

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): January 11, 2016

Interpace Diagnostics Group, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

000-24249
(Commission File Number)

22-2919486
(IRS Employer Identification No.)

Morris Corporate Center 1, Building A
300 Interpace Parkway
Parsippany, NJ 07054
(Address, including zip code, of Principal Executive Offices)

(862) 207-7800
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01. Regulation FD Disclosure.

Interpace Diagnostics Group, Inc. (the “Company”) is furnishing an Investor Presentation (the “Investor Presentation”), attached hereto as Exhibit 99.1, which the Company may use from time to time in presentations to investors and other stakeholders. The Investor Presentation will also be available on the Company’s investor relations webpage at <http://www.interpamediagnostics.com>.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise stated in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

99.1 Investor Presentation dated January 2016 (furnished and not filed for purposes of Item 7.01)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

Interpace Diagnostics Group, Inc.

Date: January 11, 2016

By: /s/ Graham G. Miao

Graham G. Miao
Executive Vice President, Chief Financial
Officer, Treasurer and Secretary

EXHIBIT INDEX

<u>EXHIBIT NUMBER</u>	<u>DESCRIPTION</u>
99.1	Investor Presentation dated January 2016 (furnished and not filed for purposes of Item 7.01)



Investor Presentation

January 2016

NASDAQ
IDXG

FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, relating to our future financial and operating performance. The company has attempted to identify forward looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are based on current expectations, assumptions and uncertainties involving judgments about, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond company's control. These statements also involve known and unknown risks, uncertainties and other factors that may cause company's actual results to be materially different from those expressed or implied by any forward-looking statement. Known and unknown risks, uncertainties and other factors include, but are not limited to, our ability to adequately finance the business, the market's acceptance of our molecular diagnostic tests; our ability to secure additional business and generate higher profit margins through sales of our molecular diagnostic tests, in-licensing or other means, projections of future revenues, growth, gross profit and anticipated internal rate of return on investments. Additionally, all forward-looking statements are subject to the risk factors detailed from time to time in the company's periodic filings with the Securities and Exchange Commission (SEC), including without limitation, the Annual Report on Form 10-K filed with the SEC on March 5, 2015 and in the company's Form 10-Q filed with the SEC on November 12, 2015. Because of these and other risks, uncertainties and assumptions, undue reliance should not be placed on these forward-looking statements. In addition, these statements speak only as of the date of this press release and, except as may be required by law, the company undertakes no obligation to revise or update publicly any forward-looking statements for any reason.

Investment Highlights

- Interpace Diagnostics (IDX) was formerly part of PDI that had both IDX and Commercial Services (CSO) businesses. PDI was renamed Interpace Diagnostics Group after the sale of CSO in December 2015
- Focused on developing and marketing molecular based diagnostic tests in high value precision pre-cancerous test markets
- Three proprietary cancer molecular tests on the market in GI and Endocrine
 - **PancraGen™** – The new standard of pancreatic cyst diagnostics
 - **ThyGenX™ and ThyraMIR™** - Next-Gen sequencing oncogene panel and miRNA classifier in combination to improve risk classification of Thyroid nodules
- Two state of the art CLIA-certified labs
- Additional pipeline tests under development including **BarreGen™** for Barrett's Esophagus, an esophageal cancer risk classifier
- Addressable potential market opportunity of \$2.7 billion with all four tests
- Revenue of approximately \$10 million in 2015, supported by IDX sales forces
- Focus for 2016: Grow recently launched ThyGenX/ThyraMIR tests and expand PancraGen market penetration

Our Mission



Providing personalized medicine through Molecular Diagnostics to advance patient care based on rigorous science.

CCTGG
CATCAG
CCGCC
CCTTCT
SGTATTG
AGGCA
TCAGAA
TCTTCG
TATCAGC
SGTGTTG
CGATCG
ACTGCT

Interpace Diagnostics Key Milestones

- AUGUST 2014: Acquired Thyroid Assets from Asuragen
- OCTOBER 2014: Acquired RedPath Inc., GI assets and CLIA lab
- DECEMBER 2014: Launched **ThyGenX™** NextGen Sequencing Thyroid Cancer Test
- FEBRUARY 2015: Published landmark study on **PancraGen™** in Endoscopy
- APRIL 2015: Launched **ThyraMIR™** microRNA Gene Expression Thyroid Cancer Test
- MAY 2015: Published the major clinical validation study in JCEM for combining **ThyGenX** and **ThyraMIR** in a single testing service
- MAY 2015: Published **BarreGen™** BASE study on Barrett's Esophagus cancer risk progression in AJG
- AUGUST 2015: Covered lives for Interpace Diagnostics products exceeded 100 million for all tests combined
- OCTOBER 2015: Data presented at ACG demonstrate that **PancraGen™** can improve detection of malignant or highly aggressive pancreatic cysts over current guidelines criteria, and improve patient outcomes in real life management decisions
- New data presented at ATA further validates the power of combination testing by **ThyGenX™** and **ThyraMIR™**, improving the preoperative diagnosis of thyroid nodules with indeterminate cytology
- DECEMBER 2015: PDI transformed into Interpace Diagnostics Group through the sale of its CSO business to focus exclusively on molecular diagnostics

Interpace Diagnostics Focus

High Value Molecular Pre-Cancerous Test Market

1. High barrier to entry due to complexity of tests and intellectual know how
2. Pre-cancerous diagnosis and prognosis focus where test pricing is higher
3. Highly complex messaging to HCPs is a capability

