August 11, 2014

OUTPERFORM

Reason for report:

INITIATION

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LEERINK

CAREDX, INC.

Post-Transplant Pure Play; Initiate at Outperform

• **Bottom Line:** We are initiating coverage of CDNA with an Outperform rating and $13 price target. CDNA has developed a strong franchise in post-transplant surveillance monitoring in heart -- a franchise we believe the company will successfully expand into other solid organs. We believe CDNA's pipeline opportunity is undervalued at current levels, and that pipeline data expected in 2015 could drive multiple expansion.

• **Need for improved surveillance of heart transplant recipients.** Survival rates for heart transplant recipients changed minimally between 1992 and 2011, which could result from excessively high immunosuppression. Biopsy is the gold standard for transplant surveillance, but it is invasive and expensive, and its interpretation subjective. These unmet needs create the market opportunity for AlloMap.

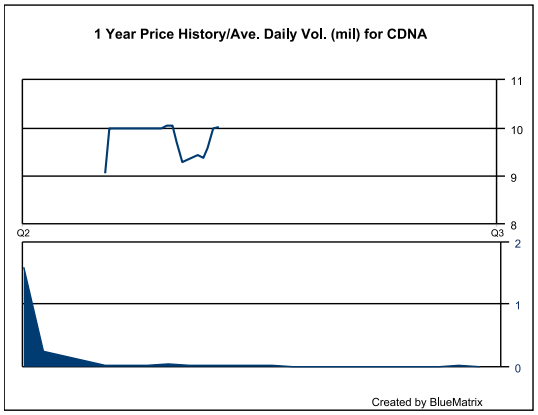
• **AlloMap solution is validated by multiple sources.** AlloMap is the only non-invasive test of its kind proven to catch rejection early, reduce biopsy, and over time predict the likelihood of future rejection, enabling clinicians to intensify or reduce immunosuppression as necessary. The product is FDA 510(k) cleared, included in the International Society of Heart and Lung Transplantation (ISHLT) heart transplant guidelines, has a seminal clinical utility study published in the *New England Journal of Medicine*, and is broadly reimbursed.

• **Potential for AlloMap use to expand.** We believe AlloMap has greenfield growth opportunity in both first-year transplant patients (~50% penetration in 2013) and patients more than 1 year removed from transplant (~15% penetration in 2013).

• **Pipeline targets larger market opportunities in transplant diagnostics.** A cell-free DNA (cfDNA) post-transplant surveillance test for kidney transplant recipients promises to be a larger market opportunity than heart transplant.

• **Uncertain revenue ramp for both existing and pipeline products the most prominent risk.** We consider the trajectory of the revenue ramp for CDNA's AlloMap product as well as its proposed kidney transplant surveillance product to be the greatest risks to the story. Though AlloMap returned to strong growth in 2014, the sustainability of that growth remains uncertain. The kidney surveillance product is subject to risks associated with any diagnostic product development plan, which include technical, regulatory, and reimbursement risks.

Key Stats:	**(NASDAQ:CDNA)**
S&P 600 Health Care Index:	**1,281.24**
Price:	**$10.02**
Price Target:	$13.00
Methodology:	3.25x EV/TTM estimated revenue ending June 2016
52 Week High:	$10.20
52 Week Low:	$8.49
Shares Outstanding (mil):	10.5
Market Capitalization (mil):	$105.2
Book Value/Share:	$2.97
Cash Per Share:	$5.20
Dividend (ann):	$0.00
Dividend Yield:	0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A	$5.0	$5.5	$5.8	$5.9	$22.1	($0.19)	($0.12)	($0.12)	($0.08)	($0.51)	NM
2014E	$5.9A	$6.1	$6.5	$7.1	$25.6	($0.21)A	($0.11)	($0.17)	($0.12)	($0.60)	NM
2015E	--	--	--	--	$30.1	--	--	--	--	($0.49)	NM
2016E	--	--	--	--	$40.2	--	--	--	--	($0.10)	NM

Source: Company Information and Leerink Partners LLC Research
Revenues in millions.

INVESTMENT THESIS

We are initiating coverage of Brisbane, California-based CareDx (CDNA) with an Outperform rating and a $13 price target. CDNA markets a non-invasive molecular gene expression test (AlloMap) of 20 genes for heart transplant recipients to diagnose acute cellular rejection, reduce use of biopsy, and better tailor immunosuppression post-transplant to patient needs. Additionally, the company is developing products for post-transplant monitoring that use nextgen sequencing (NGS) to detect cell free DNA (cfDNA). We believe the company will continue to successfully expand its core AlloMap franchise while developing its cfDNA products, which could be marketed as early as 1H15. We believe CDNA's pipeline opportunity is undervalued at current levels and thus initiate with an Outperform rating.

INVESTMENT POSITIVES

Potential for Growth in AlloMap and Pipeline

Need for improved surveillance of heart transplant recipients. Post-transplant rejection in the first year has declined from 32% of patients in 2004 to 25% in 2010 due to improved immunosuppression therapy. However, survival rates have changed minimally between 1992 and 2011, according to the ISHLT 30th official adult heart transplant report. Lack of survival improvement could result from excessively high immunosuppression, which has been associated with several co-morbidities including increased risk of cancer, infection, susceptibility to renal failure, high incidence of new onset diabetes, imbalance of blood lipid levels, hypertension, and osteoporosis. Biopsy is the gold standard for transplant surveillance, but it is invasive and expensive, and its interpretation subjective. These unmet needs create the market opportunity for AlloMap.

AlloMap solution is validated by multiple sources. AlloMap is the only non-invasive test of its kind proven to catch rejection early, reduce biopsy, and over time predict the likelihood of future rejection enabling clinicians to intensify or reduce immunosuppression as necessary. AlloMap has FDA 510(k) clearance and is mentioned in the International Society of Heart and Lung Transplantation (ISHLT) heart transplant guidelines as a means to rule out the presence of acute cellular rejection in appropriate patients. ISHLT guideline inclusion followed a seminal study published in the *New England Journal of Medicine*, which determined that a strategy of monitoring for heart transplant rejection using AlloMap, as compared to routine biopsy, was not associated with an increased risk of serious adverse outcomes yet significantly reduced the number of biopsies. This and other evidence have motivated positive coverage decisions for AlloMap from Medicare and many managed care plans.

Potential for AlloMap use to expand. There are ~25,000 heart transplant recipients living in the U.S. as of 2013, with an additional ~2,500 receiving transplants each year. Frequency of AlloMap usage over the life of a transplant varies widely center to center, but our work suggests that a U.S. market opportunity in the range of $60M - $100M is defensible. We believe AlloMap has greenfield growth opportunity in both first-year transplant patients (~50% penetration in 2013) and patients more than 1 year removed from transplant (~15% penetration in 2013). CDNA's revitalized sales efforts bore fruit with ~20% volume growth in 2013, following only ~2% growth in 2012. The

company also has recently introduced the product in Canada and plans to enable a partner to launch its test shortly in Europe.

cfDNA targets larger market opportunities in transplant diagnostics. We are optimistic about the company's pipeline cfDNA products for heart and kidney transplant recipients. Early clinical studies suggest that cfDNA tests may be comparably efficacious to biopsy in the diagnoses of acute rejection in heart patients, with potential for diagnosis of acute rejection up to 5 months earlier than biopsy. This technology would provide a non-invasive alternative to biopsy and offers the potential to scale back immunosuppression in patients deemed to be at low risk of rejection as gauged by low cfDNA over time (the "quiescent patient"). A cfDNA post-transplant surveillance test for kidney transplant recipients promises to be a larger market opportunity than heart transplant. Through its acquisition of ImmuMetrix, CDNA acquired access to a patent on cfDNA use in conjunction with post-transplant monitoring and broadened its research capabilities in this area.

INVESTMENT RISKS

AlloMap Ramp, Kidney Development Highlight Investment Risks

Size of the heart transplant market an uncertainty, as is AlloMap ramp. The market opportunity for AlloMap is inherently limited by the number of heart transplants per year. While we feel that a $60M - $100M market estimate for the U.S. opportunity is defensible, practice patterns vary widely, and odds that usage trends toward the lower end or below our range cannot be ruled out. Additionally, the ramp at which we assume AlloMap will penetrate its market opportunity is an inherent uncertainty. We take some comfort in the growth reacceleration seen in 2013, and also note that the product was only included in medical society guidelines 4 years ago, which to us suggests that ramp remains early days.

