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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

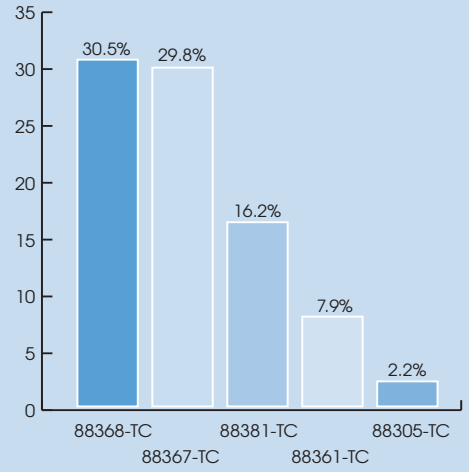
TECHNICAL RATES GET A BOOST IN PROPOSED FEE SCHEDULE FOR 2015

After two years of bad news, the Proposed Physician Fee Schedule for 2015 should bring a big sigh of relief to pathologists and labs. Technical rates for most high volume pathology codes are increasing by 2% to 5%, while professional rates are mostly unchanged.

In addition, the Proposed Rule for 2015 includes no payment changes based on site of service. So it looks like any effort on the part of CMS to link pathology technical rates to the lower rates paid by Medicare's Hospital Outpatient Prospective Payment System are on hold for at least one more year.

Meanwhile, proposed payment hikes for some key pathology technical rates are substantial. Of course, it should be recognized that these are only the proposed rates, and changes could be made when the Final Physician Fee Schedule Rule for 2015 is released on or about November 1.
Full details on pages 2-5.

Key Pathology Rate Changes for 2015



Source: Proposed PFS Rule for 2015

OIG REPORT SPOTLIGHTS LAB BILLING RED FLAGS

More than 1,000 labs had unusually high billing for Medicare Part B lab testing services reimbursed in 2010, according to a new report by the HHS Office of Inspector General (OIG). Increased auditing activity for these 1,000 labs, and possibly others, can be expected, as CMS concurred with the OIG's recommendation to review the labs identified and said it would direct Zone Program Integrity Contractors (ZPICs) to follow up and investigate the identified labs.

Importantly, the OIG acknowledged that some labs may have legitimate reasons for exceeding certain thresholds analyzed as part of the OIG's study, and stated that it did not conduct a more thorough medical record review to determine whether any of the billings were in fact inappropriate or fraudulent.

Nonetheless, the OIG report offers a window into how regulators are selecting labs for billing audits. And while the OIG report did not name specific labs, *Laboratory Economics* conducted a similar review of 2012 Medicare utilization data to compile a list of 30 labs that could get referred for ZPIC review. *Continued on pages 8-9.*

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TECHNICAL RATES GET A BOOST (*cont'd from page 1*)

CPT 88305-TC

After slashing the technical component of CPT 88305 by 52% in 2013 and then reducing it by another 3.3% in 2004, CMS has proposed raising this key service by 2.2% to $32.93 in 2015.

The professional component of CPT 88305 is proposed to stay essentially unchanged at $38.30 compared with $38.33 in 2014.

Global reimbursement for CPT 88305 will increase by 2.2% to $71.24, according to the Proposed Rule for 2015.

Big Increase for FISH Testing Technical Rates

Based on initial proposed RVUs for FISH testing, the technical component for both automated (CPT 88367) and manual (CPT 88368) are each set to increase by 30% in 2015. This will help offset some of the damage related to NCCI edits made in 2014 (see *LE*, March 2014, pp. 1-2), which stated that only one FISH probe can be billed per procedure. Prior to the NCCI edit, labs had billed one unit of service for each reportable FISH probe.

Professional rates for CPT 88367 and 88368 will remain essentially unchanged in 2015.

Global rates will rise 18% to a national limit of $312.87 for CPT 88367 and $283.52 for CPT 88368, according to the Proposed Rule for 2015.

However, there could be more changes in store for FISH testing reimbursement rates when the PFS Final Rule for 2015 is released this November. That's because the FISH testing codes 88365, 88367 and 88368 have been under review for the past two years as potentially misvalued. CMS deferred revaluation of these codes in 2014, but changes are anticipated in the Final Rule for 2015.

