know error®

Media kit

STRAND DIAGNOSTICS™

*The **person** in personalized medicine.®*

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know error®

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Media kit

What's inside

Strand Diagnostics Background Information

Headquarters: Indianapolis, IN

Founded: 2005

Service Lines: Healthcare and Forensics

Full time employees: 52

Executive Team:
Peter M. Knapp, MD, Co-founder
Ted Schenberg, Co-founder & Chief Executive Officer
Travis Morgan, Co-founder & Chief Financial Officer

Company Overview

Strand Diagnostics developed and markets the **know error® system**, which uses bar coding, forensic principles and DNA testing (also known as DNA Specimen Provenance Assignment or "DSPA" testing) to confirm that surgical biopsy samples being evaluated belong exclusively to the patient being diagnosed. Available for a diverse range of tissue types, the **know error system** brings new levels of patient safety and accuracy to the diagnostic testing cycle for breast, prostate and other cancers. Since the company's launch in 2009, hundreds of physicians in a variety of specialties, including urology, radiology, GI and oncology, have adopted the **know error system** as their standard of care for diagnosing patients with cancer.

Strand Diagnostics's forensic division, Strand Analytical Laboratories, supports law enforcement agencies with forensic DNA testing services. These strong forensic roots were leveraged in the development of the **know error system** to apply a proven technology to the problem of misidentified biopsy samples present in the healthcare system today.

Company Video

See the forensics laboratory and learn more about the **know error® system** at http://knowerror.com/about/video/.

Highlights

- A 2013 study published in the *American Journal of Clinical Pathology* indicates that **up to 3.5%**[1] **of biopsy specimens may be subject to undetected tissue transposition or contamination** which could lead to a cancer diagnosis being assigned to the wrong patient.
- **DNA Specimen Provenance Assignment testing**, performed as part of the **know error system**, was identified as a potential solution to **prevent diagnostic mistakes** due to biopsy misidentification.
- Strand Diagnostics has implemented the **know error system** in a variety of clinical settings, including large group practices, hospital systems and national reference laboratories.
- Strand Diagnostics supports both national and local philanthropies to increase awareness and cancer research.
- In March 2012, NantWorks invested $30 million in series A funding to accelerate the company's growth, scale its operations infrastructure and expand sales and marketing efforts. Dr. Soon-Shiong is a physician, surgeon, scientist and inventor who has pioneered revolutionary new treatments for diabetes and cancer. With NantWorks, his goal is to build an integrated evidence-based, genomically-informed, personalized approach to the delivery of care and the development of next generation diagnostics and therapeutics.

1. Pfeifer JD, Liu J. Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path*. 2013;139(1):93-100.

Strand Diagnostics Leadership Team

Peter M. Knapp, MD, FACS, *Co-founder & Board Member*

As co-founder of Strand Diagnostics's healthcare division, Dr. Knapp has been instrumental in bringing DNA confirmatory testing to the medical setting to protect biopsy patients. He is a board-certified urologist by trade and currently serves as the President of Urology of Indiana, LLC, a comprehensive provider of urology services with 18 clinical office locations throughout central Indiana. Dr. Knapp is a graduate of Indiana University and the Indiana University School of Medicine, where he now serves as a volunteer Clinical Associate Professor. In addition, he is a fellowship faculty member of the Indiana University Female Pelvic Medicine and Reconstructive Surgery department. Dr. Knapp completed his general surgery internship and urology residency at the University of Michigan Hospitals in Ann Arbor. He holds memberships in numerous professional organizations, including the American Urological Association, the Large Urology Group Practice Association, the Society for Urodynamics and Female Urology, the American College of Surgeons, the American Medical Association and the American Association of Clinical Urologists. He is the immediate past President of the North Central Section of the American Urological Association, past President of the Large Urology Group Practice Association and remains active in advancing health policy issues for both organizations. Dr. Knapp is named as an inventor on five patents, has authored more than 30 papers, four books and books chapters and has presented at numerous urology conferences and events throughout the U.S. and abroad. From a research perspective, Dr. Knapp has served as a principal or sub-investigator on more than 50 clinical trials.

