



MCEVOY & FARMER
DIAGNOSTIC INDUSTRY SPECIALISTS SINCE 1986

Cancer Testing Markets
in the US

•

12th Edition

•

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We have pages like this discussing the top 20 oncology labs in the US.

EXECUTIVE SUMMARY

WHO'S WHO AMONG THE COMMERCIAL LABS

Commercial Labs

The new #1 cancer testing organization is **Exact Sciences** (EXAS), after the “merger” (acquisition) of **Genomic Health** (GHDX), which closed in November. Exact Sciences took in \$810m during 2019 from one extraordinarily successful test at one very busy lab in Madison, Wisconsin Their *Cologuard* colon cancer screening test was approved by the FDA in August of 2014; revenues were \$1.5m that year. In 2019 they did nearly 2m tests at \$475/test, roughly doubling their 2018 numbers. Genomic Health also does all their work at one lab, this one near the San Francisco airport. This lab offers three proprietary tests that each cost \$3,000+. These prognostic tests save a lot of drug money, so they are widely appreciated by payers. During 2019 they did 125,000-130,000 tests and took in \$455m. Roughly 80% of their workload is the *OncotypeDX* gene expression test for breast cancer patients; the other 20% comes from their colon and prostate LDTs.

#2 **Quest** (DGX) took in \$7.7b during 2019, a slight gain of 1.9% over 2018. Just over \$1b was for oncology diagnostics. Quest employs more than 600 doctors, of which 400+ look at slides at their 46 anatomic labs. These pathologists can be expected to produce 2.8-2.9m primary stains in 2020. Quest labs do the most H&E, IHC, ISH, cervical cancer screening, and serum tumor markers. But their footprint in PCR/NGS and flow cytometry is more modest. Quest made only one significant acquisitions in the oncology space during 2019. In February they closed their acquisition of Boyce Bynum, an important clinical/molecular/anatomic lab in Missouri. Then in January of 2020 Quest announced the acquisition of Blueprint Genetics, a leading NGS lab in Finland. Quest also announced their intention last year to move all their immunoassay (including serum tumor marker) testing to one supplier. Not yet, but soon.

#3 **LabCorp** (LH) revenues for the year were \$11.5b, just 0.5% better than 2018. But 40% of that total came from Covance; the LabCorp US diagnostic businesses brought in roughly \$7b. Though undisclosed, it appears the LabCorp domestic oncology operations brought in slightly more than \$1b in 2019, nearly the same as Quest. Labcorp has 42 anatomic pathology labs and 200+ pathologists looking at histology slides, who produced 2.5-2.6m primary stains in 2019. Labcorp is #1 in flow cytometry and #2 in H&E, IHC, NGS/PCR, tumor markers, and cervical cancer screening. Labcorp and Quest together do

We have pages like this discussing the top 20 manufacturers of cancer testing products.

EXECUTIVE SUMMARY

WHO'S WHO AMONG THE MANUFACTURERS

The Manufacturers

Roche (RHHBY) is #1 with 2019 US oncology sales of **\$930-950m**. Roche remains #1 in IHC, ISH, and serum tumor markers. In the PCR/NGS segments, Roche is #1 in clinical markets, but #2 after including research markets. Roche was also #2 in HPV testing and #3 in primary staining in 2019. While still the biggest and richest, 2019 was a difficult year for Roche oncology. Roche Tissue (Ventana) was down 2% in the first half of the year and flat in the 3rd quarter. Revenues for the Tucson anatomic pathology business were nearly \$1.2b (CHF1,104) worldwide, of which \$530-560m from the US, much the same as in 2018. Perhaps 12-14% of Roche Tissue's US revenue came from primary staining and 86-88% from IHC and ISH staining. The launch of *Navify Tumor Board 2.0* and the *HER-2 Dual ISH* during 2019 were both helpful, but not enough to counteract the price erosion of 2019. In their quarterly announcements of 2019, all the growth of Roche Molecular was attributed to either infectious disease products or Asia or Europe. The *Avenio* panels are keeping up with NGS market growth, while the single-gene PCR market is in decline for everyone. The clinical lab tumor marker revenues on the 4000/6000/8000 systems seem to have been up 1%, along with the rest of the Roche immunochemistry business in North America.