Pathology Codes Under Review

FISH Testing: 88365, 88367 & 88368

Prostate Biopsies: G0416

Flow Cytometry: 88185

Immunohistochemistry: G0461 & G0462

Source: *Laboratory Economics*

Prostate Biopsy Codes

In 2014, CMS introduced four new codes for billing for pathology services for prostate biopsies:

- G0416 (surgical pathology exam, prostate needle biopsy, any method; 10-20 specimens)
- G0417 (surgical pathology exam, prostate needle biopsy, any method; 21-40 specimens)
- G0418 (surgical pathology exam, prostate needle biopsy, any method; 41-60 specimens)
- G0419 (surgical pathology exam, prostate needle biopsy, any method; greater than 60 specimens)

CMS says that the typical number of specimens evaluated for prostate biopsies is between 10 and 12, and that G0416 (10-20 specimens) represents the overwhelming majority of all Medicare claims submitted for the four G-codes. Therefore, in order to simplify coding, CMS has proposed revising the descriptor for G0416 to cover payment for all prostate biopsy pathology services, regardless of the number of specimens, and plans to delete codes G0417, G0418 and G0419. The use of CPT 88305 for billing prostate biopsies with 1-9 specimens would also be discontinued.

In 2014, G0416 was reimbursed by Medicare at a national limit of $651.26 for global claims. Reimbursement will essentially remain the same, at $651.16, under the Proposed Rule for 2015.

For example, under the Proposed Rule, a prostate biopsy with 6 pathology specimens would be reimbursed using G0416 at a global rate of $651.16. A prostate biopsy with 12 pathology specimens would also be reimbursed using G0416 at a global rate of $651.16, as would a prostate biopsy with 20 pathology specimens.

However, there could still be further changes made to G0416 because it has been identified as a potentially misvalued code for CY 2015. CMS is currently seeking public comment on the appropriate work RVUs, work time, and direct PE inputs for G0416.

"The intent of CMS is to pay pathologists less for interpreting prostate biopsy specimens," according to Jonathan Myles, MD. He says this issue is a top concern and CAP will be submitting comments to CMS.

Potential Adjustment to Immunohistochemistry?
Last year, in an effort to deter overutilization of immunohistochemistry services, CMS eliminated CPT code 88342 and replaced it with two new G-codes: G0461 (Immunohistochemistry, per specimen; first stain) and G0462 (Immunohistochemistry, per specimen; each additional stain) with interim payment amounts effective January 1, 2014.

The new G-codes made several significant changes. First, CMS shifted the billing code from one that reimburses *per slide or block* to one that pays per specimen. Second, CMS now reimburses multiple IHC stains performed as a multiplex "cocktail" as a single stain rather than as separately reimbursable services—even though each stain in the cocktail requires a separate interpretation. The bottom line was that IHC reimbursement got cut by approximately 30% (depending on the number of stains per specimen) for 2014.

Both CAP and ASCP have commented to CMS and are advocating for an alternative to the G-codes. There is hope that changes will be made in the Final Rule for 2015.

CPT 88185 Identified as "Potentially Misvalued"
Under the Proposed Rule for 2015, CPT 88185 (flowcytometry/tc add-on) is scheduled to increase by 5.3% to $56.56. However, CPT 88185 has also been identified as potentially misvalued, so its payment rate could be adjusted lower in the Final Rule.

Digital Pathology TC Rates to Rise 7.9%
The technical component for CPT 88361 is set to rise by 7.9% to $106.32 in 2015. CPT 88361 is used to bill Medicare for the preparation and reading of digital HER2, ER and PR slides from a computer monitor. Professional rates for CPT 88361 will decline slightly (-0.7%) to $59.07, while global reimbursement will increase by 4.7% to $165.39, according to the Proposed Rule for 2015. The proposed rate increase for CPT 88361 should give a small boost to the digital pathology market which has actually been shrinking in size for the past two years.

Manual Microdissection TC Rates to Rise 16.2%
The technical component for CPT 88381 is set to rise by 16% to $122.79 in 2015. CPT 88381 (manual sample preparation of microscopically identified target) is most frequently used by molecular oncology labs (e.g., Clarient, Caris MPI, Response Genetics) to bill Medicare for mutation detection tests. Professional rates for CPT 88381 will increase by 3.2% to $56.92, while global reimbursement will increase by 11.7% to $179.70, according to the Proposed Rule for 2015.

