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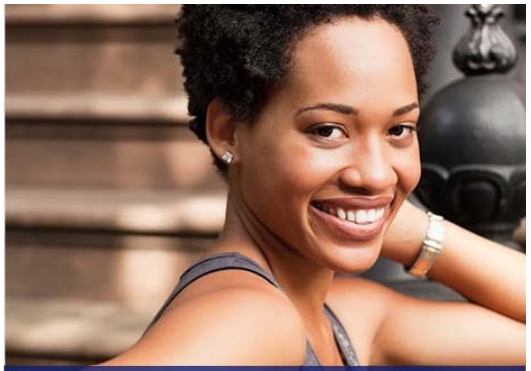
Our solutions enable women to live their best lives every day

BREAST & SKELETAL HEALTH SOLUTIONS



GYN SURGICAL SOLUTIONS

DIAGNOSTIC SOLUTIONS

Saving lives. Improving lives. Enhancing lives.

HOLOGIC®

Every day, every diagnosis is a defining moment that transforms lives.

Hologic touches the lives of

50M+

In Europe, Middle East & Africa alone, furthering diagnosis and treatment to help save lives.

PRE-01176-GBR-EN Rev 001

Expertise in Public Health and Population Based Screening

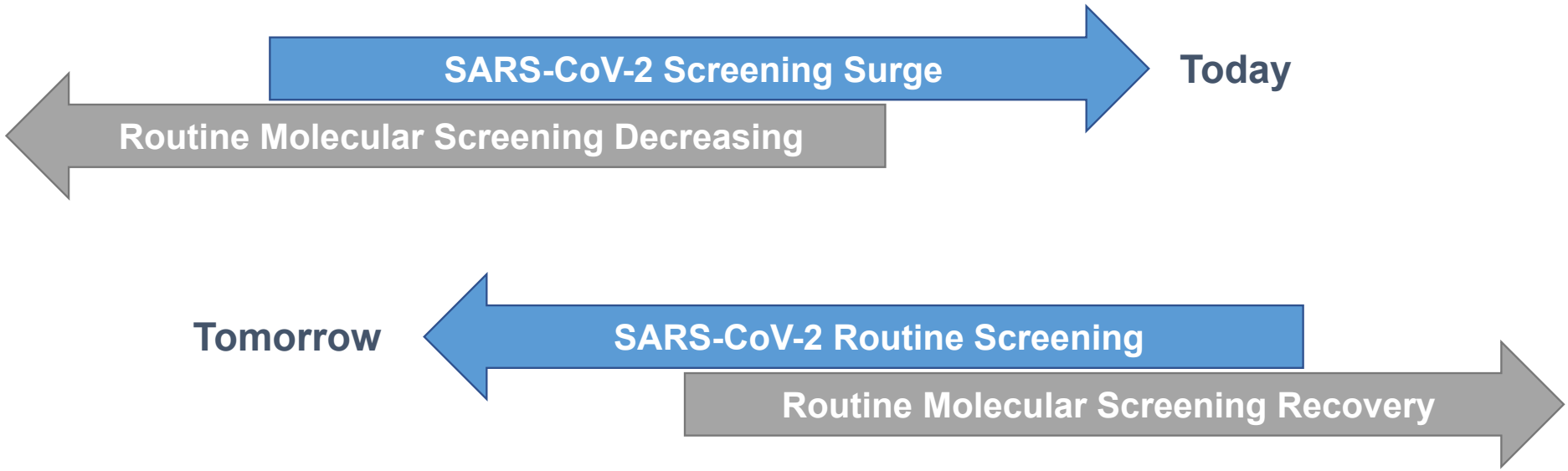
Scalable Molecular Diagnostic Solutions

Our innovative molecular solutions are used routinely in laboratories across the globe, helping laboratories to deliver accurate and timely results to clinicians and patients.

Market Leading solutions for Cervical Cancer Screening, Sexually Transmitted Infections, Viral Loads, MRSA, Respiratory Infections

Flexibility Is Required with Testing Paradigm Recovery

Different requirements for molecular solutions as we move towards recovery



The fully-automated Hologic Panther instrument brings workflow flexibility, high-throughput and extensive molecular menu to a single laboratory platform.

