

# OC's Thriving Diagnostics Industry Has Breakout Year

## COVID-19 Spurs Growth; Investor Interest Abounds

By JESSIE YOUNT

Orange County's hub of diagnostics firms largely defied healthcare employment trends in 2020.

While much of the healthcare industry suffered layoffs due to interruptions in elective procedures, the diagnostics industry saw no shortage of demand.

The sector—a collection of test makers and laboratories for infectious diseases and various cancers, specialized equipment manufacturers, and testing product suppliers—counted a local worker base of about 4,400 at the beginning of the year.

That's up 7% compared to last year, according to this week's inaugural list of OC diagnostic companies, which features 14 entries.

### Urgent Need

Employment gains were led by a number of high-volume testing providers that supported the urgent need for COVID-19 tests and related supplies.

**DiaSorin Molecular LLC** of Cypress increased its local workforce by more than 80% to 325, with a large number of hires in production.

The firm, a unit of Italy-based **DiaSorin S.p.A.**, partnered with **Toyota Engineering and Manufacturing** of Long Beach to scale its operations, even gutting office space to make room for high-volume manufacturing, according to President **John Gerace**.

"We were able to successfully scale up operations to supply over 1 million tests per month, which enables us to rapidly expand our



**Hycor Biomedical, maker of allergy testing system, nabs \$100M**

installed base of instruments while still maintaining 100% service level of our supply commitments," Gerace said.

Gerace is one of several local execs who believes COVID testing will become a mainstay of the industry.

"Every year we have a strong business testing for the flu," Gerace said. "I think COVID will follow the same trajectory."

Likewise, **BioDot Inc.**, an Irvine-based maker of ultra-low-volume dispensers that are used in the process of making tests, has grown as it's continuing to fill orders that will translate into the production of about 500 million tests in the coming months. Its local base of workers increased by nearly 60% to 63.

"Reality has set in," **Tony Lemmo**, chief executive of BioDot, told the Business Journal in September.

"We, as a society, won't go back to not knowing whether we have the flu, COVID-19 or another infectious disease."

### Investors Interested

Investments in the diagnostics sector have continued to flow.

**Fluxergy LLC**, an Irvine-based startup developing a new test analyzer system for use by physicians at the point-of-care, received a \$30 million investment from **Kingston Technology Corp.** co-founder **John Tu** last May.

The company grew its workforce nearly 90% to 75 as it pivoted from equine testing to COVID.

Though well-funded, it is still waiting on emergency use authorization for its analyzer's software, which requires additional inspection by a specialist at the **Food and Drug Administration**, Chief Commercial Officer **Ali Tina-zli** told the Business Journal in December.

Funding hasn't been limited to COVID endeavors.

**Hycor Biomedical LLC** of Garden Grove has raised about \$100 million since 2017, after an undisclosed investor acquired the company.

About half of the funds were raised last year, in support of validation activities and commercial expansion for the company's new NOVEOS System.

"This system is the first breakthrough in over 20 years in routine lab allergy testing," Chief Executive **Fei Li** told the Business Journal via email.

The system was designed to improve lab efficiencies via reductions in labor needs, cost of products and waste generated. Most importantly, the technology improves the patient experience because it requires a very small amount of blood sample for analysis, Li said.

Irvine-based liver cancer test maker **Helio Health Inc.**, formerly Laboratory for Advanced Medicine, has also raised a large amount of funds—nearly \$120 million since inception in 2015.

### Bright Future

Growth is expected to continue in 2021 for COVID test suppliers and specialty diagnostics firms.

**Ambry Genetics Corp.**, a unit of Japan-based **Konica Minolta Inc.**, now has business in both of those areas. The Aliso Viejo-based firm, which maintains one of the largest clinical labs on the West Coast, decided to provide COVID tests after a request from the state to help boost testing capacity.

While Ambry is primarily known for sophisticated tests for hereditary diseases such as cancer, it developed a saliva-based COVID test that allows patients to provide a sample at home, and receive results within 24 to 48 hours.

It has been offering tests to OC residents in partnership with the **OC Health Care Agency** for the last few months, and its software platform has engaged with over 120,000 local patients since the program launched, the company said.

At the same time, Ambry said its hereditary testing business has recovered rapidly, after a brief pause in business last spring due to the temporary closure of specialty physicians and providers.

Breast cancer diagnostics firm **Agendia Inc.** of Irvine experienced a similar lull in business in May and June before test volumes returned to pre-COVID levels over the summer.

The company still anticipates a public listing in the coming months, which will allow the firm to "promote a new strategy and accelerate our growth," Chief Executive **Mark Straley** told the Business Journal in August.

"We've hit a rhythm in terms of execution and [we're] reaching a size and scale where [the business] becomes attractive to larger institutional investors and public markets." ■