PROPOSED PHYSICIAN FEE SCHEDULE RATES FOR 2015

CPT/HCPCS	Mod	Description	2015*	2014*	Change
88108	26	Cytopath concentrate tech	23.27	22.93	1.5%
88108	TC	Cytopath concentrate tech	59.07	55.88	5.7%
88108	Global	Cytopath concentrate tech	82.33	78.81	4.5%
88112	26	Cytopath cell enhance tech	28.28	28.30	-0.1%
88112	TC	Cytopath cell enhance tech	35.08	34.75	1.0%
88112	Global	Cytopath cell enhance tech	63.36	63.05	0.5%
88120	26	Cytp urine 3-5 probes ea spec	58.35	59.11	-1.3%
88120	TC	Cytp urine 3-5 probes ea spec	553.79	559.55	-1.0%
88120	Global	Cytp urine 3-5 probes ea spec	612.14	618.66	-1.1%
88121	26	Cytp urine 3-5 probes cmptr	50.83	50.87	-0.1%
88121	TC	Cytp urine 3-5 probes cmptr	494.72	484.32	2.1%
88121	Global	Cytp urine 3-5 probes cmptr	545.56	535.19	1.9%
88173	26	Cytopath eval fna report	71.24	72.00	-1.1%
88173	TC	Cytopath eval fna report	76.61	74.87	2.3%
88173	Global	Cytopath eval fna report	147.84	146.87	0.7%
88184	TC-only	Flowcytometry/ tc 1 marker	92.72	87.77	5.6%
88185	TC-only	Flowcytometry/tc add-on	56.56	53.73	5.3%
88189	TC-only	Flowcytometry/read 16 & >	111.33	110.69	0.6%
88304	26	Tissue exam by pathologist	11.81	11.46	3.1%
88304	TC	Tissue exam by pathologist	32.93	31.88	3.3%
88304	Global	Tissue exam by pathologist	44.75	43.35	3.2%
88305	26	Tissue exam by pathologist	38.30	38.33	-0.1%
88305	TC	Tissue exam by pathologist	32.93	32.24	2.2%
88305	Global	Tissue exam by pathologist	71.24	70.57	0.9%
88307	26	Tissue exam by pathologist	84.48	84.18	0.4%
88307	TC	Tissue exam by pathologist	213.00	204.19	4.3%
88307	Global	Tissue exam by pathologist	297.48	288.37	3.2%
88309	26	Tissue exam by pathologist	149.28	149.02	0.2%
88309	TC	Tissue exam by pathologist	302.13	289.81	4.3%
88309	Global	Tissue exam by pathologist	451.41	438.83	2.9%
88312	26	Special stains group 1	27.56	27.58	-0.1%
88312	TC	Special stains group 1	67.66	66.99	1.0%
88312	Global	Special stains group 1	95.22	94.57	0.7%

*Conversion factor for 2014 is 35.8228
*Proposed Conversion Factor for 2015 is 35.7997
Note: All rates unadjusted for geographic practice cost differences
Source: *Laboratory Economics* from CMS

CPT/HCPCS	Mod	Description	2015*	2014*	Change
88313	26	Special stains group 2	12.53	12.18	2.9%
88313	TC	Special stains group 2	54.05	53.73	0.6%
88313	Global	Special stains group 2	66.58	65.91	1.0%
88321	26-only	Microslide consultation	95.22	95.29	-0.1%
88323	TC	Microslide consultation	61.57	59.47	3.5%
88323	26	Microslide consultation	88.42	88.12	0.3%
88323	Global	Microslide consultation	149.99	147.59	1.6%
88331	26	Path consult intraop 1 bloc	63.36	62.69	1.1%
88331	TC	Path consult intraop 1 bloc	37.59	36.18	3.9%
88331	Global	Path consult intraop 1 bloc	100.95	98.87	2.1%
88346	26	Immunofluorescent study	42.96	42.99	-0.1%
88346	TC	Immunofluorescent study	65.15	63.41	2.7%
88346	Global	Immunofluorescent study	108.11	106.39	1.6%
88361	26	Tumor immunohistochem/comput	59.07	59.47	-0.7%
88361	TC	Tumor immunohistochem/comput	106.32	98.51	7.9%
88361	Global	Tumor immunohistochem/comput	165.39	157.98	4.7%
88367	26	Insitu hybridization auto	62.29	62.69	-0.6%
88367	TC	Insitu hybridization auto	250.58	193.08	29.8%
88367	Global	Insitu hybridization auto	312.87	255.77	22.3%
88368	26	Insitu hybridization manual	64.79	64.84	-0.1%
88368	TC	Insitu hybridization manual	218.72	167.65	30.5%
88368	Global	Insitu hybridization manual	283.52	232.49	21.9%
88381	26	Microdissection manual	56.92	55.17	3.2%
88381	TC	Microdissection manual	122.79	105.68	16.2%
88381	Global	Microdissection manual	179.70	160.84	11.7%
G0416	26	Sat biopsy 10-20	182.93	184.49	-0.8%
G0416	TC	Sat biopsy 10-20	468.23	466.77	0.3%
G0416	Global	Sat biopsy 10-20	651.16	651.26	0.0%
G0452	26-only	Molecular pathology interpret	18.97	19.34	-1.9%
G0461	26	Immunohisto/cyto chem 1st st	30.79	30.81	-0.1%
G0461	TC	Immunohisto/cyto chem 1st st	60.14	57.67	4.3%
G0461	Global	Immunohisto/cyto chem 1st st	90.93	88.48	2.8%
G0462	26	Immunohisto/cyto chem add	12.53	12.54	-0.1%
G0462	TC	Immunohisto/cyto chem add	57.99	55.88	3.8%
G0462	Global	Immunohisto/cyto chem add	70.52	68.42	3.1%