Total walkaway molecular automation on a single instrument

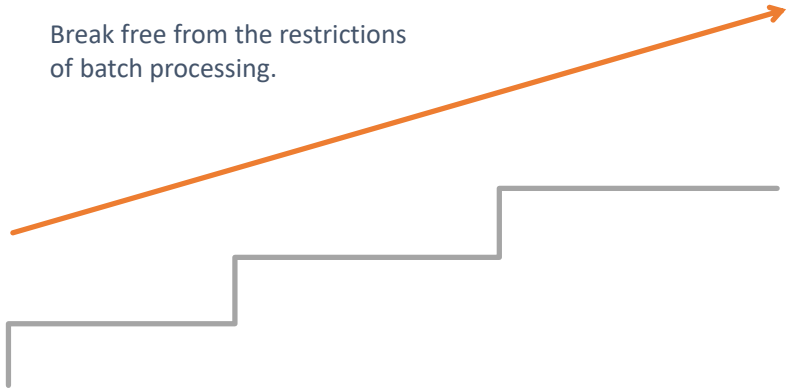
HOLOGIC®

Unparalleled workflow flexibility

HOLOGIC®

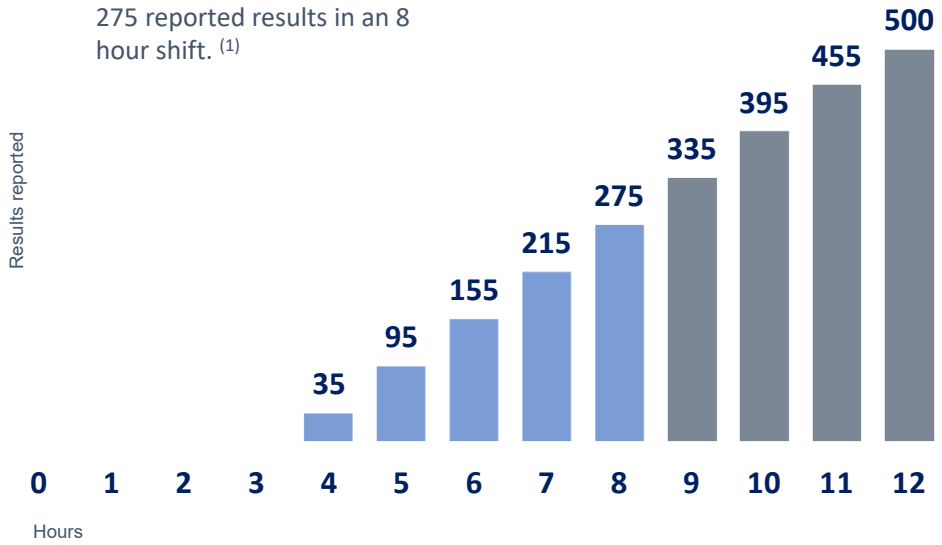
Continuous, random access loading

Break free from the restrictions of batch processing.



High throughput system

275 reported results in an 8 hour shift. [1]