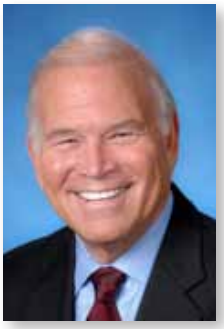
Phillip Gordon, *Board Member*

Phillip Gordon is currently the Director of the CSS Institute of Advanced Health in Phoenix, Arizona. Mr. Gordon's success story includes political and policy development in designing and implementing strategies to create new business opportunities, prevent problems or resolve conflicts facing clients. He was the Mayor of Phoenix from 2004 to 2011 and has an extensive list of community involvement. Mr. Gordon has a law degree from Arizona State University College of Law and his undergraduate work was in History and Government at the University of Arizona in Tucson, Arizona.

Elena Rochelli, *Board Member*

Elena Rochelli is an investment management professional residing in Los Angeles, California. She has an MBA from Harvard Business school and a B.A. from Princeton University in Economics. Most recently Ms. Rochelli was the Vice President of Providence Equity Partners.

Strand Diagnostics Leadership and Executive Team



Ted Schenberg, *Co-founder & Chief Executive Officer*

Ted Schenberg is a successful, serial entrepreneur, having founded and acquired several businesses including companies in the chemical, aerospace, construction and food processing industries. He has extensive experience with start-ups, turnaround situations and merger/acquisition activities, with a strong emphasis on the development of sales and marketing functions. Three of the chemical companies founded or purchased by Mr. Schenberg were subsequently sold to publicly-traded firms. He has taught courses on business and entrepreneurship at assorted venues including the prestigious Indiana University Kelly School of Business, from which he holds a Bachelor of Science in Accounting and a Masters in Business Administration.

Travis Morgan, *Co-founder & Chief Financial Officer*

After three years in the audit department of KPMG Peat Marwick focusing on small and mid-sized clients, Travis Morgan embarked on a successful career in entrepreneurship and private equity and has garnered over 20 years of experience in venture creation, management and harvest. In this role he has been instrumental in the creation, purchase and/or sale of 12 companies, including two liquidity events with large public companies. He has held the role of acting or interim CFO at eight companies in the biotech, chemical manufacturing, aerospace and private equity industries. Mr. Morgan graduated at the age of 20 from the Indiana University Kelly School of Business with a Bachelor of Science in Accounting and Finance, and is a CPA (inactive) licensed in Indiana. He also received a Masters in Business Administration from Babson University with a concentration in Entrepreneurship and International Business.

Facts about the **know error® system**

- The diagnostic testing cycle for cancer requires several steps and medical professionals working in different locations. With such a complex process executed at a large scale, the risk of Specimen Provenance Complications is an ongoing concern for physicians and patients.
- Specimen Provenance Complications (SPCs) can occur as a result of human error during any step in the complex diagnostic testing cycle. Some examples of SPCs include specimen transposition and foreign cell contamination.
- **Up to 3.5%**[1] of biopsy specimens may be subject to undetected SPCs which could lead to a cancer diagnosis being assigned to the wrong patient. These mistakes can set in motion the overtreatment of thousands of patients annually as well as delay the potentially life-saving treatments of individuals with cancer.
- DNA Specimen Provenance Assignment (DSPA) testing verifies patient identity at the molecular level by comparing the genetic profiles obtained from the patient's biopsy tissues and a DNA reference sample collected from the patient at the time of the biopsy procedure. This testing dramatically reduces the incidence of SPCs, minimizing diagnostic mistakes and diminishing their subsequent negative impact.
- The **know error® system** employs patient-specific bar coding and forensic chain-of-custody principles for the purpose of reducing errors, and a DSPA test that prevents errors from resulting in adverse patient outcomes.
- The **know error system** involves three simple steps requiring minimal disruption to the standard biopsy collection process:

  1. Swab: A DNA sample is taken by gently swabbing the inside of each cheek.

  2. Sample: The biopsy tissue sample(s) are placed in bar-coded specimen containers.

  3. DNA match: If the biopsy results come back positive for cancer (malignant), A DNA test compares the (1) swab sample with the (2) biopsy tissue sample to ensure a (3) DNA match.
- If the DSPA test determines that the DNA profiles of the reference swab and biopsy sample are a match, this information is compiled in a report to the referring laboratory. If the samples do not match, the laboratory is contacted immediately and further testing is required to properly identify the positive biopsy.
- Hundreds of physicians throughout the U.S. in a variety of specialties, including urology, radiology, GI and oncology, have adopted the **know error system** as their standard of care for diagnosing patients with cancer.
- The **know error system** yields maximum safety benefits when used prospectively with all patients within a practice (at the time of the biopsy procedure). However, DSPA testing can also be performed retrospectively to verify patient identity if a physician suspects that an error has occurred.
- The DNA collected by the **know error system** is protected by the Health Insurance Portability and Accountability Act (HIPAA), a U.S. law designed to provide privacy standards to protect patients' medical records and other health information available to health plans, doctors, hospitals and other health care providers.
- There are no harmful risks to patients using the **know error system**, as it requires only a painless cheek swab to be taken at the time of the biopsy procedure.
- DSPA is a molecular diagnostic test billed to governmental and commercial insurance providers. Therefore, patients will only be responsible for the in-network deductible, co-insurance and co-pay amounts applied by their carriers.
- A 2012 study published in *Value in Health* indicates that DSPA testing would likely be a cost-effective method for preventing treatment errors to patients resulting from biopsy misidentification.[2]

1. Pfeifer JD, Liu J. Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path*. 2013;139(1):93-100.

2. Pfeifer JD, Singleton MN, Gregory MH, et al. Development of a decision-analytic model for the application of STR-based provenance testing of transrectal prostate biopsy specimens. *Value in Health*. 2012; 15 (6): 860-867.

Overview of the **know error® system**

Cancer currently accounts for one in every four deaths in the U.S. According to recent reports from the American Cancer Society, about 1.6 million new cancer cases are expected to be diagnosed in 2014.[1] By 2030, the global cancer burden is expected to nearly double and while that increase is the result of demographic changes – a growing and aging population – it may be compounded by the adoption of unhealthy lifestyles and behaviors related to economic development, such as smoking, poor diet, and physical inactivity.[2]

The process of collecting and evaluating the biopsy specimens used to render these cancer diagnoses involves nearly 18 steps and several medical professionals working in different locations.[3] With such a complex process executed at a large scale, the risk of Specimen Provenance Complications (patient misidentification, specimen transposition or foreign cell contamination occurring in clinical or anatomical pathology) is an ongoing concern for physicians and patients. Specimen Provenance Complications (SPCs) are an inherent byproduct of the diagnostic testing cycle that, if left undetected, can lead to serious diagnostic mistakes and adverse patient outcomes. For instance, one patient may be misdiagnosed with cancer and receive unnecessary treatment that significantly alters his or her quality of life, while the other patient's cancer remains undiagnosed and continues to advance.

In a recent case documented in the *Virginia Medical Law Report*, the prostate tissue samples of a healthy patient were switched during the biopsy tissue evaluation process with the tissue samples of another patient who had cancer. The mix-up resulted in an unnecessary prostatectomy and subsequent urinary leakage and erectile dysfunction for the 60-year-old patient.[4] Another example of the magnitude of SPCs occurred recently when a woman received six radiation treatments before learning she was misdiagnosed with breast cancer. The misdiagnosis was the result of a laboratory error in which her biopsy was contaminated with another patient's malignant samples.[5] These cases have a profound impact on the physical and emotional well-being of multiple patients, not to mention significant legal and financial ramifications as well.