*Conversion factor for 2014 is 35.8228
*Proposed Conversion Factor for 2015 is 35.7997
Note: All rates unadjusted for geographic practice cost differences
Source: *Laboratory Economics* from CMS

WHO GETS HURT IF FISH RATES ARE CUT?

The FISH testing codes 88365, 88367 and 88368 are under review as potentially misvalued and reimbursement cuts are anticipated when Medicare's Physician Fee Schedule Final Rule for 2015 is released in early November.

Genoptix (Carlsbad, CA), owned by Novartis, is by far the biggest FISH testing lab in the United States based on Medicare Part B payments received. Genoptix received $16.5 million in Medicare payments from billing for CPT 88368 in 2012, according to a *Laboratory Economics*' analysis of Medicare Part B data from CMS.

NeoGenomics (Fort Myers, FL) received $9.2 million in Part B payments for FISH testing in 2012, primarily from CPT 88367.

Clarient Diagnostic Services (Aliso Viejo, CA), owned by GE Healthcare, received $7.4 million in Part B payments for FISH testing in 2012, primarily from CPT 88367 and 88368.

Bostwick Laboratories (Glen Allen, VA) also received $7.4 million in Part B payments for FISH testing in 2012. However, the majority of this revenue came from CPT 88120, which is for FISH testing on urine samples and is not under reimbursement review.

The Nation's Biggest FISH Testing Labs by Medicare Payments

Name	Location	88120	88121	88365	88367	88368	Total
Genoptix	Carlsbad, CA	$0	$0	$0	$0	$16,549,646	$16,549,646
NeoGenomics Labs	CA, FL	0	649,672	2,384	8,098,112	497,089	9,247,257
Clarient Diagnostic Services	Aliso Viejo, CA	0	257,932	194,186	1,504,010	5,489,128	7,445,256
Bostwick Laboratories	FL, NY, VA	6,323,369	196,645	0	189,194	676,691	7,385,899
Bio-Reference Labs	Elmwood Park, NJ	0	690,459	27,133	256,634	4,983,106	5,957,332
Plus Diagnostics	CA, NJ	1,617,663	7,770	0	1,739,521	149,094	3,514,048
Cytometry Specialists Inc.	Alpharetta, GA	6,664	0	14,943	0	1,599,019	1,620,626
OURLab/Prost-Data Inc.	CA, TN	1,341,199	0	0	190,910	0	1,532,109
Caris MPI	Phoenix, AZ	0	0	0	713,505	643,975	1,357,480
Sonic/CBLPath Inc.	Rye Brook, NY	793,271	0	59,137	297,940	68,592	1,218,940
Dianon Systems	CT, OK	818,228	197,392	0	0	0	1,015,620
PathGroup	CA, TN	101,844	0	236,993	488,028	57,834	884,699
Acupath Laboratories	Plainview, NY	0	727,376	5,612	0	36,955	769,943
Healthtronics Lab	Augusta, GA	697,218	0	0	67,374	0	764,592
Esoterix Genetic Laboratories	New York, NY	0	0	131,875	0	623,511	755,386
AmeriPath	CT, FL, NY, TX	120,490	0	200,058	74,421	118,150	513,119
Miraca/Onco Diagnostic Lab	Cleveland, OH	478,181	0	0	0	0	478,181
Miraca Life Sciences	Irving, TX	0	0	300,617	26,032	17,823	344,472

Source: *Laboratory Economics* from Medicare Part B Utilization Data, 2012

WILL HOSPITAL OUTREACH LABS BE COUNTED IN CLFS PRICING REFORM?

On July 14 CMS held its Annual Clinical Laboratory Public Meeting, where a hot topic of discussion was the Protecting Access to Medicare Act of 2014 (PAMA), which will modify the reimbursement rates that Medicare Part B will pay for nearly all tests on the Clinical Lab Fee Schedule. PAMA will tie the rates paid through the CLFS to private payer reimbursement beginning in 2017. Lab industry comments at the July 14 meeting focused on the need for CMS to clarify which labs must report private payer rate data and how that data should be analyzed.