**Our Commercial Expertise Aligns with Dynamics
of Molecular Diagnostics Market**

Our Marketed Molecular Tests

GI



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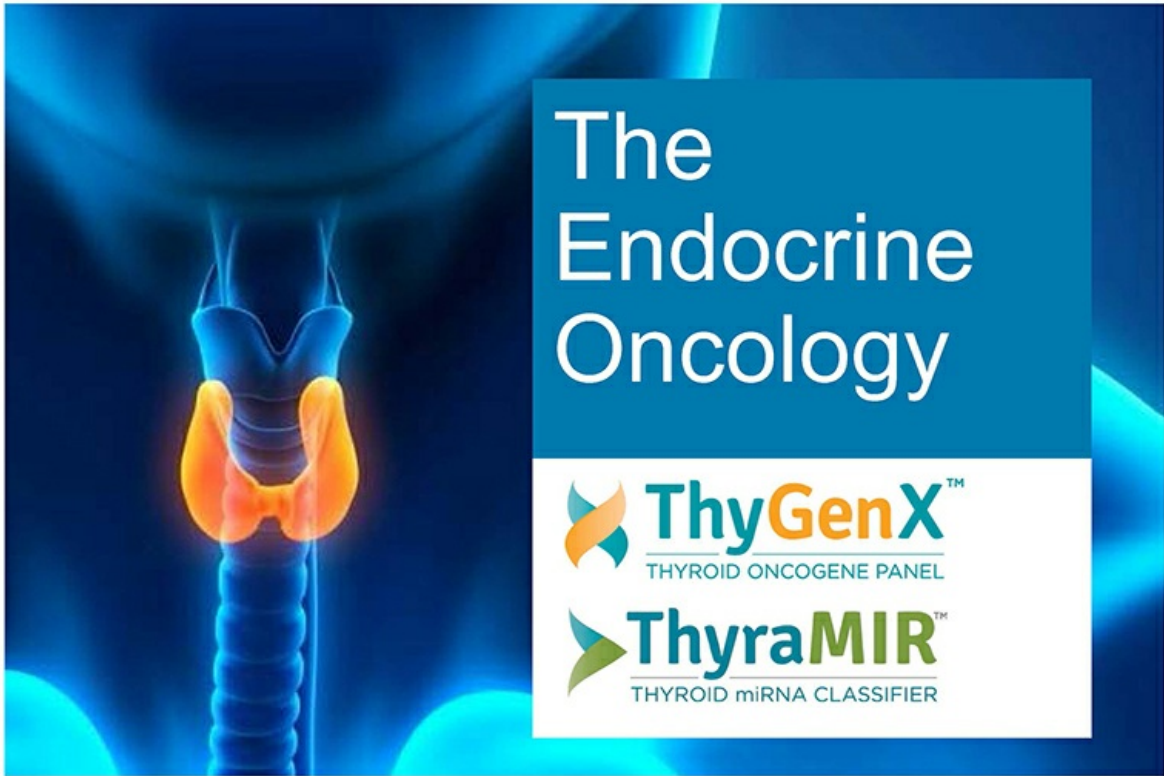
Endocrine



Current U.S. Market Opportunity

Pancreatic Cysts
\$350M

Thyroid Nodules
\$350M



The Endocrine Oncology

ThyGenX™
THYROID ONCOGENE PANEL

ThyraMIR™
THYROID miRNA CLASSIFIER

Thyroid Nodules

Common clinical problem

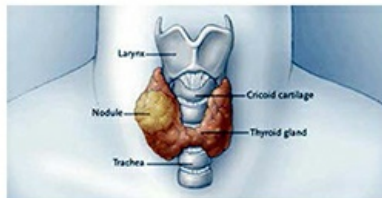
~10-18 m

US Adults have nodules

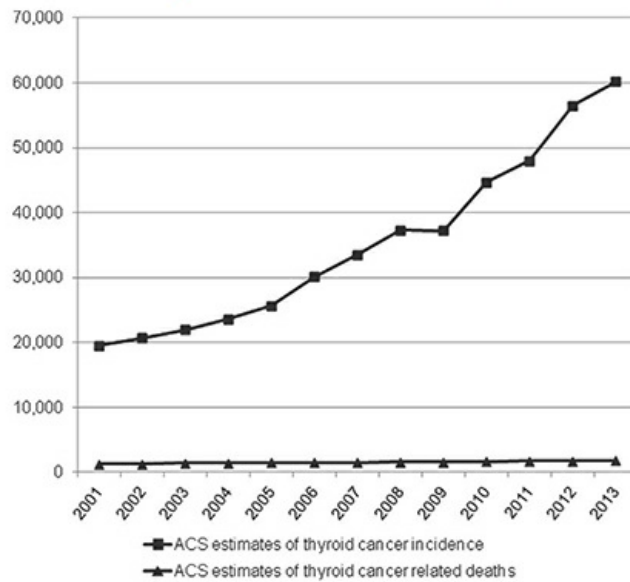
Estimated

525,000

thyroid FNA per year in US and growing



Thyroid Cancer Incidence*



Thyroid Surgery

Significant Surgical Risks

- Large incision in sensitive area and potential for significant scarring
- Risk of vocal cord damage, hoarseness, paralysis, and at the extreme, tracheotomy



Guideline Recommendations

Molecular Markers/Diagnostic Testing



2013 NCCN Guidelines

Molecular Diagnostics recommended testing on some indeterminate cytologies to minimize unnecessary surgeries

2014 American Thyroid Association Revised Guidelines

MDx Tests should be considered for suspicion of malignancy or indeterminate.



Source: Cooper DS et al. *Thyroid*. 2009;19(11):1167-1214; National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. V.1.2014; ATA Guidelines on Thyroid Nodules and Differentiated Thyroid Cancer – Highlights, Consensus, and Controversies. ICE/ENDO conference; June 21-24, 2014; Chicago, Illinois.