Development of cfDNA testing in kidney is promising, but in very early stages. CDNA plans to commercialize a test for cfDNA in kidney transplant recipients in 2016. Thus far, the company has demonstrated proof of concept for cfDNA as a marker in kidney transplant recipients, but its efforts remain early days. CDNA has secured access to samples from more than 100 kidney transplant recipients from the University of California San Francisco (UCSF) and is seeking to acquire rights to other well curated sample sets. We expect that the company could deliver results from its work with the UCSF sample set in 1H15, following which it plans to launch a prospective clinical outcomes study as early as 2H15. While kidney transplant surveillance represents a large and attractive market opportunity, the development of an effective test to monitor transplant recipients is not trivial.

Impact of proposed changes to regulatory environment uncertain. On July 31, 2014, the FDA finally issued its draft guidance for the regulation of laboratory developed tests (LDTs). The impact this guidance could have on CDNA is unclear. While CDNA's AlloMap test is FDA-cleared for the identification of heart transplant recipients who have a low probability of moderate/severe acute cellular rejection (ACR), the company is exploring utilization of AlloMap in areas that could be considered outside the scope of its current labeling. Thus, CDNA could be required to pursue FDA clearance for these expanded indications. Additionally, CDNA hadn't intended to seek FDA

clearance for its forthcoming cfDNA transplant surveillance products. Increased FDA oversight could lengthen the development timeline for these products.

COMPANY PROFILE

Owning the Hilltop in Non-Invasive Molecular Transplant Surveillance

CareDx, Inc. (CDNA) is a commercial-stage growth company that develops and markets non-invasive molecular surveillance tests for solid organ transplant patients. It has one product currently marketed in the U.S., the AlloMap non-invasive test of gene expression measuring RNA levels for 20 genes to determine the probability of moderate to severe acute cellular rejection (ACR) of a transplant both in the first year post-transplant and in the maintenance population. The test yields a single number score between 0 and 40 that indicates a patient's likelihood that a transplant is at low risk for rejection. A lower score indicates low risk of graft rejection, such that biopsy is not necessary. In practice, physicians often consider patients with a score at or above 34 as an indicator for higher risk for rejection and thus candidates for confirmatory biopsy. The test is designed to reduce unnecessary heart biopsies in patients at low risk for transplant rejection. Longitudinal AlloMap data can demonstrate lower risk of future rejection, allowing physicians to more appropriately prescribe immunosuppressants.

The company was founded in 1998 in Delaware as Hippocratic Engineering and has since had multiple identities including BioCardia, Expression Diagnostics and most recently XDx. The company has offered its AlloMap test since January 2005 and has performed more than 55,000 commercial AlloMap tests to date. The test received FDA clearance in 2008 and was included in ISHLT Practice Guidelines in August 2010.

CNDA had 55 employees as of March 31, 2014, including 20 in sales and marketing and 8 in R&D. The company currently recognizes revenue primarily in the U.S. with minimal revenue outside the U.S.

EXISTING STANDARD OF CARE FALLS SHORT

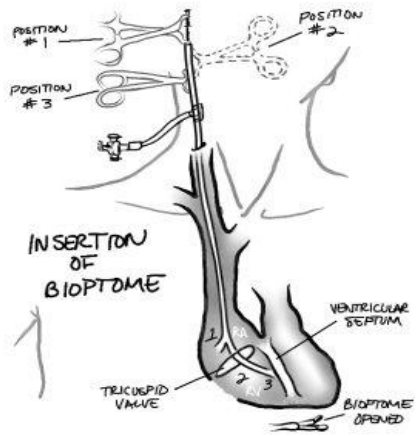
Biopsy Cumbersome, Insufficient for Tailoring Immunosuppressant Use to Patient Need

Careful surveillance is required in the months and years following a transplant procedure to ensure that the new organ is not attacked by the recipient's immune system. A number of complications can occur following heart transplant, including acute rejection, graft dysfunction, cardiac allograft vasculopathy (CAV), renal failure, high blood pressure, and high levels of cholesterol.

To reduce the risk of rejection, transplant recipients are given high doses of immunosuppressants to restrict the body from attacking the foreign donor organ, which would necessitate anti-rejection therapy that can include more immunosuppression, steroids, antibodies, or plasmapheresis. Over-immunosuppression can introduce a host of additional complications that can be serious, including increased risk of infection and cancer.

Acute rejection has historically been monitored with regular post-operative biopsy and clinical assessment. Endomyocardial biopsy is an invasive procedure performed under local anesthesia. A catheter is inserted into the right internal jugular vein, a device called a bioptome is inserted and threaded toward the heart under fluoroscopic guidance, and four to six biopsies are taken of the heart. Following the procedure a chest x-ray is performed to check for complications. The following chart offers some illustration of the endomyocardial biopsy procedure.

Endomyocardial Biopsy Is Invasive

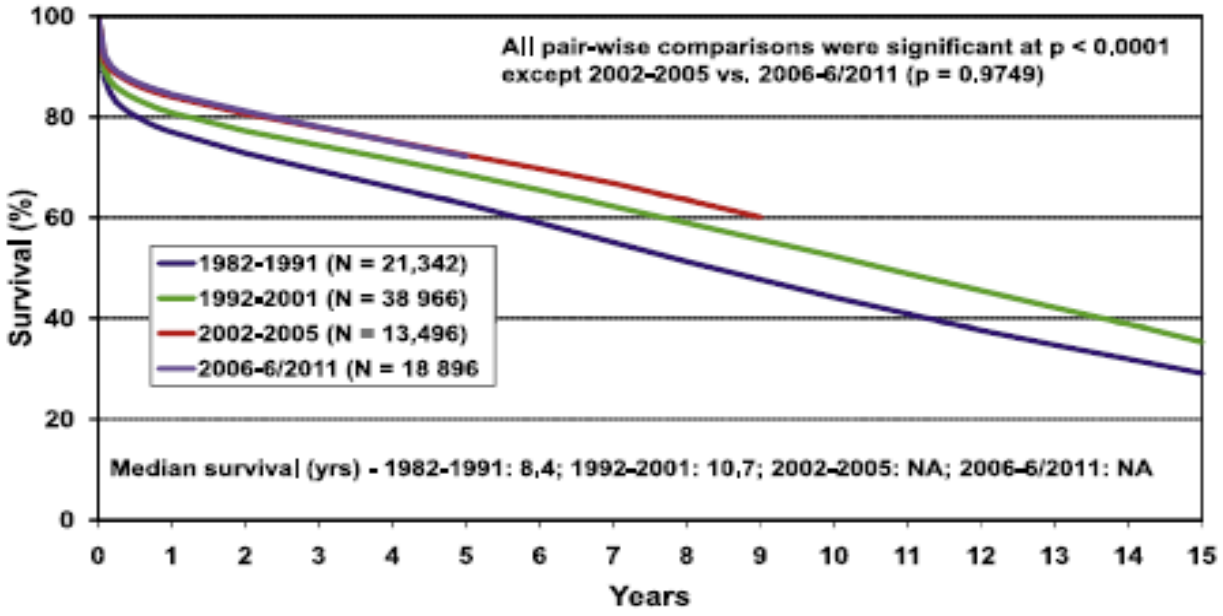


Source: CareDx, http://ugotheart.blogspot.com/2011/09/transplant-update-1.html

While the complication rate of endomyocardial biopsy is <1%, complications can be severe or even fatal. Additionally, lab interpretation of a biopsy sample is subjective and dependent upon qualitative visual assessment. Endomyocardial biopsy is also expensive, and can cost between $4,000 - $10,000 per procedure depending on a number of factors.

Despite greater use of immunosuppression to reduce the incidence of rejection, long-term survival has not changed significantly in recent years, due to a mixture of graft failure, acute rejection, cardiac transplant organ vasculopathy, infection, cancer, and renal failure. The following chart illustrates only modest gains in long-term survival since the 1980s; progress has stagnated since 2001.