Starting January 1, 2016, PAMA requires "applicable laboratories" (to be precisely defined by CMS) to report to CMS the private payer reimbursement they received for each lab test in 2015. CMS will use this information to calculate a new weighted median reimbursement rate for each lab test on the CLFS (except new tests and advanced diagnostic tests) effective January 1, 2017.

The lab industry, as represented by ACLA, ASCP and the National Independent Laboratory Association, is concerned that the private payer rates received by the largest national commercial labs will dominate the calculation and lead to significantly reduced reimbursement rates for all laboratories.

At the July 14 meeting, lab industry representatives urged CMS to clarify the definition of "applicable laboratory" so as to include and require hospital and physician office labs to report private payer data that is not part of a bundled payment. Inclusion of private payer data from hospital outreach labs and POLs would bring average payment rates up and thereby benefit all labs paid through the CLFS.

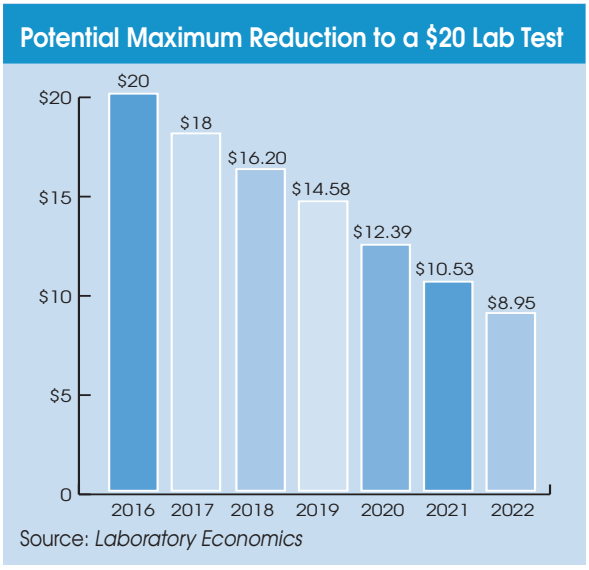
Right now, it's an open question as to whether or not CMS will consider hospital outreach labs as "applicable labs" required to submit private payer data.

Meanwhile, *Laboratory Economics* notes that the timeline for implementing the CLFS pricing reform provisions is extremely tight, given the magnitude of data involved. CMS is to issue regulations regarding payment rate reporting no later than June 30, 2015. Actual data reporting is to begin January 1, 2016, and CMS must calculate weighted medians for each individual test in time for them to take effect on January 1, 2017.

The Worst Case Scenario

Under a worst case scenario, any individual lab test code could be cut by up to a total of 55% between 2017 and 2022. PAMA allows CMS to cut each lab test rate by up to 10% each year for 2017, 2018 and 2019, and by up to 15% each year for 2020, 2021 and 2022. It also eliminates annual inflation adjustments made to the CLFS beginning in 2017. This means that a lab test reimbursed by the CLFS at $20 in 2016 could be cut to as low as $8.95 in 2022.

The Congressional Budget Office has estimated that repricing the CLFS based on private payer rates will result in total savings of $2.5 billion to the Medicare program between 2017 and 2024.



OIG REPORT SPOTLIGHTS LAB BILLING RED FLAGS (*cont'd from p. 1*)

The OIG's findings were based on its analysis of a data set including 145.6 million lab claims submitted by 94,609 labs for 23 million beneficiaries, totaling $7.3 billion in Medicare payments in 2010. The study included both independent labs and non-independent labs, such as physician office labs.

The OIG analyzed thirteen different measures including, for example, (1) average number of claims per beneficiary or ordering physician, (2) average allowed amount per beneficiary, and (3) percentage of claims with invalid or ineligible ordering-physician numbers.

The OIG considered a lab's billing to be unusually high or questionable for a particular measure if the number or percentage was greater than the 75th percentile plus three times the interquartile range. The OIG considered any lab that exceeded the thresholds for five or more of the thirteen measures of questionable billing to be an outlier. In total, 1,032 out of the 94,609 labs exceeded at least five of the thirteen measures, and, thus, were considered outliers. So only about 1% of the labs studied had questionable billing practices. The names of these labs were not disclosed.

However, using some of the same statistical red flags that OIG used, *Laboratory Economics* has compiled a short list of independent labs that are likely to draw scrutiny from Medicare contractors. We used the Part B utilization data for 2012 that was recently made public by CMS.

Specifically, we sorted the 2,743 independent clinical labs that received Medicare payments in 2012 by three factors: (1) labs with at least $1 million in allowed payments; (2) labs that received an average allowed payment of at least $300 per beneficiary served; and (3) labs that provided an average of at least 70 lab test services per beneficiary served.