Improving Thyroid Cancer Diagnosis

Use of Molecular Markers

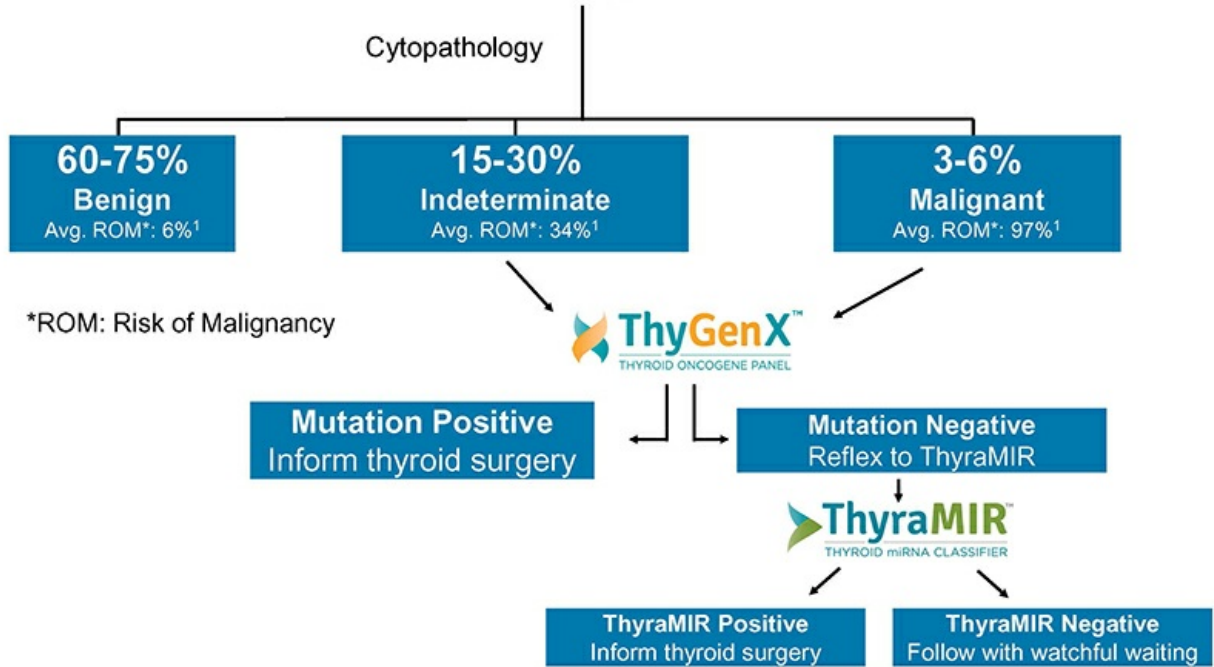
Molecular diagnostic tests help the diagnosis of thyroid cancer when cytology is indeterminate

CURRENTLY 2 MAIN PLATFORMS:

1. Mutation/Genetic Testing
“Rules-In” Cancer
 - Highly specific
 - *ThyGenX*TM
(BRAF*, KRAS, HRAS*, NRAS*, RET/PTC1*, RET/PTC3, PAX8/PPAR-3*, PIK3CA, over 100 reportable markers)
2. Gene Expression
“Rules-Out” Cancer
 - Highly sensitive
 - Veracyte Afirma GEC
 - *ThyraMIR*TM

ThyGenX™ Pathway for Thyroid Cancer Diagnosis

525,000 FNA Biopsies Annually



ThyGenX + ThyraMir offers superior solution

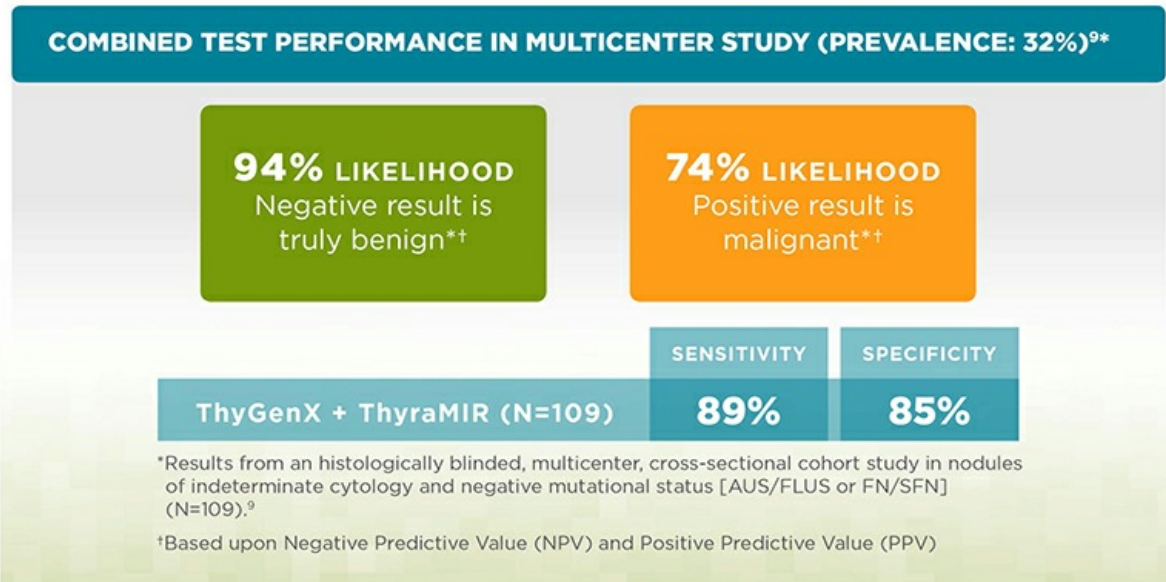
	Veracyte <i>Afirma</i> ¹	ThyGenX ThyraMIR ²
Characterize Malignancy	No	Yes
Prominent Results	Likely Benign	Benign/Malignant
PPV	47%	74%
NPV	92%	94%
Diagnostic Yield *	41%	67%
Sample Collection	Dry Ice	Room Temperature