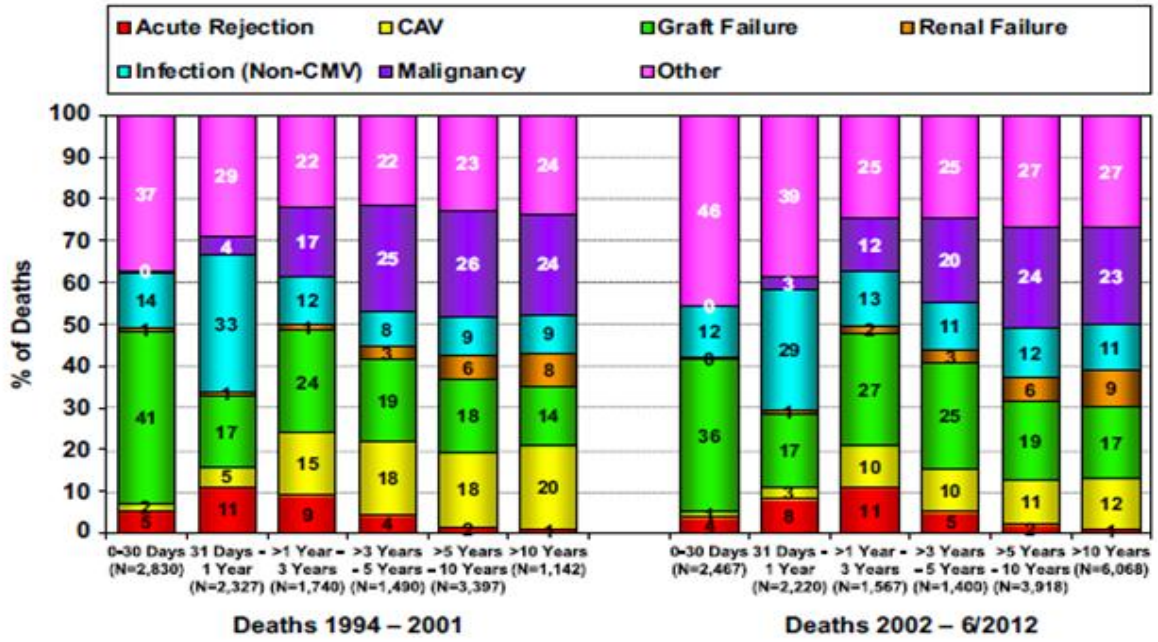
From 1992-2011, Survival Rates in Heart Transplant Patients Changed Minimally



Source: 30th Official Adult Heart Transplant Report, Registry of the International Society for Heart and Lung Transplantation, Oct. 2013

The rejection rate is highest in the first year and drops dramatically after year two. However, rejection represents only a small portion of all transplant-related deaths, with no more than 11% of deaths resulting from acute rejection in any one period – suggesting that immunosuppression use could be unnecessarily high in the transplant population, and side effects of immunosuppression could be implicated in mortality.

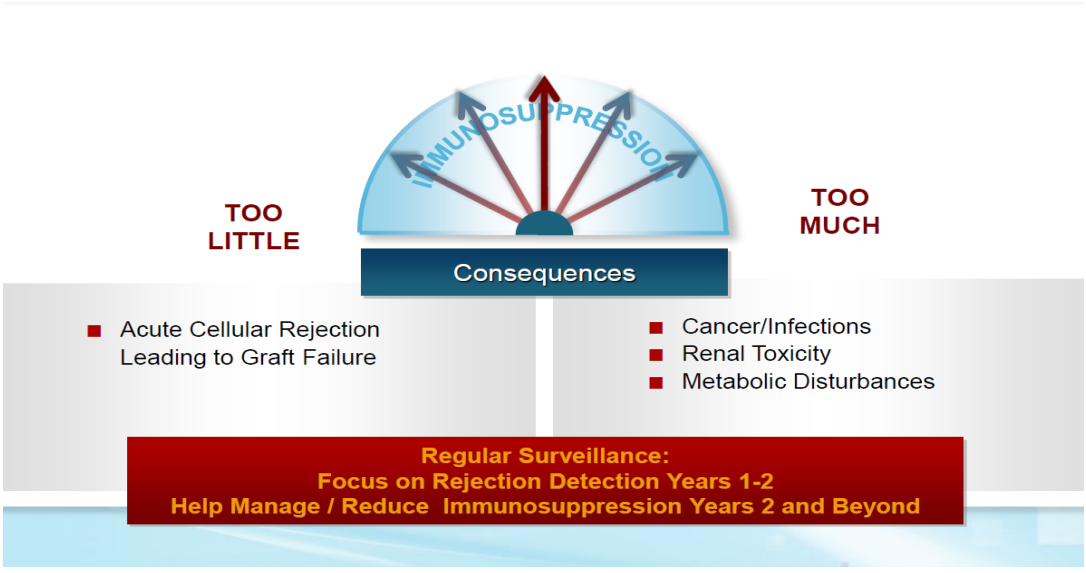
Acute Rejection Accounts for No More Than 11% of Transplant-Related Deaths



Source: 30th Official Adult Heart Transplant Report, Registry of the International Society for Heart and Lung Transplantation, Oct. 2013; CAV = cardiac allograft vasculopathy

The following chart offers an illustration of the pitfalls of inappropriate immune suppression.

Problems with Inappropriate Immunosuppression



Source: CareDx

ALLOMAP A POTENTIAL SOLUTION

AlloMap is Non-invasive, Sensitive, and Reproducible

AlloMap is an alternative to biopsy that is non-invasive and more objective than biopsy. AlloMap is the first and only molecular diagnostic tool of its kind for use in heart transplant recipients for the surveillance of rejection. Additionally, AlloMap longitudinal data could enable clinicians to tailor immunosuppressant dosing to the patient, so that those at lower risk of acute rejection are spared the negative side effects of a suppressed immune system.

AlloMap is intended for use in heart transplant patients both in the first year post-transplant and in the maintenance population beyond year one. Clinicians can choose to offer AlloMap rather than traditional biopsy, with supplemental biopsy in patients with elevated AlloMap scores.

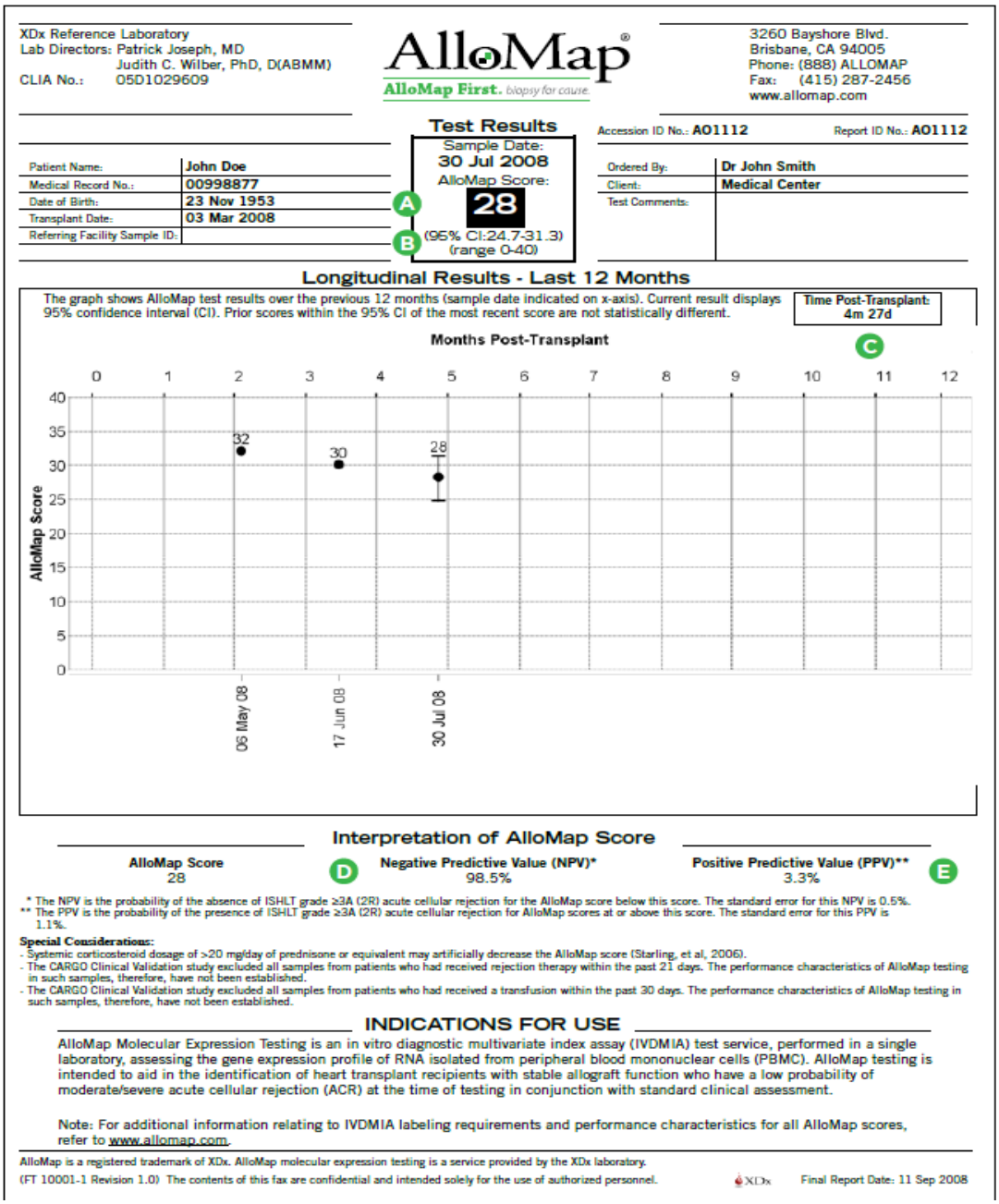
The AlloMap test requires only a blood draw in the transplant center or a hospital outpatient facility, which is then sent to the CDNA clinical laboratory. CDNA performs the testing and provides the ordering physician with a patient report, which the physician uses to plan treatment accordingly – all within a span of 2-3 days from the initial blood draw.

