McEvoy & Farmer
Diagnostic Industry Specialists since 1986

Infectious Disease Testing Markets in the US

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Fifth Edition

November 2019

CONTENTS – INFECTIOUS DISEASE TESTING MARKETS IN THE UNITED STATES IN 2019

EXECUTIVE SUMMARY

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FIVE MARKET SEGMENTS OF THREE DISTINCT TYPES – 2019 REVENUES

• Apologies for redacting the numbers – actual figures available to subscribers, updated twice a year

	Lab Revenues	**Manufacturer Revenues**	**The Establishment**	**Barbarians at the Gates**
The Small Scale/Small Menu Market	$X.Xb	$X.Xb	1. Cepheid	1. Roche
• aka Rapid/POC			2. Abbott	2. GenMark
			3. bioMérieux	3. Curetis
			4. Quidel	4. Qiagen
			5. Luminex	5. Siemens
The Two Large Scale/Large Menu Markets				
• Immunoassays in the clinical lab	$X.Xb	$X.Xb	1. Abbott	*Difficult to*
			2. Roche	*break into*
			3. Siemens	*this segment.*
			4. Beckman	
			5. Ortho	
• Bacteriology in the microbiology lab	$X.xb	$X.xb	1. BD	1. Accelerate
			2. bioMérieux	2. T-2
			3. Thermo	3. MetaSystems
			4. Beckman	4. Q-Linea
			5. Bruker	5. Qvella
The Two Large Scale/Small Menu Markets				
• Molecular lab routine testing	$X.xb	$X.xb	1. Hologic	1. NeuMoDx
			2. Roche	
			3. BD	*No one*
			4. Qiagen	*else on the*
			5. Abbott	*horizon.*
• Transfusion screening in blood banks	$X.xb	$X.xb	1. Grifols	*You'd have*
			2. Abbott	*to be crazy*
			3. Roche	*at this point*
			4. Ortho	*in history.*
All US Infectious Disease Testing 2019 Forecast	**$13.63b**	**$6.95b**		

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THE TOP 24 SUPPLIERS OF US INFECTIOUS DISEASE TESTING LABS IN 2019 (US$m)

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US$ millions Manufacturer	Total Inf. Dis Revenues **$6,950**	Rapid/POC Viral/Bacterial Testing **$X,XXX**	Molecular Lab Routine **$X,XXX**	Microbiology Lab Bacteriology **$X,XXX**	Clinical Lab Immunoassay **$X,XXX**	Blood Bank Screening **$XXX**
1. bioMérieux	x,xxx	xxx		xxx	xx	
2. Abbott	xxx	xxx	xx		xxx	xxx
3. BD	xxx	xx	xxx	xxx		
4. Roche	xxx	xx	xxx		xxx	xx
5. Cepheid	xxx	xxx				
6. Hologic	xxx		xxx			xx
7. Grifols	xxx					xxx
8. Thermo	xxx	xx		xxx		
9. Beckman	xxx			xx	xxx	
10. Quidel	xxx	xxx			xx	
11. Qiagen	xxx		xx		xx	
12. Ortho	xxx				xx	xx
13. Siemens	xxx				xxx	
14. DiaSorin	xx	xx			xx	
15. Luminex	xx	xx				
16. Meridian	xx	xx			xx	
17. Genmark	xx	xx				
18. Bio-Rad	xx	xx	xx		xx	x
19. Hardy	xx			xx		
20. Bruker	xx			xx		
21. Copan	xx			xx		
22. Oxford	xx				xx	
23. T-2	x			x		
24. Accelerate	x			x		
others		xxx	xxx	xxx	xx	x

EXECUTIVE SUMMARY

BIGGEST NEWS SINCE OUR 4TH EDITION REPORT of MARCH 2019

Our 4th edition report on infectious disease testing in the US was published in March of this year, covering the market in 2018. This 5th edition reports on events of the first three quarters of 2019, during which…

BioMérieux surpassed Abbott. After BioFire sales that were up 25% over last year's first three quarters, there's a new #1. At the end of September there were 9,800 *Film Array* instruments working worldwide, of which 8,000-8,200 were in the US. BioFire should install the 10,000th before the end of the year. In addition their *Virtuo* culture systems gained a bit of ground in 2019 against BD in US blood culture markets. The *Vidas* immunoassay business was down slightly in the US, and flat elsewhere. During the first nine months of 2019 two new E-test assays were approved and one new drug on Vitek systems.