* Diagnostic Yield is defined as % true benign that are called benign using each essay

ThyGenX/ThyraMIR testing provides 65% increase in true benign calls and 69% decrease in the number of unnecessary surgeries on benign nodules, relative to mRNA gene expression classifier (p<0.01)

ThyGenX +ThyraMIR

Combined Rule-in and Rule-out in a single testing service to better inform treatment decision



Source: Molecular testing for miRNA, mRNA and DNA on fine needle aspiration improves the pre-operative diagnosis of thyroid nodules with indeterminate cytology. J.Clin Endocrinol Metab 2015 May 12 [Epub ahead of print]

Thyroid Franchise Go-to-Market Strategy

Robust Science

- Published the major clinical validation study for ThyGenX & ThyraMIR in JCEM – the first Rule-in and Rule-out thyroid cancer test in a single testing service
- Additional study in development

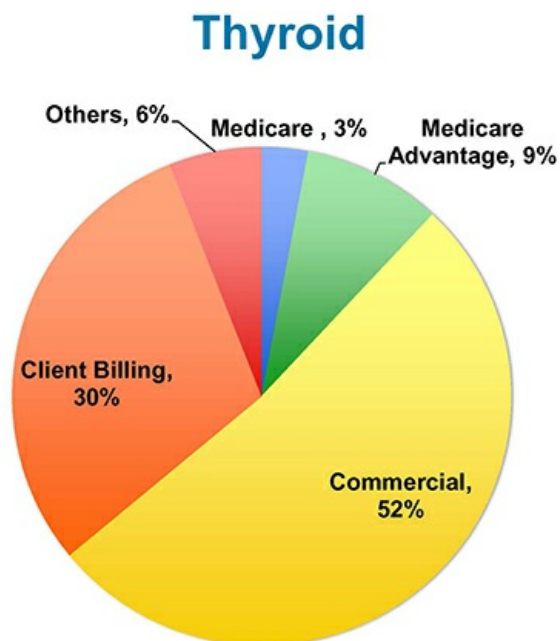
Commercial Execution

- Expanded sales force in early 2015
- Launched ThyGenX 12/2014 and ThyraMIR 4/2015
- Deploy established commercial capabilities
 - Marketing Campaign and Messaging
 - Medical Education and Patient Advocacy

Coverage and Reimbursement

- ThyGenX covered by Medicare LCD; ThyraMIR in preparation for Medicare LCD
- Over 90 million lives covered for ThyGenX **including Aetna**
- A major regional BCBS recently issued coverage for both ThyGenX and ThyraMIR

Thyroid Tests - Payor Type and Coverage



- ThyGenX under Medicare LCD; ThyraMIR Medicare LCD application in progress
- A major regional BCBS coverage for both ThyGenX and ThyraMIR
- Over 90 million lives covered for ThyGenX including **Aetna**

*Payer mix % based on claim submissions;
May vary by month



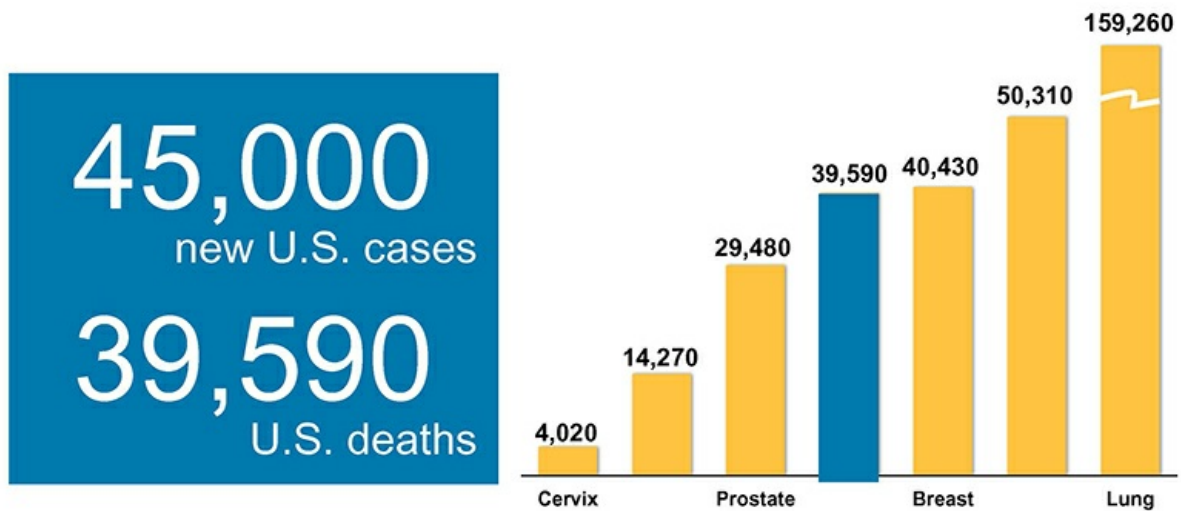
**Pancreatic Cysts
Cancer Risk**

PANCRAGEN™
PANCREATIC CANCER RISK CLASSIFIER

Powered by PathFinderTG®

Pancreatic Cancer:

The Fourth Leading U.S. Cancer Killer



- 5-year survival rate 7.2%
- Pancreatic cancer 3% of new cancer cases in US, 12% of deaths of common cancers