From Blood Draw to Output in 2-3 Days

Source: CareDx

The chart below illustrates a typical AlloMap patient report.

Example of an AlloMap Patient Report



XDx Reference Laboratory
Lab Directors: Patrick Joseph, MD
Judith C. Wilber, PhD, D(ABMM)
CLIA No.: 05D1029609

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Test Results
Sample Date: 30 Jul 2008
AlloMap Score: 28 (A)
(95% CI:24.7-31.3) (B)
(range 0-40)

Accession ID No.: A01112 Report ID No.: A01112

Patient Name:	John Doe
Medical Record No.:	00998877
Date of Birth:	23 Nov 1953
Transplant Date:	03 Mar 2008
Referring Facility Sample ID:	
Ordered By:	Dr John Smith
Client:	Medical Center
Test Comments:	

Longitudinal Results - Last 12 Months

The graph shows AlloMap test results over the previous 12 months (sample date indicated on x-axis). Current result displays 95% confidence interval (CI). Prior scores within the 95% CI of the most recent score are not statistically different.

Time Post-Transplant: 4m 27d

Months Post-Transplant (C)

Interpretation of AlloMap Score

AlloMap Score	Negative Predictive Value (NPV)* (D)	Positive Predictive Value (PPV)** (E)
28	98.5%	3.3%

* The NPV is the probability of the absence of ISHLT grade ≥3A (2R) acute cellular rejection for the AlloMap score below this score. The standard error for this NPV is 0.5%.
** The PPV is the probability of the presence of ISHLT grade ≥3A (2R) acute cellular rejection for AlloMap scores at or above this score. The standard error for this PPV is 1.1%.

Special Considerations:
- Systemic corticosteroid dosage of >20 mg/day of prednisone or equivalent may artificially decrease the AlloMap score (Starling, et al, 2006).
- The CARGO Clinical Validation study excluded all samples from patients who had received rejection therapy within the past 21 days. The performance characteristics of AlloMap testing in such samples, therefore, have not been established.
- The CARGO Clinical Validation study excluded all samples from patients who had received a transfusion within the past 30 days. The performance characteristics of AlloMap testing in such samples, therefore, have not been established.

INDICATIONS FOR USE

AlloMap Molecular Expression Testing is an in vitro diagnostic multivariate index assay (IVDMIA) test service, performed in a single laboratory, assessing the gene expression profile of RNA isolated from peripheral blood mononuclear cells (PBMC). AlloMap testing is intended to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment.

Note: For additional information relating to IVDMIA labeling requirements and performance characteristics for all AlloMap scores, refer to www.allomap.com.

XDx Final Report Date: 11 Sep 2008

Source: CareDx

ALLOMAP'S VALIDITY CONFIRMED BY MULTIPLE STUDIES

CARGO Was the Beginning, IMAGE the Turning Point

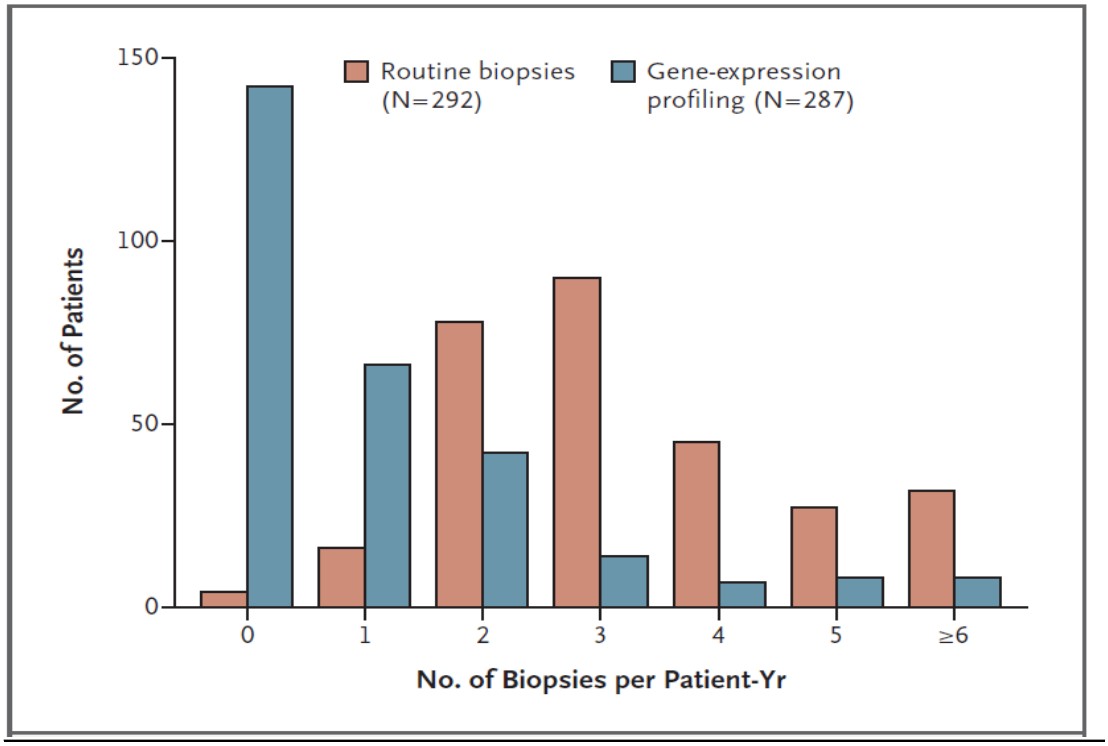
Clinical validity of AlloMap technology has been confirmed through numerous clinical trials involving over 2,000 patients cumulatively.

- ***CARGO:*** Multicenter longitudinal study; 9 U.S. transplant centers, 4,900 blood samples, 700 heart transplant recipients; demonstrated effectiveness of AlloMap in detecting low probability of acute cellular rejection in transplant recipients (negative predictive value)
- ***CARGO II:*** Multicenter longitudinal study; 13 EU and 4 U.S. transplant centers, 6,900 blood samples, 741 heart transplant recipients; confirmed results of CARGO study
- ***IMAGE:*** Prospective trial of 602 heart transplant recipients over two years; demonstrated non-inferiority of AlloMap to biopsy in routine monitoring of transplant recipients 6-60 months after transplant; published in the *New England Journal of Medicine* in April 2010 and contributed to ISHLT guideline inclusion in August 2010
- ***EIMAGE:*** Short-term trial of 60 heart transplant recipients from 2 months – 1 year post-transplant; demonstrated clinical outcomes for AlloMap-managed patients are comparable to outcomes for traditionally managed patients (biopsy + steroid tapering)
- ***AlloMap Score Variability:*** One study based on IMAGE sample set of 369 patients and another based on CARGO II sample set of 108 recipients; both suggest AlloMap score variability over time can predict future risk of organ dysfunction or death, independent of single AlloMap scores suggesting probability of acute cellular rejection
- ***Outcomes AlloMap Registry:*** Multi-year, multi-center registry of long-term outcomes of transplant recipients monitored by regular AlloMap testing involving over 2,000 patients and 8,000 samples.

The IMAGE study is largely considered the seminal trial for AlloMap, and its publication motivated AlloMap's inclusion in ISHLT guidelines. ISHLT guidelines recommend that AlloMap can be used to rule out the presence of acute cellular rejection (ACR) of grade 2R or greater in appropriate low- risk patients, between 6 months and 5 years after heart transplant (level of evidence: B).

In IMAGE, the investigators randomly assigned 602 patients who had undergone cardiac transplantation to be monitored for rejection with the use of AlloMap or with the use of routine endomyocardial biopsy. The results showed that surveillance with AlloMap was non-inferior to surveillance with biopsy, yet patients who were monitored with AlloMap underwent fewer biopsies per person-year of follow-up than did patients who were monitored with endomyocardial biopsies. In fact, the majority of patients (88%) in the AlloMap group underwent 2 biopsies or fewer per patient year, and 50% did not require a biopsy during the study at all. The following chart illustrates these results.