To prevent these types of issues and enhance diagnostic accuracy and safety for biopsy patients, Strand Diagnostics developed the **know error® system**. This innovative system uses patient-specific bar coding and forensic chain-of-custody principles for the purpose of reducing errors, and DNA testing (also known as DNA Specimen Provenance Assignment or "DSPA" testing) for the purpose of identifying errors before adverse patient outcomes occur. The DSPA test verifies patient identity at the molecular level by comparing genetic profiles obtained from the patient's biopsy tissues and DNA reference sample, taken via cheek swab at the time of the biopsy procedure. Through these combined features, the **know error system** ensures that surgical biopsy samples being evaluated belong exclusively to the patient being diagnosed, allowing physicians to proceed confidently with treatment recommendations.

In terms of frequency of error, a 2013 study published in the *American Journal of Clinical Pathology* indicates that up to 3.5%[6] of biopsy specimens may be subject to undetected tissue transposition or contamination which could lead to a cancer diagnosis being assigned to the wrong patient. Furthermore, each case involves at least two individuals, meaning this error rate actually underestimates the percentage of patients affected by incidents of biopsy misidentification.

Adding DNA confirmation—taking a DNA timeout—completes the diagnostic testing cycle and provides physicians and patients alike with the assurance that the positive biopsy specimen is that of the patient in question. While still in the early stages of adoption, hundreds of physicians in a variety of specialties, including urology, radiology, GI and oncology, are using the **know error system** as their standard of care for diagnosing patients with cancer.

1. American Cancer Society. Cancer Facts & Figures 2014. Atlanta: American Cancer Society; 2014.
2. American Cancer Society. Global Cancer Facts & Figures 2nd Edition. Atlanta: American Cancer Society; 2011.
3. Bronner M. DNA fingerprint analysis for specimen identification. *Cleveland Clinic Clinical and Translational Pathology Research*. 2006; Fall: 5-7.
4. Virginia Medical Law Report. Med-mal claim brought for complications after surgery. ©Virginia Lawyers Media, January 2012.
5. Boniello K. 'False cancer' lawsuit. *New York Post*. http://www.nypost.com/p/news/local/manhattan/false_cancer_lawsuit_15twqx6rOl0W1c8sY2YU0J. Published December 21, 2011. Accessed May 13, 2012.
6. Pfeifer JD, Liu J. Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path*. 2013;139(1):93-100.

Know Error Prostate Biopsy Kit Components

The **know error® system** uses bar coding, forensic principles and DNA matching to confirm that surgical biopsy specimens being evaluated belong exclusively to the patient being diagnosed. All standard prostate biopsy kits contain the items pictured below:

Swab Return Envelope
A prepaid shipping envelope is used to return the swabs to our DNA lab immediately after the biopsy procedure.

Labels and Security Seals
Bar code labels can be placed on patient files as needed. An orange label is provided for placement on the requisition to request Know Error DSPA testing. The security seal is intended to secure the biopsy kit when the procedure is complete.

Specimen Collection Jars
These jars are used to collect the patient's tissue sample(s) and are sent to pathology for evaluation after the biopsy procedure.

Pathology Lab Components
This box contains the vials to transport tissue scrolls (taken from positive specimens) and a prepaid shipping mailer to return them to our DNA lab for analysis.

Reference Swabs
Buccal swabs are used to swab the patient's cheek to collect a DNA reference sample before the biopsy procedure.

Patient Information Card
This card is given to the patient at the time of the biopsy to explain the **know error® system** and DNA collection process.

Three Steps to DNA Confirmation

1 Swab
Your DNA sample is taken by gently swabbing the inside of your cheek.

2 Sample
Your biopsy tissue sample(s) are placed in bar-coded specimen containers.

3 DNA Match
A DNA test compares your (1) swab sample with the (2) biopsy tissue sample to ensure a (3) DNA match.

Know Error Breast Biopsy Kit Components

The **know error® system** uses bar coding, forensic principles and DNA matching to confirm that surgical biopsy specimens being evaluated belong exclusively to the patient being diagnosed. All standard breast biopsy kits contain the items pictured below:

Swab Return Envelope
A prepaid shipping envelope is used to return the swabs to our DNA lab immediately after the biopsy procedure.