We emphasize that just because a lab met these statistical thresholds does not mean that the lab has done anything wrong. On the other hand, several of the labs on the list have had billing issues.

For example, D & G Holdings, LLC (Pleasant Hill, LA), which does business as Doctors Lab, had its Medicare billing privileges revoked effective June 29, 2013 because it allegedly billed for lab tests provided to deceased beneficiaries. D & G appealed the decision to an administrative law judge who found that CMS failed to establish a basis for the revocation of the lab's Medicare billing privileges. Medicare utilization data shows that D & G billed Medicare for 3,509,721 lab test services for 4,538 beneficiaries in 2012—an average of 773 services per Part B beneficiary.

Last year, Kan-Di-Ki, LLC (Burbank, CA), also known as Diagnostic Laboratories and Radiology, agreed to pay $17.5 million to the United States and California to resolve allegations that it submitted false claims to the Medicare and Medi-Cal programs. Medicare utilization data shows that Kan-Di-Ki performed an average of 93 lab test services per Part B beneficiary in 2012.

In addition, as previously reported by *LE*, Natural Molecular Testing Corp. (NMTC—Renton, WA) lost its Medicare billing privileges in early 2013 and later filed for Chapter 11 bankruptcy reorganization. NMTC performed 2.992 million tests for 22760 Part B beneficiaries in 2012—an average of 131 services per Part B beneficiary.

Overall, all 2,743 independent clinical labs billed an average of 14 tests per Part B beneficiary and received an average payment of $192 per beneficiary in 2012.

INDEPENDENT LABS WITH HIGHEST PART B SERVICES PER BENEFICIARY, 2012

LABORATORY NAME	CITY	ST	NUMBER BENEFIC	NUMBER SERVICES	ALLOWED AMOUNT	SERVICES/ BENEFIC	AMOUNT/ BENEFIC
D & G HOLDINGS, LLC	PLEASANT HILL	LA	4,538	3,509,721	$4,129,908	773	$910
PRECISION TESTING LABORATORIES INC	SOUTHBRIDGE	MA	382	143,736	3,179,179	376	8,322
ATLANTIC DIAGNOSTIC LABORATORIES	BENSALEM	PA	6,493	2,442,931	3,609,951	376	556
ELITE LAB SERVICES LLC	TYLER	TX	12,690	4,425,107	7,157,654	349	564
MYRIAD GENETIC LABORATORIES	SALT LAKE CITY	UT	16,554	3,889,582	54,460,003	235	3,290
COMPANION DX REFERENCE LAB, LLC	HOUSTON	TX	1,165	230,905	2,488,661	198	2,136
VALLEY DIAGNOSTIC LABORATORIES INC	GALLIPOLIS	OH	3,052	535,713	1,028,659	176	337
MEDICAL CENTER LABORATORIES II, LTD.	HOUSTON	TX	19,542	3,310,016	8,040,183	169	411
O'HARE CLINICAL LAB SERVICES	CREST HILL	IL	3,496	561,525	1,165,381	161	333
METROSTAT CLINICAL LABORATORY, INC	GARLAND	TX	13,091	2,070,946	4,782,258	158	365
UNIVERSITY OF MIAMI	MIAMI	FL	1,644	239,664	4,071,692	146	2,477
AXIS DIAGNOSTICS, INC.	LANGHORNE	PA	9,469	1,350,669	2,901,417	143	306
NATURAL MOLECULAR TESTING CORP.	RENTON	WA	22,760	2,991,516	70,268,621	131	3,087
AMBRY GENETICS CORPORATION	ALISO VIEJO	CA	994	126,049	2,687,747	127	2,704
CMLAB INC	PEMBROKE PINES	FL	11,259	1,368,901	3,828,517	122	340
PHARMACOGENETICS DIAGNOSTICS LAB	LOUISVILLE	KY	2,691	308,361	4,040,670	115	1,502
ASSURERX HEALTH, INC.	MASON	OH	4,176	452,858	9,846,215	108	2,358
AMERICAN INT'L BIOTECH (AIBIOTECH)	RICHMOND	VA	6,429	655,572	15,358,775	102	2,389
LIFESCAN LABORATORY, INC.	SKOKIE	IL	14,963	1,491,741	4,518,132	100	302
PROFESSIONAL CLINICAL LAB, INC.	AUSTIN	TX	10,967	1,079,878	3,725,830	98	340
KAN-DI-KI, LLC	BURBANK	CA	71,688	6,660,442	22,878,385	93	319
TRANSGENOMIC, INC.	NEW HAVEN	CT	899	79,652	1,664,345	89	1,851
ECCOLAB GROUP CO	MIAMI	FL	16,462	1,416,638	6,258,434	86	380
ADVANCED CLINICAL LAB	METAIRIE	LA	4,669	395,132	1,444,308	85	309
QUEST/ATHENA DIAGNOSTICS	WORCESTER	MA	5,989	500,342	3,366,479	84	562
PATHOLOGY SERVICES ORG LLC	LANSING	MI	1,125	88,172	1,833,271	78	1,630
U.S. LAB & RADIOLOGY, INC.	BROCKTON	MA	20,470	1,602,384	6,584,544	78	322
RESPONSE GENETICS, INC.	LOS ANGELES	CA	2,874	212,974	4,757,774	74	1,655
AMERIDRUG LABORATORIES INC	LOVELAND	CO	2,113	149,612	2,819,878	71	1,335
NEXUS LAB 2.0 LLC	DANVILLE	KY	3,730	259,706	6,573,304	70	1,762
ALL INDEPENDENT CLINICAL LABS			26,223,745	364,776,133	$5,044,477,997	14	$192