Frequency of Endomyocardial Biopsies Performed in IMAGE Trial



Source: Pham et al. "Gene-Expression Profiling for Rejection Surveillance after Cardiac Transplantation", New England Journal of Medicine*, April 22, 2010*

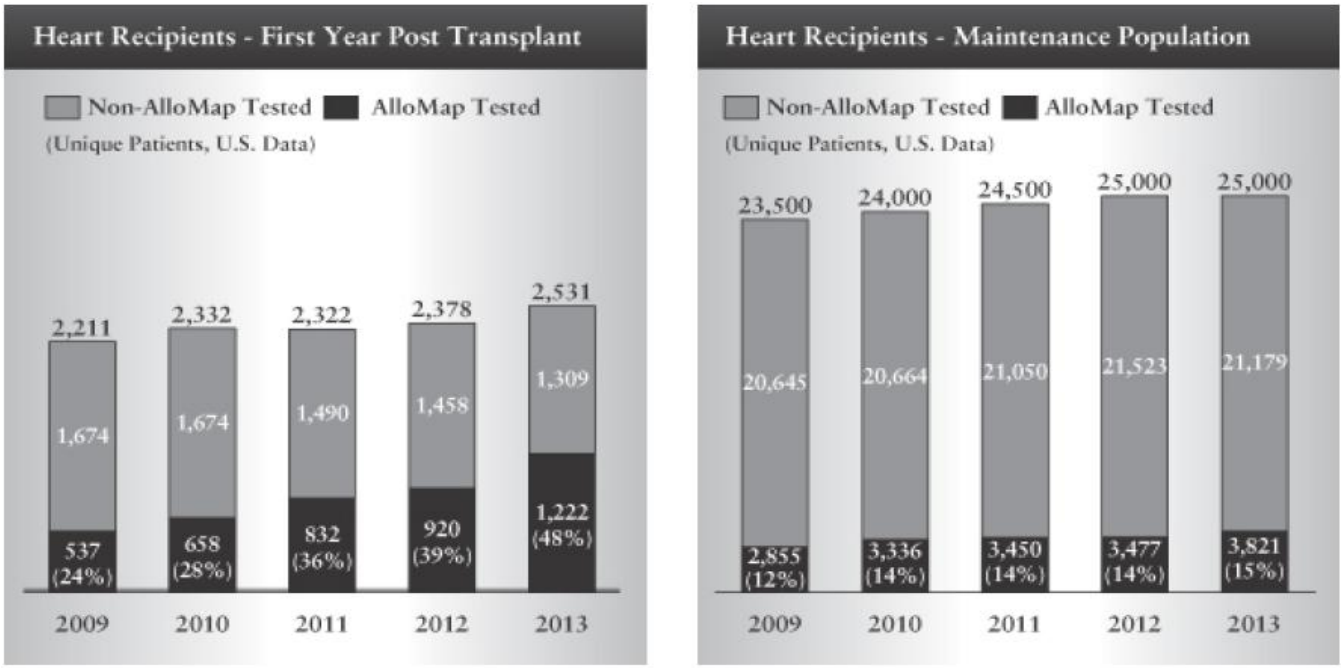
In addition, patient quality of life was noticeably higher in years 1 and 2 post-transplant as scored by the Medical Outcomes Study 12-Item Short Form Health Survey (SF-12).

Room for Growth in Heart Transplant Surveillance

Maintenance Population, International Expansion Offer Growth Opportunities

CDNA's AlloMap product is currently used in 105 of the 126 heart transplant centers in the U.S., which represents good penetration but still some amount of greenfield opportunity. The company plans to continue to actively promote AlloMap's use in the maintenance population -- those patients who are a year or more removed from heart transplant. In 2013, the test was only used in ~15% of patients living with a heart transplant for more than one year, which compares to ~50% usage from eligible first-year heart transplant recipients. The following table illustrates how AlloMap's usage in these two patient populations has progressed over time.

Comparison of AlloMap Usage in 1st Year vs. Maintenance Population



Source: CareDx

The company hopes to increasingly encourage utilization of AlloMap in the maintenance population. Incremental studies and publications should help this cause, including recent publications on the utility of AlloMap score variability over time, as an independent predictor of future organ dysfunction could aid this cause.

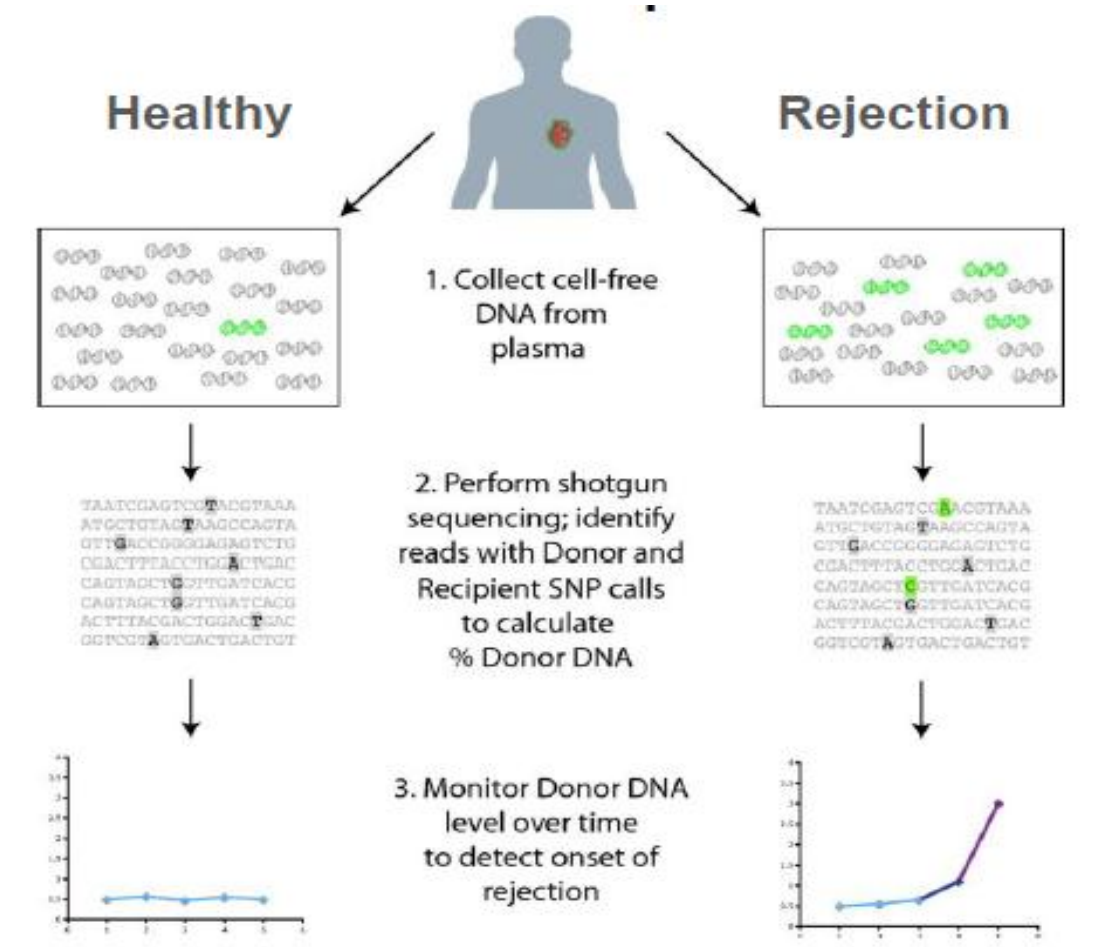
Additionally, the opportunity to expand utilization of AlloMap internationally is almost entirely untapped. CDNA has a partnership with LifeLabs in Canada and Diaxonhit in Europe to offer the test internationally.