#2 Illumina (ILMN) had another great year; their US oncology sales grew by 16%. Some old threats vanished (Qiagen), some new threats emerged (Genapsys, Genexus), and some old threats persevered (Oxford). Their PacBio deal fell apart, but that didn't matter to oncology markets. These days if you want to be taken seriously in oncology research, you must have either a small stable of NovaSeqs (\$900k each) or a large stable of NextSeqs (\$250k each). Illumina took in about \$3.5b in 2019, but after subtracting their microarray revenues and NGS service revenues, there remains about \$2.5b of NGS *product* revenues. About a third of Illumina's NGS product revenues come from labs doing either cancer research or clinical panels. So \$820-840m of Illumina's NGS product revenues are cancer related. Perhaps a quarter of their microarray sales come from oncology research. So altogether Illumina saw nearly a billion dollars in cancer revenue during 2019. More than half (**\$520-540m**) came from US labs. Illumina is the essential supplier of Myriad, Foundation, Caris, Invitae, Ambry, GeneDx, Veracyte, and Interpace. American Labs offering clinical

We have pages like this covering all the M&A deals of the last six years.

EXECUTIVE SUMMARY

SIGNIFICANT M&A ACTIVITY OF THE LAST FIVE YEARS – 2014 - 2017

| When | Buyer | Seller | Price | Revenues (year of acquisition) | Price/Revenues |
|-------------|-------------------|---------------------------|----------------------------------|-----------------------------------|--------------------------|
| 2017 | | | | | |
| September | Exellere Partners | Biocare | \$120-140m for 50-55% | \$35-40m | 6.0-7.0 charitable price |
| September | Avista Capital | Miraca's US labs | \$135m for 85% | \$265m | 0.42 cry me a river |
| July | Konica Minolta | Ambry Genetics | \$800m down \$200m later (maybe) | \$280m ? | 3.14 low NGS multiple |
| January | Ampersand Capital | Genoptix | undisclosed | \$60m | unknown |
| January | Bio-Rad | Raindance | \$75m | \$30m | 2.50 |
| 2016 | | | | | |
| July | Bio-Techne | Advanced Cell Diagnostics | \$250m | \$25m | 10.0 |
| 2015 | | | | | |
| November | Neogenomics | GE's Clariant | \$310m | \$127m | 2.44 |
| 2014 | | | | | |
| December | Leica | Devicor | undisclosed | \$170m | unknown |
| October | Sigma-Aldrich | CellMarque | \$170m | \$30m | 5.7 |
| October | BioCare | Cymogen | undisclosed | <\$5m | unknown |
| September | E. Merck | Sigma-Aldrich | \$17b | \$2.7b | 6.3 |
| April | Bio-Rad | GnuBio | \$60m | <\$1m | 60++ |

We have pages like this covering all the M&A deals of the last six years.

EXECUTIVE SUMMARY

SIGNIFICANT M&A ACTIVITY OF THE LAST FIVE YEARS – 2014 - 2017

2017

Bio-Rad bought **RainDance** for \$75m in January 2017, for 2.5 times revenues, far less than RainDance appeared to be worth when they were planning the IPO that never happened in 2015. RainDance had burned \$160m worth of smart money (GE Ventures, Myriad, among others) by the time Bio-Rad ate them.

When **Novartis** bought **Genoptix** for \$470m in 2011, Genoptix revenues were about \$190m/year. They had another two or three good years, and then when code-stacking ended in 2014, they were unable to adapt. The same thing happened to Genoptix that happened to Clariant. Novartis, like GE, had bought at the top of the market, and saw their investment in lab services deteriorate until they were begging to escape. A private equity firm, Amersand Capital, took Genoptix off their hands for an undisclosed pittance in January 2017.

In July of 2017 **Konica Minolta** announced their \$1b purchase of **Ambry Genetics**, intended to be \$800m up front with a possible \$200m in milestone payments. After three years of spectacular growth, Ambry (like Clariant and Genoptix) became collateral damage caused by the implosion of the code-stacking reimbursement system. Ambry emerged more successfully than GE or Novartis. The Dunlop family got more than three times revenues for their lab.

In September of 2017 the three **Biocare** partners secured their retirements. Terms were not disclosed, but the Denver private equity firm **Exellere Partners** are thought to have invested \$140-160m for a stake of 50ish percent. This seems reasonable, as it would value Biocare at 6-7 times revenues, comparable to what CellMarque and Sigma managed to fetch

Also in September of 2017 came the really scary news. **Miraca** of Japan, one of the shrewdest and most efficient operators in the anatomic pathology business, was bailing out of the US market. In 2011 Caris had sold their anatomic pathology business to Miraca for \$725m, wanting to focus on the tumor profiling business, and no doubt anticipating better than Miraca could the reimbursement reductions that were soon to hit routine histology testing. Between 2013 and 2017 Miraca's average payments per procedure declined by

We have pages like this covering the top twenty manufacturers (see contents pages above).