# THE LIST

## MEDICAL DIAGNOSTICS & TESTING COS.

### ▶ NEXT WEEK'S LISTS

Commercial Banks,  
Venture Capital Firms

RANKED BY NUMBER OF OC EMPLOYEES

Rank	Company name •Address	Company logo	OC employees •yearly % change	Companywide employees •yearly % change	Product(s) description	Top local official(s) •Title •Phone/Fax	
1	<b>Quest Diagnostics Inc.</b> 33608 Ortega Highway, Ste. B San Juan Capistrano 92675-2042 Website: questdiagnostics.com Email: mediacontact@questdiagnostics.com		1,933 6%	47,000 0%	Diagnostic information services	Stephen H. Rusckowski chairman/CEO/president (949) 728-4000/(949) 728-4985	
2	<b>Beckman Coulter Inc.</b> 250 S. Kraemer Blvd. Brea 92821-6232 Website: beckmancoulter.com		850 0%	11,000 0%	Diagnostic systems used in complex biomedical testing for clinical chemistry, immunoassay, hematology, microbiology, urinalysis, automation and clinical informatics	Julie Sawyer Montgomery president, Beckman Coulter Diagnostics (714) 993-5321/(800) 232-3828	
3	<b>Ambry Genetics Corp.</b> 1 Enterprise Aliso Viejo 92656-2606 Website: ambrygen.com Email: info@ambrygen.com		535 -4%	851 20%	Comprehensive genetic testing (screening and diagnosis) for hereditary cancer, hereditary cardiovascular disease, neurodevelopmental disorders, epilepsy, rare disease, exome	Aaron Elliott CEO (949) 900-5500/(949) 900-5501	
4	<b>DiaSorin Molecular LLC</b> 11331 Valley View St. Cypress 90630-5300 Website: molecular.diasorin.com Email: marketing-info_molecular@diasorin.com		325 86%	400 60%	Simplexa Bordetella Direct, C. difficile Direct, COVID-19 Direct, Flu A/B & RSV Direct Gen II, GBS Direct (Group B Streptococcus), Group A Strep Direct, HSV 1 & 2 Direct, VZV Direct, VZV Swab Direct	John Gerace president, DiaSorin Molecular (562) 240-6500/(714) 243-4703	
5	<b>Zymo Research Corp.</b> 17062 Murphy Ave. Irvine 92614-5914 Website: zymoresearch.com Email: info@zymoresearch.com		200 33%	200 33%	Nucleic acid stabilization and purification technologies; products for epigenetics, DNA, RNA, E. coli, and yeast based research	Xi Yu Jia president (949) 679-1190/(949) 266-9452	
6	<b>MDxHealth</b> 15279 Alton Parkway, Ste. 100 Irvine 92618-2600 Website: mdxhealth.com Email: info@mdxhealth.com		123 2%	163 3%	ConfirmMDx: tissue test to improve the identification of men at risk for undetected clinically significant prostate cancer after a negative biopsy; SelectMDx: highly predictive urine test to help identify men at risk for aggressive prostate cancer prior to initial biopsy	Michael K. McGarrity CEO/director (866) 259-5644/(949) 788-0014	
7	<b>Agendia Inc.</b> 22 Morgan Irvine 92618-2022 Website: agendia.com Email: customercare@agendia.com		120 29%	174 23%	MammaPrint: genomic test used to predict risk of breast cancer recurrence; Blueprint: molecular subtyping test used to predict likely tumor behavior	Mark R. Straley CEO (888) 321-2732	
8	<b>Hycor Biomedical LLC</b> 7272 Chapman Ave. Garden Grove 92841-2103 Website: hycorbiomedical.com Email: info@hycorbiomedical.com		83 -34%	102 -28%	In-vitro diagnostic products	Fei Li CEO/chairwoman (800) 382-2527/(714) 933-3222	
9	<b>Fluxergy LLC</b> 30 Fairbanks, Ste. 110 Irvine 92618-1688 Website: fluxergy.com Email: info@fluxergy.com		75 88%	75 88%	Fluxergy Analyzer System: uses patented microfluidics and a highly integrated sensor system to produce a more flexible and cost-effective testing platform	Tej Patel/Ali Tinazli president, co-founder/chief commercial officer (949) 305-4201	
10	<b>BioDot Inc.</b> 2852 Alton Parkway Irvine 92606-5104 Website: biodot.com Email: rob.rich@biodot.com		63 58%	92 39%	Specializes in the development and manufacturing of precision, high-throughput, low volume, fluid dispensing systems across point-of-care diagnostics, clinical diagnostics and the life sciences	Anthony Lemmo CEO (949) 440-3685	
11	<b>Biomerica Inc.</b> 17571 Von Karman Ave. Irvine 92614-6207 Website: biomerica.com Email: info@biomerica.com		42 <sup>(1)</sup> NA	65 14%	Testing kits to detect medical problems ranging from allergies, ulcers, and cancer to infertility and diabetes	Zackary Irani chairman/CEO (949) 645-2111/(949) 553-1231	
12	<b>Oncocyte Corp.</b> 15 Cushing Irvine 92618-4220 Website: oncocyte.com Email: info@oncocyte.com		24 -31%	57 12%	DetermaRxTM: treatment stratification test to identify patients with stage I and IIA non-squamous non-small cell lung cancer who may benefit from adjuvant chemotherapy; DetermaIOTM: multivariate gene expression test to identify immune checkpoint inhibitor responders (for research only)	Ronald Andrews CEO/president (949) 409-7600	
13	<b>PreludeDX</b> 26051 Merit Circle, Ste. 103 Laguna Hills 92653-7008 Website: preludedx.com Email: info@preludedx.com		16 0%	22 -15%	Genomic test for women diagnosed with Stage 0 breast cancer that analyzes their tumor's unique genetic makeup to predict whether or not radiation therapy would be beneficial	Dan Forche CEO/president (888) 211-3247/(888) 909-3247	
14	<b>Helio Health Inc.</b> 9950 Research Drive Irvine 92618-4309 Website: heliohealth.com Email: info@heliohealth.com		11 83%	95 4%	Blood test for the detection and screening of liver cancer	Kenneth Chahine CEO (646) 677-1838	

Abbreviations: NA: not applicable

Note: To the best of our knowledge, this information is accurate as of press time. While every effort is made to ensure the accuracy and thoroughness of the list, omissions and typographical errors sometimes occur. Unless otherwise noted, the information on this list was provided by the companies themselves. List may not be reprinted without permission of the editor. Photos show the first

top official listed.

<sup>(1)</sup> Business Journal estimate