PIPELINE TARGETING LARGER MARKET OPPORTUNITIES

cfDNA Detection Enables Entry Into Kidney Transplant Surveillance

Cell-free DNA (cfDNA) are short segments of free-floating DNA in the bloodstream released during cell death. cfDNA can be extracted from the blood and analyzed using next-generation sequencing (NGS), a technique that has become commonly used in prenatal testing to detect fetal aneuploidies. The same technique can be used in transplant recipients to pick up DNA in the bloodstream, with percent donor vs. host DNA as an indicator of transplant rejection.

cfDNA Process in Pre-Natal Testing



Source: CareDx

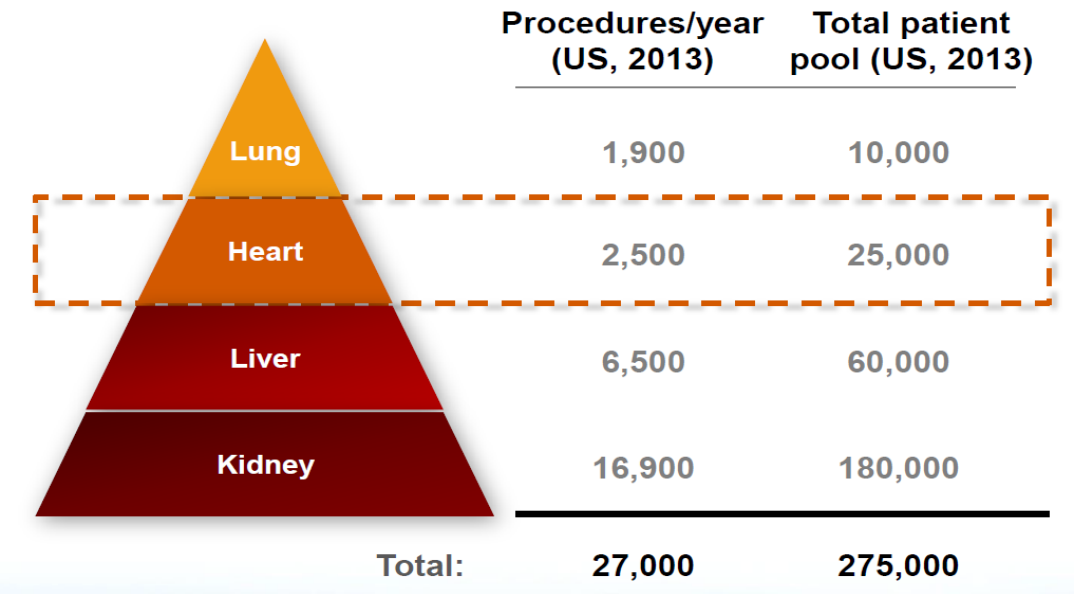
Multiple proof of concept studies have proven the effectiveness of cfDNA in detecting both cellular and antibody mediated heart transplant rejection in pediatric and adult patients. One study additionally suggested that cfDNA can detect rejection up to 5 months before biopsy, and can be used in conjunction with AlloMap as a tool to predict future rejection. CDNA has already demonstrated its own proof of concept using cfDNA as a biomarker for rejection in both heart and kidney transplant recipients. Data presented by its collaborator in July at the World Transplant Congress demonstrated that graft-derived cfDNA proportion in heart and kidney transplant recipients' blood is significantly higher in patients who had biopsy-confirmed rejection compared to that found in transplant recipients who did not have any evidence of rejection at the time of blood sampling.

On July 31, CDNA began enrolling its first patients in a clinical study to assess the usefulness of cfDNA technology in diagnosing rejection in heart transplant recipients. The company plans to initially develop a cfDNA test for heart transplant surveillance to augment its existing AlloMap test

and demonstrate feasibility of this approach. CDNA intends for its cfDNA heart product to be an addendum to the AlloMap line rather than a stand-alone source of revenue.

cfDNA technology is compelling, in part, because it promises universal applicability in transplant surveillance -- the ability to detect any source of rejection, whether it is cellular or antibody-mediated, for any solid organ. Of particular interest is the large kidney transplant market. As the following table illustrates, the frequency of kidney transplants outstrips that of other solid organs by far.

Kidney Is the Most Frequently Transplanted Solid Organ

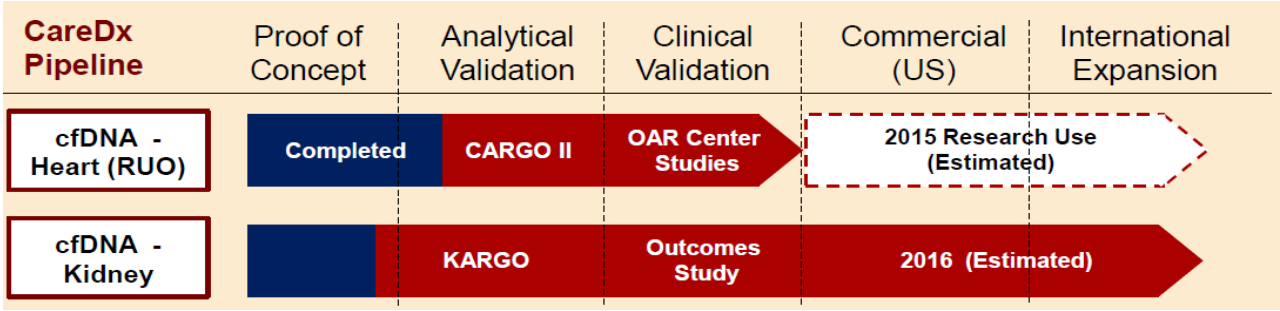


Source: CareDx

The current biomarker in kidney transplant surveillance is serum creatinine. Serum creatinine is the marker for general kidney health and not specific to rejection. Thus, the marker is a poor indicator of transplant health and often catches rejection after significant damage has been done. cfDNA in contrast promises to have higher sensitivity to predict which patients are at higher risk of rejection and catch rejection earlier in the process. This could enable physicians to tailor immunosuppression therapy to reduce negative side effects. More than a diagnostic tool, cfDNA could be a stratification tool to separate stable patients from those at high risk of rejection to coordinate care going forward. While a cfDNA test would be dramatically more expensive than creatinine, the value proposition lies in the potential future reduction of cost from hemodialysis, diabetes treatment, and other treatment for comorbidities caused by over-immunosuppression or rejection caught in a late stage.

CDNA plans to launch a research use only version of its cfDNA heart test in 2015, and commercially launch its cfDNA kidney test in 2016. The following chart illustrates the company's proposed pipeline development timeline.

Timeline of cfDNA Clinical Trials and Development



Source: CareDx

MARKET OPPORTUNITY WILL GROW WITH NEW PRODUCTS

Wide Range of Outcomes Possible, Depending on Clinical Protocol

Assessing the true market opportunity for CDNA's products is challenging because practice patterns vary widely center to center. However, we feel comfortable that a range of $60M - $100M U.S. opportunity is defensible using reasonable assumptions. The high end uses the average usage pattern over 10 years post-transplant, based on conversations with 9 MEDACorp specialists, ISHLT guidelines, transplant center protocols, and payer reimbursement policies. This suggests a U.S. market opportunity of ~37,000 tests annually, which at a price of $2,700 per test (our rough estimate of AlloMap's average reimbursement, on cases where it receives reimbursement), leads to a $100M opportunity. If instead we use the median usage pattern over 10 years for the same group (median reduces the influence of one power user), we arrive at a U.S. market opportunity of ~27,500 tests annually. At a price of ~$2,150 per test (arrived at by dividing 2013 volume into 2013 revenue, which includes tests not reimbursed), this analysis yields a U.S. market opportunity of $60M.

The market opportunity for CDNA's kidney test is less certain and will depend heavily on proposed utilization as well as price per test. We believe both will be a function of the test's clinical data, and we don't expect to have any glimpse at data until 2015. We do know that the volume of kidney transplants is 7x that of heart transplants annually, which corresponds to a ~7x increase in the potential maintenance population as well. Absent better information, we think it's reasonable to assume that usage of the kidney test mirrors that of AlloMap. This leads us to a low-end U.S. market opportunity assumption of ~$200M at $1,000 per test, and a high end of nearly $400M at $1,500 per test. The price range of $1,000 - $1,500 is our best assessment of what the market will tolerate, and is predicated in part on pricing for cfDNA testing in the prenatal arena.

BROAD REIMBURSEMENT IN PLACE

Reimbursement Success in ~175M Lives, 78% Reimbursement Rate

CDNA has received positive coverage decisions for its AlloMap test from Medicare and many third- party payers, including Wellpoint, Aetna, Humana, and Cigna. In total, the company counts >175M lives in the U.S. currently covered for AlloMap. In 2013, Medicare accounted for 39% of AlloMap volume and 53% of revenue. As of March 31, 2014, CDNA had been reimbursed for approximately 78% of AlloMap results delivered in the 12 months ended September 30, 2013.

PRODUCTS ARE PATENT PROTECTED

AlloMap Well Protected; Immunetrix Deal Strengthens cfDNA Estate

CDNA's core AlloMap test is protected by 16 issued U.S. patents. Its freedom to operate in cfDNA was bolstered by its acquisition of ImmuMetrix. An outline of its patent estate is illustrated in the following chart.