120,000 Pancreatic Cysts Annually

- **The clinical dilemma:**

- Current guideline tests are unreliable and poorly predict cancer risk
 - Cyst fluid tested for CEA, amylase, and cytology (1st line tests)

Pancreatic cysts:

2-5%

risk of cancer increasing with age¹

- **The result:**

- 80% of all surgeries are for benign disease
 - Unnecessary healthcare costs
 - High morbidity (30%) and mortality (2%)² associated with these surgeries
- Pancreatic cancers go undetected

Pancreatic cysts:

80%

surgeries are benign

**90%
Accuracy
At Predicting
Malignant
Pancreatic
Cysts**

Multi-faceted algorithm-based platform

1. Oncogene mutations (KRAS, GNAS) and 15 markers
2. DNA quantification
3. Loss of heterozygosity
4. CEA & Amylase biomarkers
5. Cytology results

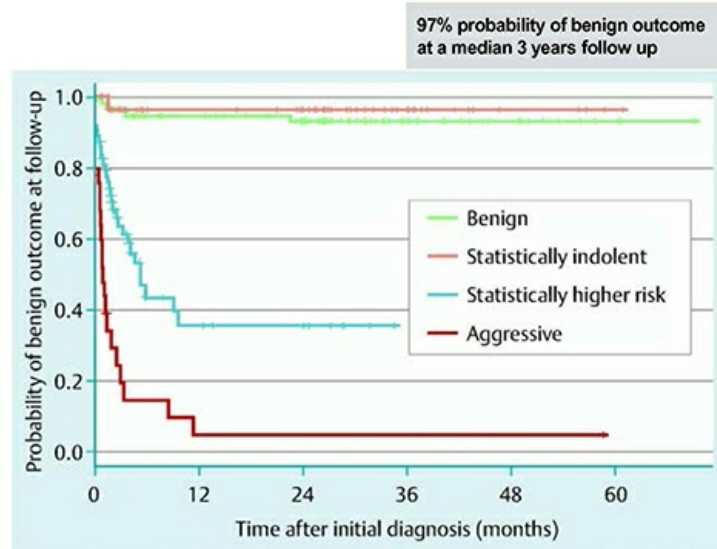
Substantial Improvement Over Guidelines

Results published in leading GI journal, *Endoscopy*

Performance of all patients (n=492)	<i>PancraGen</i> [™]	ICG Sendai Guidelines	P-Value
Accuracy	90%	52%	N/A
Specificity	91%	46%	<0.0001
PPV	58%	21%	<0.0001
NPV	97%	97%	0.88
Sensitivity	83%	91%	0.17

Pancreatic Cysts: Clinical Validity and Utility

79% of patients who met Sendai guidelines for surgery actually had benign outcomes and surgery could have been avoided.



PFTG provides an effective strategy of risk stratification of malignancy for optimal patient care

PancraGen More Accurately Predicts Malignant Pancreatic Cysts

Results published in leading GI journal, *Endoscopy*

- 84% of the patients recommended for surgery by Sendai were benign or indolent
- PancraGen may reduce unnecessary surgeries by 66%
- Patients with “aggressive” PancraGen diagnosis were 76 times more likely to progress to malignancy

PancaGen Go-to-Market Strategy

Robust Science

- Published National Pancreatic Cyst Registry study in *Endoscopy* 2015
- Published health economic and outcome study in *Endoscopy International Open* 2015
 - PancaGen is the most cost effective strategy in patient management

Commercial Execution

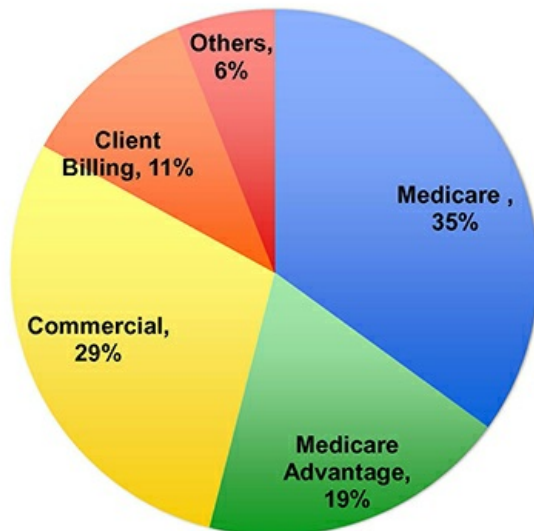
- Deploy established commercial capabilities
 - Marketing Campaign and Messaging
 - Medical Education and Patient Advocacy

Coverage and Reimbursement

- Reimbursement by Medicare LCD (\$3,100/test); Permanent LCD expected in Q4 2015
- Over 70 million lives covered including managed care plans