MANUFACTURER PROFILE
BIOCARTIS

 NOT YET IN THE TOP TWENTY, BUT GROWING FAST

Company:

 Biocartis
 Mechelen, Belgium (near Brussels)
www.biocartis.com

Importance

Good and fast single-gene companions; don't expect them to be cheap

Who's Who:

| | <u>Since...</u> |
|---|-----------------|
| Dr. Rudi Pauwels – Founder | 1/08 |
| Dr. Herman Verrelst – CEO | 9/17 |
| Mr. Piet Houwen – COO | 4/19 |
| Mr. Edwoud Welten – CFO | 9/15 |
| Mr. Geert Maertens – Chief Scientific Officer | 4/09 |
| Dr. Erik Vossenaar – VP, Business Development | 2/10 |
| Mr. Vishal Sikri – GM, United States | 4/17 |
| Mr. Raf Pasmans – Export Business Director | 2/14 |

2019 Big Picture Revenues

| | |
|--------|---------------------------|
| Global | \$40.7m ≈ €37.3m reported |
| US | \$8-10m |

| 2019 US Segment Revenues | Main Platforms | Rank | Share | US\$m Rev. |
|---|-----------------------|-----------------|---------------|-------------------|
| <u>Molecular lab, companion diagnostics</u> | <i>Idylla</i> | unranked | <1% | \$8-10m |
| Total revenues | | unranked | <1% | \$8-10m |

We have pages like this covering the top twenty manufacturers (see contents pages above).

MANUFACTURER PROFILE
BIOCARTIS

 NOT YET IN THE TOP TWENTY, BUT GROWING FAST

| | | | |
|-----------------------|-----------|--------|----------------------|
| Stock performance (€) | 4-24-15 : | €11.50 | IPO |
| • BCART.BR | 1-1-16: | €13.11 | |
| | 1-1-17: | €10.70 | |
| | 1-1-18: | €13.20 | |
| | 1-1-19: | €9.90 | |
| | 1-1-20: | €5.72 | down 42% during 2019 |
| | 3-7-20: | €4.58 | |

| Recent publicly reported results (€million) | <u>US</u> | <u>ROW</u> | <u>Total</u> | <u>Growth</u> |
|---|------------|-------------|--------------|---------------|
| • Full year 2019 | Est. | est. | reported | reported |
| Product revenues | 5.0 | 19.2 | 24.2 | +29% |
| Collaboration revenues | 3.0 | 10.5 | 13.5 | +55% |
| Totals | 8.0 | 29.7 | 37.7 | +32% |

175,000 cartridges sold during 2019

| | | |
|--------------------------------------|-------------------------|----------|
| Other recent financial reporting (€) | Market Capitalization | €279m |
| • March 7, 2020 | Enterprise value | €238m |
| | Last 12 months revenues | €37.7m |
| | EBITDA | (€46.1m) |
| | Cash | €179m |
| | Debt | €167m |
| | Price Sales | 8.13 |
| | Debt Equity | 197.18 |

-
- | | |
|-------------------|---|
| Otherwise notable | <ul style="list-style-type: none"> • <i>Idylla</i> is an automated RT-PCR instrument that runs BRAF, KRAS & NRAS– results in 90 minutes! Fast MSI earned CE mark in 2019. • 337 new instruments placed worldwide in 2019 • Total installed base was 1,310 at the end of 2019 |
|-------------------|---|

We have pages like this covering the top twenty labs (see contents pages above).

MANUFACTURER PROFILE
MYRIAD

#5 US CANCER TESTING LAB

Lab Myriad Genetics
320 Wakara Way
Salt Lake City, UT 84108
www.myriad.com

Importance World's busiest NGS lab

| Who's Who | | <u>Since...</u> |
|-----------|---|-----------------|
| | Mr. Brian Riggsbee – Interim CEO | 10/14 |
| | Mr. Alexander Ford – President, Myriad Genetic Labs | 6/10 |
| | Mr. Gary E. King – EVP, International Operations | 7/10 |
| | Dr. Jerry Lanchbury, Chief Scientific Officer | 9/02 |
| | Dr. Patrick Burke – EVP, Emerging Products | 6/01 |
| | Dr. Bryan Dechiaro – EVP, Clinical Development | 8/12 |

2019 Big Picture Revenues

| | |
|-------------|------------|
| Global | \$851m |
| US patients | \$790-800m |
| US oncology | \$510-530m |

