# Virtual KOL Event to Discuss Insight Molecular Diagnostics' In-House dd-cfDNA Testing for Kidney Transplant Patients

NASDAQ:IMDX

August 2025

iMDxinc.com

# Agenda

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| Introduction | **Andrea James**<br>Chief Financial Officer, Insight Molecular Diagnostics |
| IMDX Kitted Strategy & GraftAssureDx Trial | **Josh Riggs**<br>President & Chief Executive Officer, Insight Molecular Diagnostics |
| dd-cfDNA Testing in Transplant Care | **Anthony Langone, MD**<br>Vanderbilt University |
| Question and Answer Session | **Anthony Langone, MD**<br>Vanderbilt University<br><br>**Josh Riggs**<br>President & Chief Executive Officer, Insight Molecular Diagnostics<br><br>**Andrea James**<br>Chief Financial Officer, Insight Molecular Diagnostics<br><br>**Ekkehard Schuetz**<br>Chief Science Officer, Insight Molecular Diagnostics |

# Forward-Looking Statements

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# Mission

## Democratize access to novel molecular diagnostic testing to improve patient outcomes

# U.S. transplant market

## Ripe for disruption

In the U.S., donor-derived cell free DNA (dd-cfDNA) testing is delivered via **restrictive central lab service model.** Two companies command ~90% market share[1].

## Highly concentrated

About 250 kidney transplant centers nationwide. Fewer than 100 generate ~80% of transplant volume[2]

## Established science

More than **90% of U.S. transplant surgeons** order dd-cfDNA tests. Physicians send more than 200,000 tests per year[1] to outside labs **because they do not have a way to test in house**

1. Internal estimate based on publicly available data
2. UNOS data; As of 2021, https://unos.org/about/national-organ-transplant-system/

# Global partnership with Bio-Rad supports ‘land & expand’ strategy

| GraftAssure CORE™ Personalized Transplant Monitoring | GraftAssure IQ™ For Research Use Only | GraftAssure Dx™ Decentralized Transplant Monitoring |
|---|---|---|
| Laboratory Developed Tests (LDT) | Research Use Only Kit (RUO) | In Vitro Diagnostics Kit (IVD) (in development) |
| Innovation center is monetizable | Land | Expand |

# GraftAssureDx FDA Trial: Validation of dd-cfDNA for Kidney Transplant Monitoring

## Goal of the study

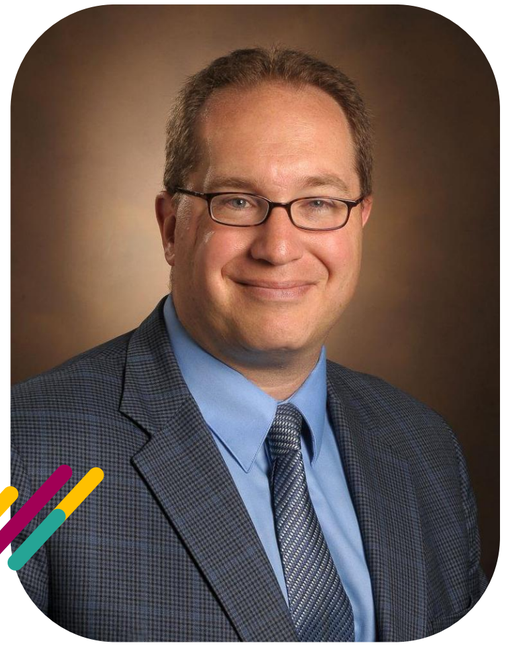
- To see how effectively the test works at correctly assessing if a patient *does* or *does not* have organ rejection. We will validate the accuracy of GraftAssureDx compared to biopsy results with the goal to show non-inferiority to other standard of care measures.
- When a patient comes in for biopsy, blood is drawn, dd-cfDNA values are generated on-site, a +/- call is made using our proprietary software and is then compared to biopsy result (according to Banff 2022).
- Estimated enrollment 125 to 150 patients.
- 5+ centers in U.S. with at least 1 in E.U.