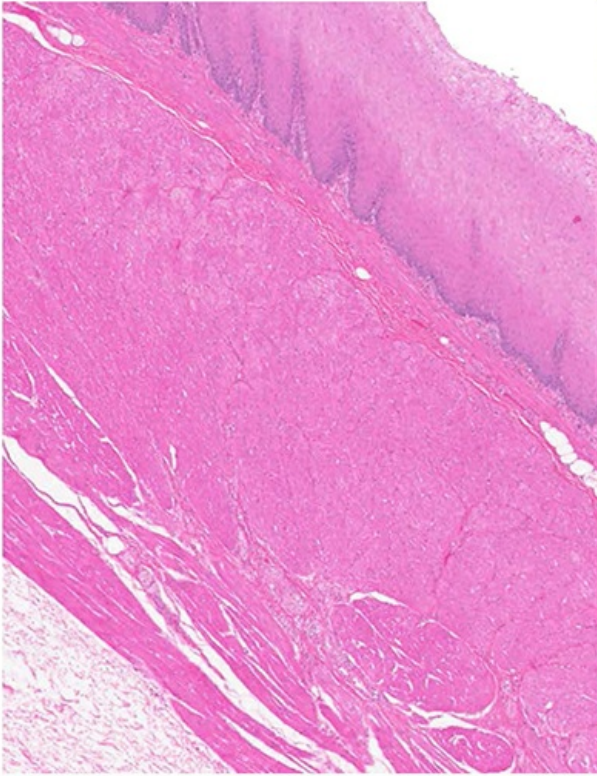
PancraGen - Payor Type Mix and Coverage

PancraGen*



*Payer mix % based on claim submissions;
May vary by month

- Medicare LCD reimbursement at \$3100
- Updated LCD eliminates previous “evidence development” coverage condition
- Over 70 million lives covered including Medicare and managed care plans

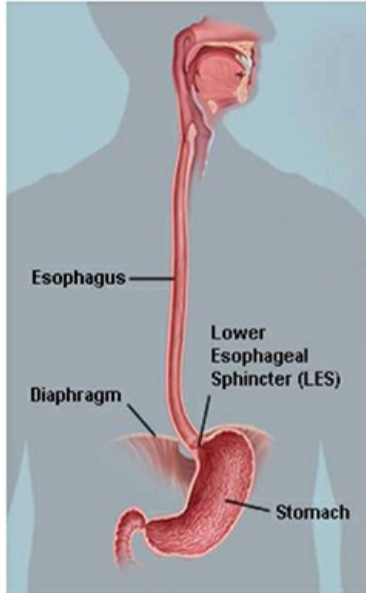


Barrett's Esophagus
Risk of progression to cancer



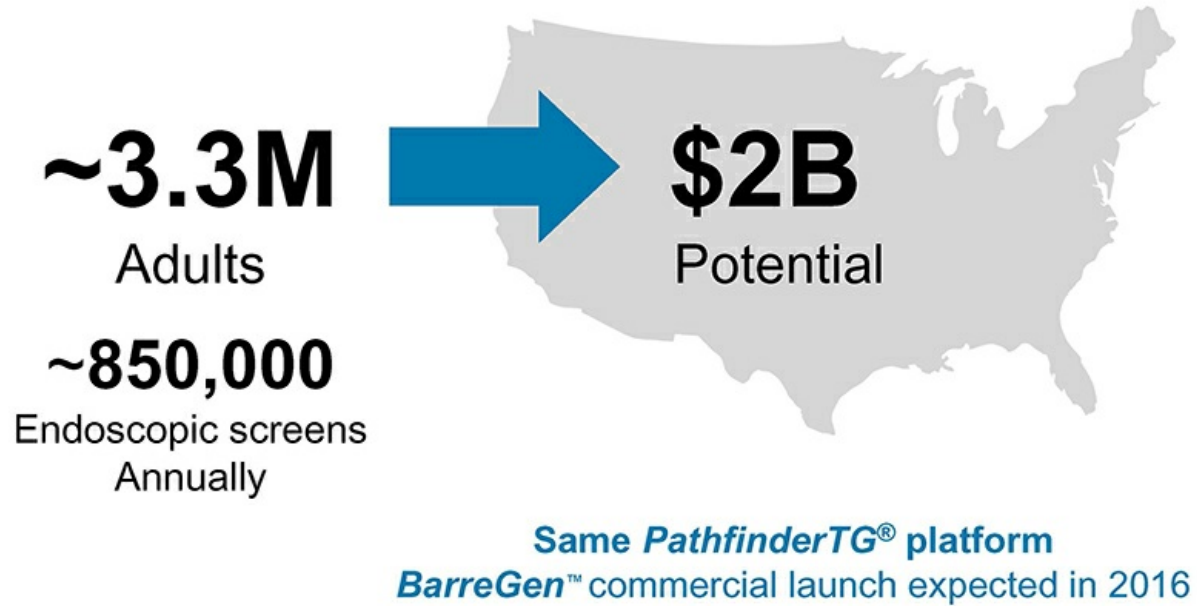
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What is Barrett's Esophagus?



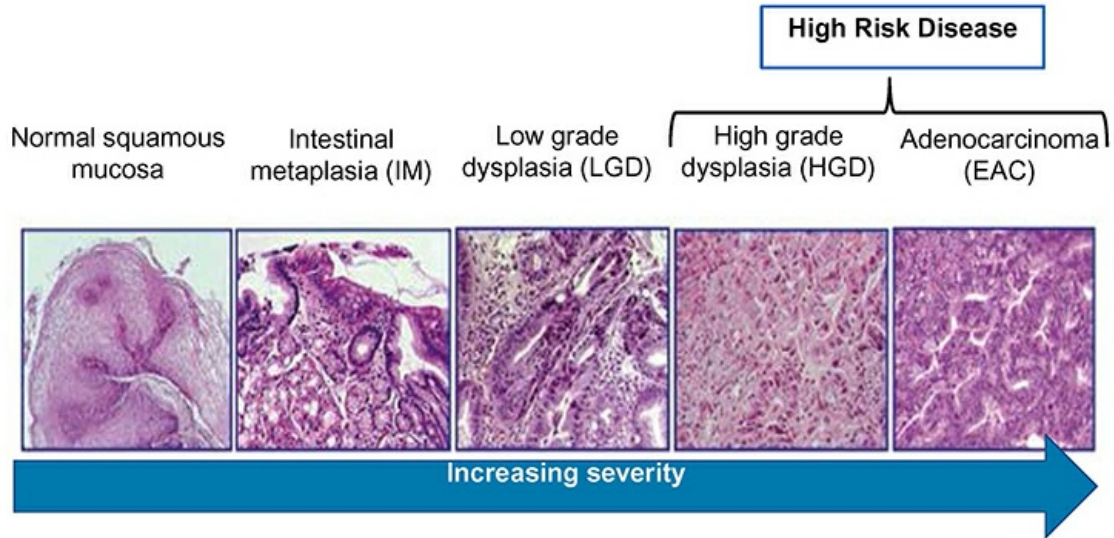
- Gastroesophageal reflux very common (10-20% US adults)
- 6% progress to Barrett's Esophagus (**~3.3 million adults**)
- Barrett's Esophagus precedes esophageal cancer (EAC) infrequently (1-2%)
- Ablation (Barrx) has emerged as a treatment and prevention strategy
- Current tests cannot predict which patients will progress to EAC – a high unmet need for a molecular diagnostic test