Source: *Laboratory Economics* from Medicare Part B Utilization Data, 2012

NEOGENOMICS BUYS PATH LOGIC FOR $6 MILLION

NeoGenomics (Fort Myers, FL) has acquired Path Labs LLC d/b/a Path Logic (West Sacramento, CA) for $6 million. The purchase price is equal to 0.6x Path Logic's revenue of $10 million in 2013. The transaction includes Path Logic's main laboratory in West Sacramento, California, as well as a smaller lab in Santa Ana and a courier office in Fresno.

The eight pathologists at Path Logic will maintain ownership of their professional services corporation and have signed a long-term contract to provide interpretations to NeoGenomics.

Path Logic was originally founded in 1999 by three pathologists, Peter Kolbeck, MD, Stephen Bauer, MD, and Oliver Stanton, MD. They sold Path Logic to the private equity firm Mainsail Partners in early 2010. And now Mainsail has sold Path Logic's technical lab operations to NeoGenomics.

NeoGenomics currently has a staff of nine pathologists, primarily specializing in hematopathology. The acquisition of Path Logic brings eight contracted pathologists with sub-specialization in renal pathology, cytopathology, dermatopathology, gastropathology and uropathology, according to Douglas VanOort, Chairman and CEO of NeoGenomics. He says added pathologists will allow NeoGenomics to expand its professional interpretation services.

In particular, VanOort says the addition of Path Logic's pathologists will help NeoGenomics serve its new contract with Covance Inc. NeoGenomics signed an exclusive five-year contract, effective May 2014, to provide the professional read for Covance's worldwide clinical trials business for oncology. Covance is the world's largest clinical trial laboratory services provider (with locations in the United States, Switzerland, Singapore and China; 2013 revenue from its clinical trials lab business was $775 million).

In addition, VanOort sees opportunities for NeoGenomics to sell its molecular and FISH testing services to Path Logic clients in northern California, a region where NeoGenomics has until now had a limited presence.

Meanwhile, *Laboratory Economics* notes that NeoGenomics may be positioning itself to make some larger acquisitions in the near future. The company recently filed a registration with the SEC for a $100 million equity shelf. The registration allows NeoGenomics to sell, from time to time, up to $100 million of common stock, preferred stock, warrants, or any combination thereof.

Finally, NeoGenomics reported first-half results on July 17. Net income increased to $376,000 in the six months ended June 30, 2014 from $276,000 in the same period a year ago; revenue was up 24% to $38.9 million. Average revenue per requisition declined 4.6% to $719 per req, while volume increased 30% to 54,058 reqs.

INCYTE BUYS ACUPATH LABORATORY IN SEATTLE

Incyte Diagnostics has acquired Accupath Laboratory Services, Inc. (Seattle, Wa). Accupath has provided clinical and anatomic pathology services to the Seattle area for over 50 years. Accupath's owner, Robert R. Hasselbrack, MD, is joining Incyte Diagnostics and will focus on the development of a next-generation pathology practice outreach program for clinicians in the Pacific Northwest. Incyte Diagnostics' Bellevue laboratory will begin servicing Accupath's current clients on July 1st. Purchase price and details of the acquisition were not disclosed.

CAREDX SEEKS UP TO $50.5 MILLION FROM IPO

CareDX (Brisbane, CA), formerly named XDx Inc., has filed plans to raise gross proceeds of up to $50.5 million through an IPO of 3.1 million shares priced at between $15 and $17. At the midpoint of the proposed range, it would command a fully diluted market value of $175 million. The IPO is being managed by Piper Jaffray, Leerink Partners, Raymond James and Mizuho Securities. The company plans to trade on the Nasdaq under the ticker symbol CDNA.