Donor-Derived Cell-Free DNA (dd-cfDNA)
ClinicalTrials.gov ID NCT07060716

# Primary Endpoint

| Outcome Measure | Measure Descriptions |
| --- | --- |
| **Clinical validation** of the dd-cfDNA test when compared to biopsy-confirmed rejection assessing non-inferiority to the currently used dd-cfDNA tests | **Relative percentage of dd-cfDNA levels of 0.5% and absolute values of 50cp/mL** are considered to be the diagnostic cutoff for rejection, which will be refined during the pre-study phase.<br><br>**Clinical sensitivity of the dd-cfDNA test shall be better or equal to published values (≥56%).**<br>Current literature shows an average sensitivity of approximately 69% with a SD of 13%. Therefore, 56% represents the lower boundary (average - 1SD) of the distribution of published values.<br><br>**Clinical Specificity of the dd-cfDNA test shall be better or equal to published values (≥75%).**<br>Current literature shows an average specificity of approximately 81% with a SD of 6%. Therefore, 75% represents the lower boundary (average - 1SD) of the distribution of published values.<br><br>**Predictive values** are mathematically derived from sensitivity and specificity using the Bayes' theorem. Therefore, success criteria are defined as the lower boundary of the current literature at any given a priori probability. E.g., for an a priori probability of 20%,<br><br>the **lower boundary for Negative Predictive Value (NPV) shall be 85%.**<br>the **lower boundary for Positive Predictive Value (PPV) shall be 49%.** |

# Introduction to Dr. Tony Langone



Anthony Langone, MD is an Associate Professor of Medicine in the Division of Nephrology and Hypertension within the Department of Medicine at Vanderbilt University Medical Center. He received his undergraduate degree from Cornell University where he graduated with honors. He completed his medical degree at the State University of New York at Buffalo School of Medicine and completed his residency at Baylor College of Medicine where he graduated AOA and with the McIntosh award, top resident honors. He completed general and renal transplantation fellowships at Vanderbilt and was elected chief fellow in 2001. Dr. Langone's clinical focus is on kidney and pancreas transplantation, amyloidosis and multiple myeloma. His research interests include ameliorating drug side effects and new drug and biomarker discovery. His professional activities include being an active member of the DCE Committee, the Nephrology Fellowship Clinical Competency Committee, a renal representative and founding member of the Vanderbilt Amyloidosis Multidisciplinary Program (VAMP), and the Medical Director of Medical Specialties Clinic. Dr. Langone is a Fellow of the American Society of Transplantation (FAST) and a member of the American Society of Nephrology (ASN). He is an active participant in multiple American Society of Transplantation Community of Practices (COPs).

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# Today’s topics

- Background of dd-cfDNA
- Clinical utility of dd-cfDNA: Current and future applications
- Benefits of bringing dd-cfDNA testing in-house

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Background of dd-cfDNA

Clinical utility of dd-cfDNA: Current and future applications

Benefits of bringing dd-cfDNA testing in-house

## What is dd-cfDNA?

Biomarker detects donor organ DNA fragments in the blood - levels rise when the organ is injured

## Why is dd-cfDNA a preferred biomarker?

Supported by peer-reviewed publications and incorporated into standard of care, including The American Society of Transplant Surgeons and The International Society for Heart & Lung Transplantation position statements

Background of dd-cfDNA

Clinical utility of dd-cfDNA: Current and future applications

Benefits of bringing dd-cfDNA testing in-house

## Current

Detects rejection earlier than standard monitoring; helps reduce number of biopsies

## Future

Therapeutic efficacy monitoring (Anti-CD38 etc.), and more

Background of dd-cfDNA

Clinical utility of dd-cfDNA: Current and future applications

**Benefits of bringing dd-cfDNA testing in-house**

- Local lab access cuts turnaround from 5 to 7 days to within same day, improving decision-making speed enabling fast therapeutic interventions
- Expands reach into greater than 400 U.S transplant programs and community nephrology practices

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# Q&A

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# Thank you!

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