Labels and Security Seals
Bar code labels can be placed on patient files as needed. An orange label is provided for placement on the requisition to request Know Error DSPA testing. The security seal is intended to secure the biopsy kit when the procedure is complete.

Specimen Collection Jars
These jars are used to collect the patient's tissue sample(s) and are sent to pathology for evaluation after the biopsy procedure.

Pathology Lab Components
This box contains the vials to transport tissue scrolls (taken from positive specimens) and a prepaid shipping mailer to return them to our DNA lab for analysis.

Reference Swabs
Buccal swabs are used to swab the patient's cheek to collect a DNA reference sample before the biopsy procedure.

Patient Information Card
This card is given to the patient at the time of the biopsy to explain the **know error® system** and DNA collection process.

Three Steps to DNA Confirmation

1 Swab
Your DNA sample is taken by gently swabbing the inside of your cheek.

2 Sample
Your biopsy tissue sample(s) are placed in bar-coded specimen containers.

3 DNA Match
A DNA test compares your (1) swab sample with the (2) biopsy tissue sample to ensure a (3) DNA match.

Know Error Biopsy Specimen Kit Components

The **know error® system** uses bar coding, forensic principles and DNA matching to confirm that surgical biopsy specimens being evaluated belong exclusively to the patient being diagnosed. This kit is most commonly used for bladder, cervical, colon and endometrial tissue biopsies. All biopsy specimen kits contain the items pictured below:

Swab Return Envelope
A prepaid shipping envelope is used to return the swabs to our DNA lab immediately after the biopsy procedure.

Labels and Security Seals
Bar code labels can be placed on patient files as needed. An orange label is provided for placement on the requisition to request Know Error DSPA testing. The security seal is intended to secure the biopsy kit when the procedure is complete.

Pathology Lab Components
This envelope contains the vials to transport tissue scrolls (taken from positive specimens) and a prepaid shipping mailer to return them to our DNA lab for analysis.

Specimen Collection Jars
These jars are used to collect the patient's tissue sample(s) and are sent to pathology for evaluation after the biopsy procedure.

Reference Swabs
Buccal swabs are used to swab the patient's cheek to collect a DNA reference sample before the biopsy procedure.

Patient Information Card
This card is given to the patient at the time of the biopsy to explain the **know error® system** and DNA collection process.

Three Steps to DNA Confirmation

1 Swab
Your DNA sample is taken by gently swabbing the inside of your cheek.

2 Sample
Your biopsy tissue sample(s) are placed in bar-coded specimen containers.

3 DNA Match
A DNA test compares your (1) swab sample with the (2) biopsy tissue sample to ensure a (3) DNA match.

Know Error Kit for Retrospective Use

The Specimen Source Verification (SSV) Kit uses the Know Error DNA Specimen Provenance Assignment (DSPA) testing to solve unexpected cases of misidentified specimens. We now widely offer retrospective DNA confirmation testing to help support physicians and laboratories across the U.S. and Canada. The kit components include:

Swab Return Envelope
A prepaid shipping envelope is used to return the swabs to our DNA lab immediately after the biopsy procedure.

Pathology Lab Components
Inside of Part C, this envelope contains the vials to transport tissue scrolls for DSPA testing and a prepaid shipping mailer to return them to our DNA lab for analysis.

Patient Information Card
This card is given to the patient at the time of the biopsy to explain the **know error® system** and DNA collection process.

Requisition, Labels and Security Seal
A requisition for Know Error DSPA testing is provided. Bar code labels can be placed on patient files as needed. The security seal can be used to secure the swab bag when the procedure is complete.

Reference Swabs
Buccal swabs are used to swab the patient's cheek to collect a DNA reference sample before the biopsy procedure.

Media Contact

Strand Diagnostics's public relations team from Schwartz MSL is available to discuss media coverage opportunities, coordinate interviews and answer a variety of questions regarding press releases, company information, etc.

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