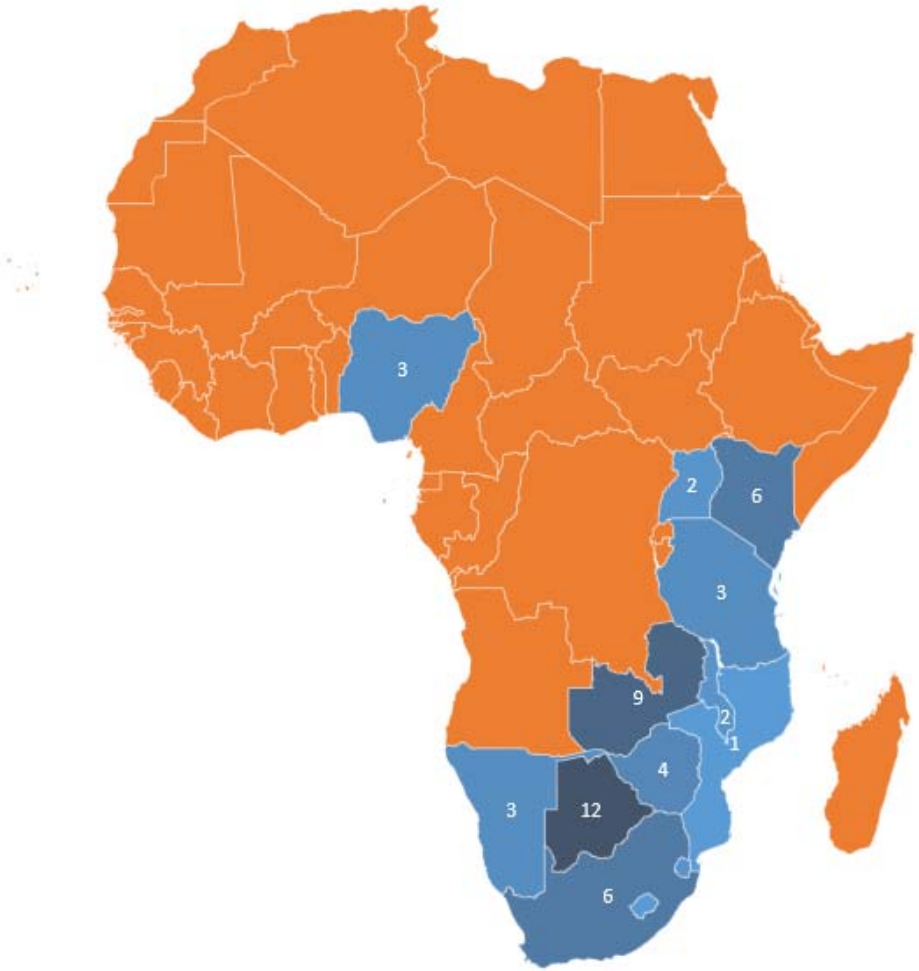


Optimise turnaround time to deliver superior clinician service.

1. Panther/Panther Fusion System Operator's Manual AW-18851-001 Rev. 001 (EN) San Diego, Ca; Hologic Inc. 2019

Panther install base in Africa

Total of 54 instruments in 13 countries



Aptima SARS-CoV-2 Assay

Novel Coronavirus screening for the Panther instrument

HOLOGIC®

Dual target sample to result, molecular amplification assay to detect virus in respiratory samples.

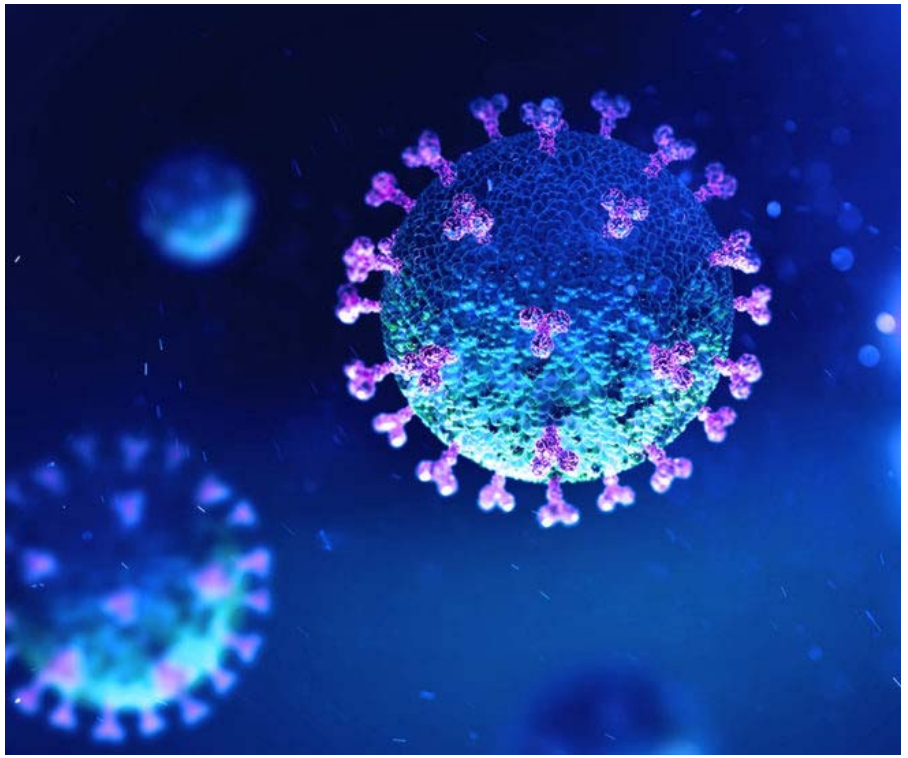
Test runs on existing installed platforms, the Panther instrument.