BarreGen for Barrett's Esophagus



BarreGen for Barrett's Esophagus

Barrett's is currently diagnosed by pathology



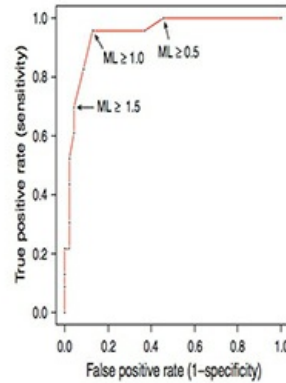
Esophageal Cancer Risk Classifier

- Millions in US undergo expensive, unnecessary procedures to prevent EAC
- Growing evidence that Barrett's recur post-ablation (est. 20+%) and the recurrence may create more aggressive disease state
- BarreGen determines risk of progression from Barrett's to cancer prior to the onset of HGD or EAC
 - Early detection and prevention of cancer
 - Avoidance of unnecessary interventions with undesirable side effects
 - Reduction in healthcare costs

BarreGen™ Clinical Results

Results of BASE study published in Am J. Gastroenterol (AJG)

90% accuracy to predict Barrett's Esophagus progression to cancer



	Patient ML
Performance Characteristics	e1
Sensitivity (%)	96
Specificity (%)	87
Accuracy (%)	90
Odds ratio	146.7 (p<0.0001)*

1. Case-control study N= 69 patients (46 controls and 23 cases).
2. Mutational load (ML) to measure genetic instability (LOH) associated with tumor suppressor genes
3. Based on ML score, BarreGen predicts risk of BE for future progression to cancer

BarreGen™ - Multi-stage Introduction

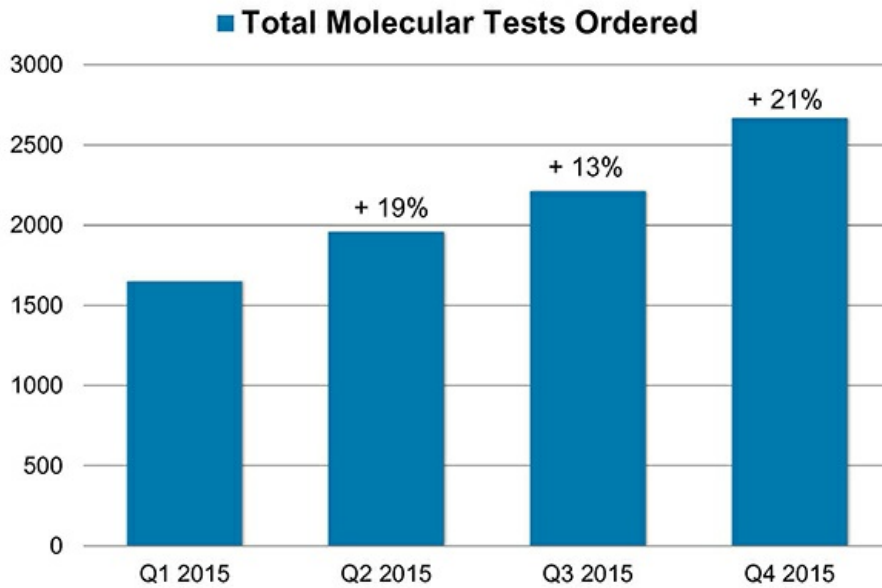
- Clinical experience program initiated Q4 2015
 - Scientific advisory board and select KOLs
- Soft launch planned in 2016
 - Prognostic value in determining cancer progression risk
 - **BASE** study Eluri 2015¹ (n=69)
 - Diagnostic value in detecting true dysplasia (HGD) in BE
 - Ellsworth 2012 study² (n=271) and Khara 2014 study³ (n=415)
- Additional clinical studies underway
 - Interim results of the on-going **BELONG** study are inconclusive but suggest that alternative tissue fixation methodology may of value to improve BarreGen performance for mutation detection
- Establish collaborations with Barrett's Center of Excellence