CareDx markets a proprietary laboratory-developed test ("AlloMap") that helps to determine the risk of rejection of a new heart in transplant candidates. All testing is performed at the company's CLIA-certified laboratory in Brisbane, California. The list price of AlloMap is $3,600.

The company said in its SEC filing that it had a $3.5 million net loss on revenue of $22.1 million in 2013. That compares with a loss of about $5.1 million on revenue of $20.5 million in 2012. The volume of delivered tests was 10,064 tests in 2013 versus 8,337 tests in 2012. Since being formed in 1998, CareDX has accumulated losses totaling $161.5 million.

To date, CareDX has raised more than $120 million in funding from private equity investors. Its biggest stakeholders are Kleiner Perkins Caufield & Byers (17% stake), TPG Biotech (16.5%), Sprout Group (11.1%), Intel Capital (10.2%), Burrill & Co. (9.4%), DAG Ventures (7.3%) and Integral Capital Partners (5.6%).

AURORA COMPLETES ACQUISITION OF TWO PATHOLOGY GROUPS

Aurora Diagnostics has completed two acquisitions, including a previously announced deal to buy Mid-Atlantic Pathology Services Inc. (Sterling, VA). MAPS is a dermatopathology lab with four pathologists that serves the Northern Virginia and greater Washington, DC areas. In addition, Aurora has purchased Hallmark Pathology, P.C. (Medford, MA). Hallmark provides anatomic pathology services for two community hospitals in the greater Boston area.

DIGIPATH TO OPEN MARIJUANA TESTING LAB IN LAS VEGAS

DigiPath Inc. (Las Vegas, NV) has received approval from the Clark County Commission to open a cannabis testing laboratory in Las Vegas. DigiPath is hoping for final approval by the State of Nevada within the next few months. DigiPath Labs plans to analyze both the dried plant material as well as byproducts from the cannabis plant for potency and contaminants.

In addition, DigiPath has hired Oak Tree Educational Partners Inc. (New York City), which operates vocational training schools, to help develop weekend seminars, online courses and instructor-led courses to train and educate students in the medical marijuana business.

Last year, the Nevada legislature passed a law to allow regulated access to medical marijuana. The law makes the drug legal for medical consumption in Nevada, and the state is in the process of granting licenses for up to 66 medical marijuana dispensaries as well as cultivators, product manufacturers, and testing labs.

Up until now, DigiPath had been focused on marketing digital pathology systems (see *LE*, June 2014, page 10).

LAB STOCKS UP 13% YTD

Fourteen lab stocks increased an average of 13% year to date through July 17. In comparison, the S&P 500 Index is up 7%. The top-performing lab stock so far this year is Myriad Genetics, up 84%, followed by Enzo Biochem, up 73%. LabCorp is up 17% and Quest Diagnostics is up by 15%.

Company (ticker)	Stock Price 7/17/14	Stock Price 12/31/13	2014 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Bio-Reference (BRLI)	$30.78	$25.54	21%	$853	22.0	1.1	3.0
Cancer Genetics Inc. (CGIX)	9.53	13.78	-31%	88	NA	13.3	2.1
CombiMatrix (CBMX)	2.21	2.30	-4%	24	NA	3.9	2.0
Enzo Biochem (ENZ)	5.05	2.92	73%	221	NA	2.3	5.8
Foundation Medicine (FMI)	26.82	23.82	13%	756	NA	21.9	6.3
Genomic Health (GHDX)	27.12	29.27	-7%	847	NA	3.2	6.1
LabCorp (LH)	106.64	91.37	17%	9,040	17.8	1.6	3.6
LipoScience (LPDX)	3.28	4.25	-23%	50	NA	1.0	1.1
Myriad Genetics (MYGN)	38.52	20.98	84%	2,880	16.3	3.8	4.0
NeoGenomics (NEO)	5.41	3.62	49%	269	132.0	3.2	9.7
Psychemedics (PMD)	14.18	14.69	-3%	75	20.3	2.8	6.1
Quest Diagnostics (DGX)	61.55	53.54	15%	8,890	11.3	1.3	2.2
Response Genetics (RGDX)	0.86	1.16	-26%	33	NA	1.8	13.5
Sonic Healthcare (SHL.AX)	17.68	16.58	7%	7,086	19.4	1.9	2.3
Unweighted Averages			13%		34.1	4.5	4.8

Source: Bloomberg and Zacks

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