Extraction and amplification fully automated on Panther instrument.

Simple workflow requirements minimize the need for additional staff training.

Significantly increase testing capacity by running up to 1020 tests in 24 hours.

Providing a scalable, robust solution that allows laboratories to rapidly rise to the diagnostic challenge.



Clarity and confidence in every diagnosis

HOLOGIC®

Multiple Sampling Options to Meet Your Service Requirements

Sample collection in Virus Transport Medium (VTM)

- One simple manual transfer step before automated assay processing
- Multiple VTM validated for use
- Validated sample type for Panther Fusion Respiratory Panel Testing

Supporting a flexible high throughput solution whilst minimizing operator hands-on time.

Clarity and confidence in every diagnosis

Multiple Sampling Options to Meet Your service requirements

Sample collection with the Aptima Multitest Kit

- No Pre-analytical sample processing
- True sample to result processing
- Specimen stable at room temperature.

Sample collection in Virus Transport Medium

- One simple transfer step before automated assay processing

Multitest Kit Collection (OP/Nasal)

No sample transfer. Load directly on Panther

Aptima sample collection medium inactivates live virus protecting clinicians and lab staff

Fusion SARS-CoV-2 Clinical Performance

Scalable Molecular Diagnostic Solutions

HOLOGIC®

J Clin Microbiol. 2020 Apr 27;JCM.00743-20. doi: 10.1128/JCM.00743-20. Online ahead of print.

Comparison of Four Molecular *In Vitro* Diagnostic Assays for the Detection of SARS-CoV-2 in Nasopharyngeal Specimens

Wei Zhen [1], Ryhana Manji [1], Elizabeth Smith [1], Gregory J Berry [2 3]

Affiliations + expand

PMID: 32341143 DOI: 10.1128/JCM.00743-20

Molecular Assay		Reference Standard [a] Positive	Reference Standard [a] Negative	(± 95% CI) [bc] Kappa (κ)[d]	(± 95% CI) [bc] Sensitivity	(± 95% CI) [bc] Specificity
Modified CDC						
	Positive	51	1[e]	0.98 (0.94-1)	100%	98%
	Negative	0	52		(0.93-1)	(0.89- 0.99)
DiaSorin Molecular				1.0 (0.99-1)		
	Positive	51	0		100%	100%
	Negative	0	53		(0.93-1)	(0.93-1)
GenMark						
	Positive	49	0	0.96 (0.91- 1)	96%	100%
	Negative	2[f]	53		(0.87- 0.99)	(0.93- 1)
Hologic						
	Positive	51	2[g]	0.96 (0.91- 1)	100%	96%
	Negative	0	51		(0.93- 1)	(0.87-0.99)

95% detection limit (LoD) was 83 +/- 36 copies/mL for ORF1ab

Sensitivity of 100% (51/51)

Specificity of 96% (51/53), 98% upon interrogation

- Two false positives, interrogation showed one positive and one negative, respectively

Aptima SARS-CoV2 Clinical Performance

Scalable Molecular Diagnostic Solutions

Table 3: Aptima SARS-CoV-2 Clinical Agreement

		Panther Fusion SARS-CoV-2 Assay	
		Positive	Negative
Aptima SARS-CoV-2 Assay	Positive	50	1
	Negative	0	54

Positive Percent Agreement: (95% CI): 100% (92.9% – 100%)
Negative Percent Agreement: (95% CI): 98.2% (90.4% – 99.7%)
Overall Agreement: (95% CI): 99.0% (94.8% – 99.8%)

The clinical performance was evaluated in comparison to the Panther Fusion SARS-CoV-2 EUA assay, using a panel of 105 remnant clinical nasopharyngeal specimens collected from US patients.

Aptima SARS-CoV-2 assay (TMA) showed positive and negative agreements of 100% and 98.2%, respectively.

No additional analysis has been undertaken on the one discordant sample.

- **The design goal of having similar or better performance to the Panther Fusion SARS-CoV-2 Assay has been achieved.**

Analytical and clinical comparison of Aptima SARS-CoV2

J Clin Microbiol. 2020 Jun 22;JCM.01134-20. doi: 10.1128/JCM.01134-20. Online ahead of print.