¹ Eluri et al. Am J Gastroenterology 2015, 110:828-834

² Ellsworth et al. BMC Gastroenterology 2012, 12:181

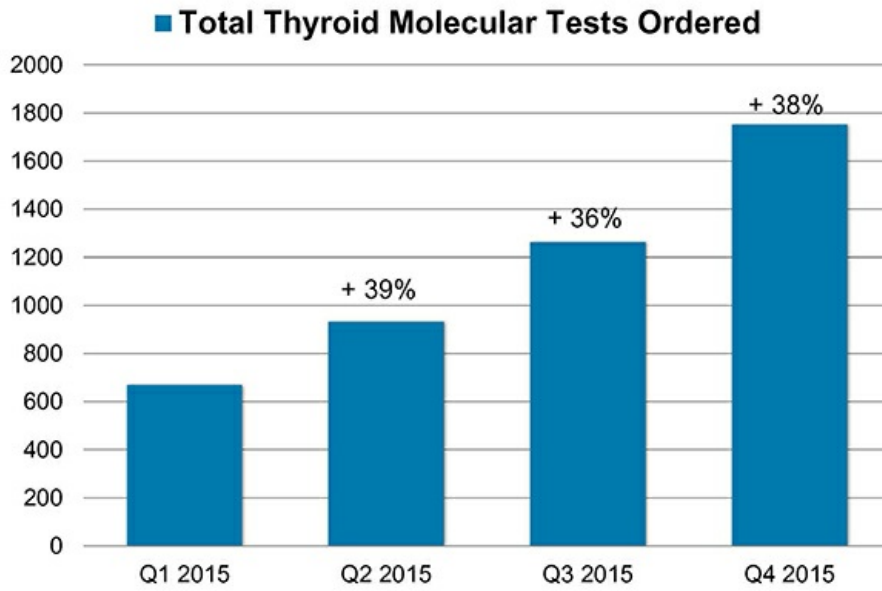
³ Khara et al. J. Gastrointestinal Cancer 2014 DOI 10.1007/s12029-013-9570-y

Number of Molecular Tests Ordered Rising



Total Molecular Tests include PancreGen and Thyroid Tests

Number of Thyroid Tests Ordered Growing



Total Thyroid Molecular Tests include ThyGenX and ThyraMIR

Appendix

MDx Market Shares (%) by Sector

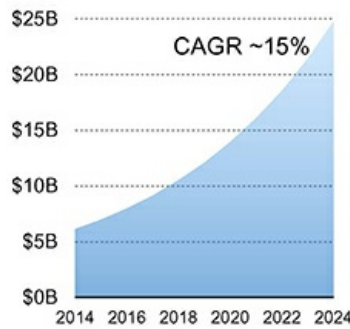
The Fastest Growing Segment is Oncology

2014 MDx Market Share



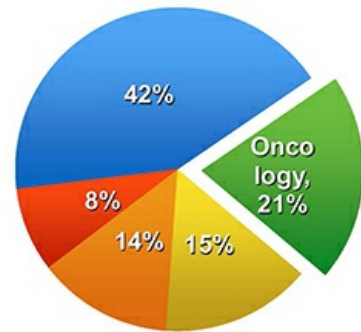
- Molecular Diagnostics (MDx)
- Traditional Diagnostics

Global MDx Market Forecast



U.S. Accounts for over 50% of global

By Segment



- Infectious Disease
- Oncology
- Blood
- Genetics
- Tissue Typing

Current Pancreatic Cysts Guidelines

Sendai guidelines 2012 and ACG guidelines 2007 strongly favor surgical resection because of the inability of first-line tests to predict biological behavior and aggressiveness.

***PancraGen*[™] establishes a new standard for the prognosis and diagnosis of pancreatic cysts**

Clinically Validated

- Over 25,000 clinical cases analyzed
- Over 200 peer-reviewed articles



Clinical Meaningful and Actionable Results

Example Report: PFTG Pancreas

PANCRAGEN
PANCREATIC CANCER RISK CLASSIFIER
Powered by **PathFinder™**

SUMMARY REPORT

Interpace Diagnostics Accession #: RPIX-XXXX
Case Accessioned: 01/23/2015
Specimen Received: 01/02/2015
External Accession: XXX-XXXX

Patient Name: PUBLIC, JANE Q
MRN: 00-123456
DOB - Age - Sex: 01/01/1950 - 63 yrs - Female
Ordering Physician: Smith, Mark M

Specimens Received
 1. Buccal Brush (Ext Part 1, Collected 01/01/2015)
 2. Pancreatic Body Cyst Fluid (Ext Part 3, Collected 01/01/2015)

Documents Received
 Cytology Report
 EUS Report, Pancreas
 Pathology Report

INTEGRATED DIAGNOSIS

	Benign	Statistically Indolent	Statistically Higher Risk	Aggressive
Biological Behavior	This Patient			

MOLECULAR RESULTS

DNA Quantity	Low
DNA Quality	Poor
Oncogene Point Mutations	
KRAS Point Mutation	No mutation detected
GNAS Point Mutation	Not ordered
Tumor Suppressor Genes (LOH)	No LOH detected

NON-MOLECULAR RESULTS

Pancreatic Cyst Fluid	
ApoA2	less than 0.2 ng/mL
Amylase	152 U/L

COMMENT

The biological behavior of this patient's lesion falls into the Category of "Benign."

Please note that, because cystic lesions of the pancreas can be complex lesions containing multiple cystic spaces and multifocal areas of heterogeneous pathology, sampling variation may occasionally result in under diagnosis of existing pathology. Clinical correlation and integration of the molecular results with clinical findings is required to minimize this possibility.

Notwithstanding the benign molecular features that are present here, close follow-up is recommended given the relatively large size of the cystic process. One approach to be considered is to repeat the imaging and/or aspiration and perform both clinical and molecular analyses of this cyst, if future clinical follow-up warrants additional studies. By comparing subsequent findings with the initial baseline studies, the stability, regression, or progression of mutational change can be determined.

INTERPRETED BY

Sydney D. Finkelstein, MD
 Medical Director

January 28, 2015
 Date

Interpace Diagnostics | 800.456.9865 | www.interpacediagnostics.com

Summary Report - Page 1 of 1
PUBLIC, JANE Q

- PFTG Diagnosis
- Patient management recommendations
 - Based on patient outcome data
 - Provided by board certified anatomical pathologists

New Thyroid Cancer Detection Paradigm

Combined Rule-in and Rule-out cancer in a single testing service to better inform treatment decision