Broad Patent Estate

	Coverage/ Benefit	Intellectual Property
CareDx Core IP	AlloMap & Gene Expression in Transplantation	**Issued Patents** • Sixteen issued United States patents, related to transplant rejection and autoimmunity • Five issued United States patents covering methods of diagnosing transplant rejection using 9 of the 11 informative genes measured in AlloMap. Patent expiry ranges from 2021 to 2024 • Additional coverage in EU and Canada
	Cell-Free DNA	**Patent Application** • Patent application on file covering CareDx method of using cfDNA to detect organ rejection
CareDx IP from ImmuMetrix	Methods of detection using cfDNA for organ rejection	**Issued Patent** • Exclusive license to Stanford University patent for diagnosis of graft rejection in organ transplant patients
	Adjacent Product Areas	**Patent Application** • Adjacent IP for diagnosis of transplanted tissue

Source: CareDx

In May, CDNA acquired ImmuMetrix, a development-stage diagnostics company founded by Stephen Quake. ImmuMetrix has an issued patent for cfDNA use in conjunction with post-transplant monitoring, in addition to key R&D personnel experienced in the development of cfDNA tests. In June, ILMN entered into a supply agreement to provide NGS and microarray equipment to CDNA, a partnership that will support development and commercial release of cfDNA products (ILMN is also an investor in CDNA).

COMPETITION IS THIN

AlloMap's Primary Competition Is Standard of Care/Biopsy; Non-Invasive Competition Weak

The gold standard treatment for heart transplant surveillance is biopsy, with a few non-invasive measures available that we see as competitive. We do not believe the various non-invasive imaging modalities or the Heartsbreath test are viable as stand-alone surveillance techniques. The following table offers a description and limitations of some of these modalities.

Summary of Non-Invasive Transplant Surveillance Methods

Method	Description	Limitations
Cardiac MRI	Cellular + functional T2-weighted CMRI can measure macrophage, T- and B-lymphocyte prevalence to indicate acute rejection.	More often used to confirm diagnoses rather than to diagnose because these variables tend to be expressed later in rejection; MRI is not viable for all patients.
Echocardiogram	Blood velocity and diastolic profile can indicate rejection of transplanted organ; tissue doppler imaging specifically can measure systolic and diastolic velocities to screen for left ventricular diastolic dysfunction, an indicator of rejection.	No single echocardiographic measure has been clinically proven to diagnose rejection; biopsy must be used in combination.
Heartsbreath	A breath test to measure methylated alkanes, which has been clinically proven as a marker of transplant rejection.	Not a standalone treatment; used in combination with biopsy to separate more and less severe rejection.

Source: FDA, Journal of the American College of Cardiology, Current Cardiovascular Imaging Reports, Sociedade Brasileira de Cardiologia, Leerink Partners Research

We'll note that the imaging options receive a Level of Evidence C designation from ISHLT for non-invasive monitoring of acute heart transplant rejection, which is inferior to AlloMap's Level of Evidence B. We don't believe the Heartsbreath test has meaningful, if any, commercial insurance coverage, and the product is not covered by Medicare.

We expect that the market for cfDNA tests for transplant surveillance could be more competitive. A couple of private companies have indicated an interest in this arena, though the transplant market is tangent to the core focus for both, so it is unclear to us how much resources they will devote to the effort. Transplant Genomics looks to have the most direct interest, and recently acquired a license to patent rights relating to kidney and liver transplant diagnostics using plasma proteomic signatures. We wouldn't be surprised to see TMO's One Lambda business, a market leader in transplant diagnostics, take a look at this area down the road, if it hasn't already. DGX markets a renal transplant monitoring test that monitors RNA genetic markets (FOXP3, Granzyme B, Perforin, IP10) to assess the risk of acute cellular rejection in renal transplant patients, though we don't believe this test has gotten much traction.

KEY MODEL ASSUMPTIONS

Continued Growth in AlloMap; Revenue from Kidney in 2016

While we believe AlloMap growth will moderate from the ~20% level enjoyed in 2013, we believe CDNA's efforts will continue to drive double-digit U.S. volume growth and we have forecasted a CAGR of ~15% over the next 3 years. To be conservative, we haven't assumed meaningful AlloMap revenue outside the U.S. in our model. We've assumed only a nominal amount of kidney revenue in our 2015 forecast ($150k) and assume this grows to $5M in 2016. While we wouldn't expect that CDNA's kidney product will have a Medicare reimbursement decision by 2016, we do believe there is opportunity for CDNA to generate revenue from Medicare while still in clinical studies. This is similar to Palmetto's current arrangement with MDxHealth for its ConfirmMDx prostate cancer test.

We assume modest gross margin expansion from 1Q14 levels (to 65.5% in 2016E from 63.5% in 1Q14), and only ~$10M of incremental cash burn to breakeven. CDNA was cash flow positive in 1Q14, but we assume it will use the proceeds of its recent initial public offering to fund R&D and SG&A expansion.

VALUATION

We Believe Multiple Expansion Warranted

CDNA currently trades at ~3x forward-twelve month (FTM) revenue, which is a discount to the emerging growth tools/diagnostics peer group median of ~5x FTM revenue (an average of 2014E and 2015E; see table, below).

Emerging Growth Tools/Diagnostics Multiples

Company	Ticker	Current price 8/07/2014	Mkt Cap (M$)	Revenue (M$) 2014e	Revenue (M$) 2015e	'14/ 15 Growth	Mkt cap / rev 2014e	Mkt cap / rev 2015e
Accelerate	AXDX	$17.00	$758	nm	nm	nm	nm	nm
BG Medicine	BGMD	0.88	$30	$6	$13	125%	5.3x	2.4x
Combimatrix	CBMX	2.01	$22	$8	$12	51%	2.7x	1.8x
Cerus	CERS	3.74	$271	$38	$54	41%	7.1x	5.0x
Cancer Genetics	CGIX	10.10	$94	$15	$38	156%	6.2x	2.4x
Diadexus	DDXS	0.70	$38	$29	$33	13%	1.3x	1.2x
Exact Sciences	EXAS	16.04	$1,328	$2	$74	3473%	638.7x	17.9x
Fluidigm	FLDM	26.28	$737	$116	$148	28%	6.4x	5.0x
Foundation Medicine	FMI	23.63	$666	$58	$109	87%	11.5x	6.1x
GenMark	GNMK	11.12	$463	$25	$38	48%	18.2x	12.3x
Genomic Health	GHDX	25.26	$789	$282	$315	11%	2.8x	2.5x
Cellular Dynamics	ICEL	12.25	$193	$19	$41	115%	10.2x	4.7x
Liposcience	LPDX	2.99	$46	$39	$39	(0%)	1.2x	1.2x
Nanosphere	NSPH	0.95	$73	$15	$26	79%	5.0x	2.8x
Nanostring	NSTG	11.45	$207	$48	$72	52%	4.3x	2.9x
Oxford Immunotec	OXFD	13.25	$233	$49	$67	36%	4.7x	3.5x
PacBio	PACB	4.74	$334	$47	$63	33%	7.1x	5.3x
Sequenom	SQNM	3.81	$443	$169	$219	30%	2.6x	2.0x
Trovagene	TROV	3.15	$60	$0	$5	1752%	225.5x	12.2x
Veracyte	VCYT	14.51	$307	$40	$77	90%	7.6x	4.0x
Vermillion	VRML	2.02	$72	nm	nm	nm	nm	nm
Intrexon	XON	$22.54	$2,228	$48	$80	67%	46.8x	28.0x
MEDIAN (OVERALL)						52%	6.3x	3.7x

Source: FactSet estimates

We believe some discount is warranted, both because CDNA targets a more limited market opportunity with its existing product, and because we project slower revenue growth for the company than the median company in this comp list is projected to grow per FactSet estimates. However, we think there is room for multiple expansion over the next 12 months as the company achieves milestones on its cfDNA product development efforts. Our $13 price target reflects an enterprise value (using projected levels of debt and cash) that is ~3.25x our revenue estimate for the twelve months ended June 2016.

RISKS TO VALUATION

CDNA's risks include, but are not limited to: the trajectory of the AlloMap revenue ramp, the ability to successfully develop and commercialize products using cfDNA for transplant surveillance, and the impact of a changing regulatory environment in the U.S. for diagnostics.

MANAGEMENT

Peter Maag, Chief Executive Officer. Dr. Maag has over 20 years of executive management experience in the pharmaceutical and diagnostic industry. Prior to joining CDNA, Dr. Maag was President of Novartis Diagnostics. Dr. Maag also led a couple of Novartis' key affiliates as Country President, Germany, and Country President, Korea. He also served as the Head of Strategy for Novartis Pharmaceuticals. Prior to joining Novartis, Dr. Maag worked for 6 years at McKinsey & Company in New Jersey and Germany, focusing on pharmaceuticals and globalization strategies. Dr. Maag studied pharmaceutical sciences in Heidelberg and London, and received his Ph.D. from the University of Berlin, Germany.