Analytical and Clinical Comparison of Three Nucleic Acid Amplification Tests for SARS-CoV-2 Detection

Elizabeth Smith [1], Wei Zhen [1], Ryhana Manji [1], Deborah Schron [2], Scott Duong [1 2], Gregory J Berry [3 2]

Table 4. Basic assay characteristics and workflow parameters of three EUA SARS-CoV-2 NAATs

	Hologic Panther Fusion SARS-CoV-2 Assay	Hologic Aptima SARS-CoV-2 Assay	BioFire COVID-19 Test
Detection platform/System	Panther Fusion	Panther or Panther Fusion	BioFire FilmArray Torch System—12 bay tower
Sample type[a]	NP, OPS, LRT, NS	NP, OPS, NS, nasal wash/aspirate	NP
Sample volume required (µL)	500 µl (250 µl for LRT)	500 µl	300 µl
Target region of SARS-CoV-2	two regions of ORF1ab	two regions of ORF1ab	two regions of ORF1ab and ORF8
Analytical sensitivity per claim	0.01 $TCID_{50}$/ml	0.01 $TCID_{50}$/ml	0.022 $TCID_{50}$/ml (330 genomic copies /ml)
Observed analytical sensitivity - **Inactivated Virus**	1000 genomic copies/ ml	500 genomic copies/ ml	500 genomic copies/ ml
Observed analytical sensitivity - **RNA Transcript**	62.5 copies/ ml	62.5 copies/ ml	125 copies/ ml
High throughput processing	Yes	Yes	No
Throughput- Samples per run	120 with continuous loading	120 with continuous loading	12
Hands on Time/ sample	1 minute	1 minute	3 minutes
Hands on Time/Run	2 hours / 120 samples	2 hours / 120 samples	36 minutes / 12 samples
Assay Processing Time/ Run	4 hours 35 minutes / 120 samples	5 hours 30 minutes / 120 samples	45 minutes / 12 samples
Time to first result	2 hours 25 minutes	3 hours 30 minutes	45 min
Overall Turn Around Time/ Run	6 hours 35 minutes / 120 samples	7 hours 30 minutes / 120 samples	1 hour 21 minutes / 12 samples
Maximum Sample throughput in 8/24 hrs	335 / 1150	275 / 1020	72 / 216

- **Highest flexibility for sample types**
- **Best analytical sensitivity**
- **Least hands-on time per run**
- **Very high throughput**

Comparison of Aptima SARS CoV2 – clinical sensitivity

J Clin Virol. 2020 Jun 10 : 104501. PMCID: PMC7286273
doi: 10.1016/j.jcv.2020.104501 [Epub ahead of print]

High-Throughput Transcription-mediated amplification on the Hologic Panther is a highly sensitive method of detection for SARS-CoV-2

Andrew J. Gorzalski,[a,1] Honglin Tian,[a,1] Chris Laverdure,[a,1] Sergey Morzunov,[a] Subhash C. Verma,[b] Stephanie VanHooser,[a] and Mark W. Pandori[a,c,*]

Table 2. Analytical Sensivity Comparison

copies/ml*	TMA** reactivity	Taqpath RT-PCR reactivity†	CDC RT-PCR††
5.5x10e5	5/5 (100%)	5/5 (100%)	5/5 (100%)
5.5x10e4	5/5 (100%)	5/5*** (100%)	2/5 (40%)
5.5x10e3	5/5 (100%)	0/5 (0%)	0/5 (0%)
5.5x10e2	1/5 (20%)	0/5 (0%)	0/5 (0%)
5.5X10e1	0/5 (0%)	0/5 (0%)	0/5 (0%)
5.5x10e0	0/5 (0%)	0/5 (0%)	0/5 (0%)

*concentration of SARS-CoV-2 genomic RNA, BEI Resources, NR-52285
**Hologic Panther SARS-CoV-2 Assay
† ThermoFisher Taqpath COVID-19 Multiplex Assay
†† CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel
***specimens were reactive for only one of three genes in assay

Performance of TMA and RT-PCR on nasopharyngeal specimens.

	TMA	RT-PCR*
NEGATIVE	64	61
POSITIVE	52	51

* RT-PCR generated 4 inconclusive results; two inconclusive results were positive by TMA, two were negative.

Pre-proof

Highest analytical and clinical sensitivity compared to Standard-Of-Care assays

THANK YOU


APTIMA
Specimen Transfer Tube
APTIMA
Swab Specimen Transport Tube
Tomcat