2019 US Segment Revenues

| | Rank | Share | US\$m Rev. |
|---------|------|--------|------------|
| PCR/NGS | #1 | 12-13% | \$510-530m |

| | | | |
|------------------------|----------|---------|---------------------|
| Stock performance (\$) | 1-1-15 : | \$37.42 | |
| • MYGN | 1-1-16: | \$38.97 | |
| | 1-1-17: | \$16.18 | |
| | 1-1-18: | \$36.88 | |
| | 1-1-19: | \$28.19 | |
| | 1-1-20: | \$26.52 | down 6% during 2019 |
| | 3-7-20: | \$16.37 | then it got worse |

We have pages like this covering the top twenty labs (see contents pages above).

MANUFACTURER PROFILE
MYRIAD

#5 US CANCER TESTING LAB

| Recent publicly reported results (\$million) | <u>US</u> | <u>ROW</u> | <u>Total</u> | <u>Growth</u> |
|---|------------|------------|--------------|---------------|
| • Full year 2019 (July '18-June '19) | Est. | est. | reported | reported |
| Hereditary cancer | 440 | 39 | 479 | +2% |
| GeneSight | 100 | 12 | 112 | -11% |
| Prenatal | 105 | | 105 | new |
| VectraDA | 44 | 4 | 48 | -14% |
| Prolaris | 23 | 2 | 25 | +16% |
| EndoPredict | 9 | 1 | 10 | +18% |
| Other | 8 | 0 | 8 | -5% |
| Molecular diagnostic totals | 731 | 58 | 789 | +13% |
| Pharma/clinical service revenue | 51 | 11 | 62 | +15% |
| Totals | 782 | 68 | 851 | +14% |

| | | | | |
|---------------------------------------|-------------------------|---------|-------------|-------|
| Other recent financial reporting (\$) | Market Capitalization | \$1.25b | Price Sales | 1.53 |
| • March 7, 2020 | Enterprise value | \$1.40b | Debt Equity | 27.53 |
| | Last 12 months revenues | \$851m | | |
| | EBITDA | \$59m | | |
| | Cash | \$141m | | |
| | Debt | \$296m | | |

Otherwise notable

The #5 oncology lab is Myriad Genetics, the world's #1 NGS lab (by revenue). Myriad's lab in Salt Lake City took in \$851m during their fiscal 2019 (July '18-June '19), of which \$510-520m came from their NGS and PCR cancer panels. Myriad pioneered BRCA testing in the US, then lost the mother of all patent wars, then repackaged their BRCA business into bigger panels. They have since gotten into the prognostic testing business, but their *MyRisk* panel represents 92% of their oncology revenues. Their *Prolaris* prostate cancer prognostic brought in about \$25m during 2018-19, *EndoPredict* accounted for perhaps \$10m, and *MyPath Melanoma* about \$5m. Late in 2019 Myriad accelerated their overseas efforts by offering kit versions of *EndoPredict* in Europe. *Prolaris* and *MyPath Melanoma* are said to be on the way. The international expansion is essential; oncology revenues have been down 8-10% in recent quarters. In November guidance for the 2019-2020 year was lowered from \$865-875 to \$800-810m.

We have pages like this covering the top sixty cancer centers (see contents pages above).

| HOSPITAL PROFILE | EPPLEY CANCER CENTER |
|-------------------------------|---|
| | U NEBRASKA MEDICAL CENTER HOSPITAL |
| Institution | Eppley Cancer Center 985950 Nebraska Medical Center Omaha, Nebraska 68198 |
| University affiliation | University of Nebraska |
| Main link | www.unmc.edu |
| 2019 estimates | |
| • Licensed Beds | 610 |
| • Beds Currently | 537 |
| • Inpatient days | 142,389 |
| • Outpatient visits | 842,522 |
| • Histology cases | 14,000 |
| • Cytology cases | 13,000 |
| Oncology Department | |
| • 25 oncologists | |
| • Head of Medical Oncology | Dr. Ken Cowan |
| • Head of Surgical Oncology | Dr. Mark Carlson |
| • Head of Radiation Oncology | Dr. Janina Baranowska-Kortylewicz |
| Pathology Department | https://www.unmc.edu/pathology/ |
| • 26 pathologists | |
| • Head of Anatomic Pathology | Dr. Audrey Lazenby |
| • Head of Clinical Pathology | Dr. James Wisecarver |
| • Head of Molecular Pathology | Dr. Alison Cushman-Vokoun |