James Yee, M.D., Ph.D., Executive Vice President and Chief Medical Officer. Dr. James Yee brings more than 25 years of research and development experience. Most recently, Dr. Yee served as Vice President and Head of Development for Celera Genomics. Prior to his work at Celera, Dr. Yee served as Vice President of Clinical and Pre-Clinical Research for the Inflammatory and Viral Diseases Unit at Roche Pharmaceuticals. Earlier in his career, Dr. Yee held a variety of research and development positions of increasing responsibility at Syntex Corporation, including Vice President and Director of the Institute for Clinical Medicine. Dr. Yee received his Bachelor's degree from the University of California at Berkeley in electrical engineering and computer science. Dr. Yee went on to earn a Ph.D. in biophysics at University of California at Berkeley. He attended the University of California, Los Angeles School of Medicine, where he earned his medical degree, and he is board certified in internal medicine.

Matthew J. Meyer, Chief Business Officer. Matthew J. Meyer has served as Chief Business Officer since February 2012. Prior to that, he served as Vice President of Corporate Development and Legal Affairs starting in August 2010. Before joining CDNA, Mr. Meyer was Vice President, Business Development and General Counsel at Cerimon Pharmaceuticals from January 2008 to August 2010. Prior to that, Mr. Meyer held senior management positions at Draeger Medical Systems, the U.S. subsidiary of the German-based global medical device company, most recently serving as Vice President and General Counsel. In his earlier career, Mr. Meyer held positions of increasing responsibility at Novartis Pharma AG in Basel, Switzerland. Mr. Meyer graduated cum

laude with a Bachelor of Arts degree from Cornell University. He earned his Juris Doctor degree from Villanova University School of Law.

Mitchell J. Nelles, Ph.D., Chief Operating Officer. Dr. Nelles joined CareDx from bioMerieux Inc, where he was Vice President of North America Research and Development. Prior to his work at bioMerieux, Dr. Nelles served as the Vice President of R&D at TriPath Oncology (TriPath Imaging). Earlier in his career, Dr. Nelles held a variety of technical and managerial positions of increasing responsibility, including Vice President, Transfusion Medicine and Immunodiagnostic Assay R&D at Ortho Clinical Diagnostics (Johnson & Johnson). Dr. Nelles received his Bachelor's degree from Rutgers College in biological sciences, his Ph.D. in immunology/biomedical sciences from the University of Texas, Health Sciences Center at Dallas (UTHSCD)/Southwestern Medical School, and completed postdoctoral training in immune regulation at Brandeis University.

Ken Ludlum, MBA, Chief Financial Officer. Mr. Ludlum has more than 25 years of experience in the medical device industry, most recently serving as the Vice President and Chief Financial Officer of EndoGastric Solutions, Inc, a medical device company based in San Mateo, California. He has served as chief financial officer at several public companies. Mr. Ludlum holds a Bachelor of Science degree in business from Lehigh University and a Master of Business Administration degree from Columbia University.

CareDx (CDNA)

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Income statement

Period Ended *($ thousands)*	2012	2013	Mar-14	Jun-14e	Sep-14e	Dec-14e	2014e	2015e	2016e
Revenues									
Testing revenue	**$19,730**	**$21,672**	**$5,834**	**$6,009**	**$6,429**	**$6,960**	**$25,231**	**$29,342**	**$38,571**
Other	721	426	90	90	90	90	360	800	1,600
Total revenues	20,451	22,099	5,924	6,099	6,519	7,050	25,591	30,142	40,171
Cost of service	7,930	9,078	2,162	2,195	2,314	2,468	9,139	10,550	13,859
Gross profit	12,521	13,021	3,762	3,903	4,204	4,583	16,452	19,593	26,312
SG&A	10,111	10,701	3,269	3,324	3,455	3,455	13,502	15,373	18,077
R&D	4,752	3,176	720	732	1,956	1,904	5,311	7,837	7,633
Operating income (loss)	**(2,342)**	**(856)**	**(227)**	**(152)**	**(1,206)**	**(776)**	**(2,361)**	**(3,617)**	**603**
Interest expense (income)	2,703	2,150	548	526	520	439	2,033	1,647	1,649
Other, net	14	536	529	0	0	0	529	0	0
Pretax income	(5,059)	(3,542)	(1,304)	(678)	(1,726)	(1,215)	(4,922)	(5,264)	(1,047)
Taxes	0	0	0	0	0	0	0	0	0
Net income	($5,059)	($3,542)	($1,304)	($678)	($1,726)	($1,215)	($4,922)	($5,264)	($1,047)
Basic shares outstanding	6,913	6,923	6,172	6,172	10,040	10,521	8,226	10,646	10,846
Diluted shares outstanding	6,913	6,923	6,172	6,172	10,040	10,521	8,226	10,646	10,846
EPS diluted	**($0.73)**	**($0.51)**	**($0.21)**	**($0.11)**	**($0.17)**	**($0.12)**	**($0.60)**	**($0.49)**	**($0.10)**
EPS growth									
Revenue growth		9.8%	21.3%	12.7%	12.5%	19.7%	16.4%	16.3%	31.5%
Volume (Ths)	8,337	10,064	2,792	2,861	2,990	3,164	11,807	13,578	15,615
Gross margin	61.2%	58.9%	63.5%	64.0%	64.5%	65.0%	64.3%	65.0%	65.5%
SG&A % of revenue	49.4%	48.4%	55.2%	54.5%	53.0%	49.0%	52.8%	51.0%	45.0%
R&D % of revenue	23.2%	14.4%	12.2%	12.0%	30.0%	27.0%	20.8%	26.0%	19.0%
Operating margin	**(11.5%)**	**(3.9%)**	**(3.8%)**	**(2.5%)**	**(18.5%)**	**(11.0%)**	**(9.2%)**	**(12.0%)**	**1.5%**
Tax rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
D&A expense	$1,072	$663	$106	$80	$86	$93	$365	$391	$514
EBITDA	**($1,270)**	**($193)**	**($121)**	**($72)**	**($1,120)**	**($683)**	**($1,996)**	**($3,226)**	**$1,117**
Free cash flow									
Operating cash flow	($1,776)	($546)	$180				($2,946)	($4,241)	$117
CapX	(141)	(98)	(19)				(668)	(661)	(1,121)
Free cash flow	($1,917)	($644)	$161				($3,613)	($4,903)	($1,003)

Notes:

Source: Company reports and Leerink Partners estimates

CareDx (CDNA)

Balance sheet

Period Ended *($ thousands)*	Dec-13	Mar-14	Jun-14e	Sep-14e	Dec-14e
Assets					
Cash, equivalents, ST investments, restricted cash	$5,128	$4,837	$8,853	$52,245	$51,063
Accounts receivable	2,270	2,093	2,005	2,143	2,318
Inventory	518	725	529	558	595
Prepaid expenses and other current assets	255	1,825	488	521	564
Total current assets	8,171	9,480	11,875	55,468	54,539
Property and equipment, net	1,553	1,466	1,602	1,714	1,856
Restricted cash / LT investments	147	147	147	147	147
Other assets	2	2	2	2	2
Total assets	$9,873	$11,095	$13,626	$57,331	$56,544
Liabilities and shareholders' equity					
Notes payable - current portion	$4,461	$5,485	$6,625	$4,975	$4,975
Accounts payable	618	781	657	770	823
Accruals	2,434	4,247	2,439	2,607	2,820
Other liabilities	80	65	65	65	65
Total current liabilities	7,593	10,578	9,787	8,418	8,683
Notes payable - long-term portion	10,914	9,591	13,451	10,101	10,101
Other liabilities	6,837	7,648	7,648	7,648	7,648
Total liabilities	$25,344	$27,817	$30,886	$26,167	$26,432
Convertible preferred stock	$135,202	$135,202	$135,202	$0	$0
Shareholders' equity	($150,673)	($151,924)	($152,462)	$31,165	$30,112
Total liabilities and shareholders' equity	$9,873	$11,095	$13,626	$57,331	$56,544

Source: Company reports and Leerink Partners estimates

Disclosures Appendix

Analyst Certification

I, Dan Leonard, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Distribution of Ratings/Investment Banking Services (IB) as of 06/30/14				
			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	138	69.00	50	36.20
HOLD [MP]	62	31.00	2	3.20
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

Important Disclosures

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