200090 | EUA#200091 © All Rights Reserved Spectrum Solutions | MARCH 2020

Discover your advantage.