#2 Abbott got their CE mark for *Alinity m* in March; approval by the FDA should come in 2020. *Alinity s* was FDA-approved for transfusion screening in July. The *Alere i* instrument was rechristened *ID Now* late in 2018, and offers flu/strep results in less than 15 minutes, so it has become one of the most popular POC respiratory instruments. The Alere GI product line benefitted from this year's struggles at Meridian. Abbott got a CE mark for a 15-minute HBsAg in February, which we'll be seeing in the US next year. These reinforcements arrived none too soon; Alere was down 1.7% and Abbott Molecular was down 9.5% for the first nine months of the year.

#3 BD is still ahead of bioMérieux in big bacteriology, but not by much. BD claims double-digit growth for the *BD Max* molecular systems during the first three quarters, which sounds plausible given their decision to develop small panels, now that there's a big-panel revolt brewing in in the US. We can believe 10-12% growth during the first three quarters in their domestic *Max* business. The new high-volume *Cor* system earned its CE mark in June, so we should see

We have pages like this one covering the top twenty manufacturers of microbiology products (see list on page 2 above).

MANUFACTURER PROFILE	**HOLOGIC**	
	#6 IN US INFECTIOUS DISEASE TESTING	
Company	Hologic Bedford, Massachusetts www.hologic.com	
Importance	#1 in US central lab STI testing	
Who's Who		Since
	Mr. Stephen MacMillan – CEO	12/13
	Ms. Karleen Oberton – CFO	5/06
	Dr. Jay Stein – Co-Founder, SVP, CTO	10/85
	Mr. Patrick Brady – SVP, Global Supply Chain	10/18
	Mr. Kevin Thornal – President, Diagnostics Solutions Div.	6/14
	Mr. Mike Shih – Senior Manager, Instrumentation	6/13

2018 Big Picture Revenues		
All of Hologic - Global	$3.2b	
Diagnostics - Global	$1.1-1.2b	
Diagnostics – US	$800-850m	
Infectious disease testing – US	$410-420m	minus cytology and perinatal

2019 US Segment Revenues	**Platforms**	**Rank**	**Share**	**Revenues**
• Molecular lab, routine testing	Panther•PantherFusion	#1	36-38%	$430-450m
• Blood bank, small menu screening	Panther Procleix	N/A	N/A	$30-40m
Infectious disease totals		**#6**	**6-7%**	**$450-470m**

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MANUFACTURER PROFILE	**HOLOGIC**
	#6 IN US INFECTIOUS DISEASE TESTING

Stock performance		
• HOLX	1-1-15:	$26.76
	1-1-16:	$36.55
	1-1-17:	$39.88
	1-1-18:	$43.98
	1-1-19:	$41.10
	11-21-19:	$49.50

Recent publicly reported results ($m)		NoAm	ROW	Total	Growth
• First nine months of 2019	• Diagnostics	685	213	898	+4.8%
	Molecular Diagnostics	409	93	503	+10.2%
	Blood Screening	42	<-incl.	41	-1.5%
	Cytology & Perinatal	234	120	354	-2.9%
	• Breast Health	767	204	971	+9.1%
	• Medical Aesthetics	116	122	238	-11.5%
	• Gyn/Surg	268	54	322	+2.3%
	• Skeletal Health	43	27	70	+4.1%
	Totals:	**1,880**	**622**	**2,501**	**+4.2%**

Other financial reporting		
• November 21, 2019	Market Capitalization	$13.23b
	Enterprise Value	$15.68b
	Last 12 Months Sales	$3.37b
	EBITDA	$1.04b
	Cash	$0.60b
	Debt	$3.06b
	Price Sales	3.98
	Debt Equity	134.04

Otherwise notable

- Panther has been the apex predator of CT/NG markets since 2012.
- Panther is both fastest among its competitors, and also has the best menu.
- 1,700 Panther systems worldwide, of which 1,000-1,100 are in the US.
- Since early 2017, Panther has also been hard to beat in viral load markets.
- In 2018, new *Fusion* module made Panther a fierce respiratory competitor.
- Expect to see more Seegene multiplex panels on Panther Fusion.
- Small panel Fusion menu looks smart post Palmetto coverage decision.