Media kit

STRAND DIAGNOSTICS™

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

STRAND DIAGNOSTICS

know error®

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888-924-6779

Media kit

What's inside

Strand Diagnostics Background Information

Headquarters: Indianapolis, IN

Service Lines: Healthcare and Forensics

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

Founded: 2005

Full time employees: 52

Company Overview

Strand Diagnostics developed and markets the **know error® system**, which uses unique patient bar-coding, forensic principles and DNA testing (also known as DNA Specimen Provenance Assay or DSPA) to confirm that surgical biopsy samples being evaluated are free from contamination and belong exclusively to the patient being diagnosed. Available for a diverse range of tissue types, the **know error system** enhances patient safety and accuracy in 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 study published in 2013 by the *American Journal of Clinical Pathology* indicates that **up to 3.5% 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.
- *The Journal of Urology* published a study in 2015 that found 1 in 200 men undergoing a prostate biopsy are affected by a Specimen Provenance Complication (SPC) which costs healthcare over $880,000,000[2] per year.
- In 2015 a study in the *American Journal of Clinical Pathology* documented that 2% of the clinical next-generation sequencing (NGS) samples tested were so significantly contaminated by another's DNA (human-to-human specimen contamination) that test results were confounded, and 3% of the samples had greater than a 5% contamination.[3]
- **DNA Specimen Provenance Assay**, performed as part of the **know error system**, was identified as a potential solution to **prevent diagnostic mistakes** due to biopsy SPCs.
- Strand Diagnostics has implemented the patented **know error system** in a variety of clinical settings, including large group practices, cancer centers, hospital systems and national reference laboratories as a way to enhance patient safety and diagnostic accuracy in the biopsy process. As of May 2017, over 275,000 patients have been protected by use of the **know error system**.
- Strand Diagnostics supports both national and local philanthropies to increase awareness and cancer research.

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

2. Wojno, K., Hornberger, J., Schellhammer, P., Dai, M., Morgan, T.; The clinical and economic implications of specimen provenance complications in diagnostic prostate biopsies, *The Journal of Urology* 2015 Apr;193(4):1170-7.

3. J. K. Sehn, MD, D. H. Spencer, MD, PhD, J. D. Pfeifer, MD, PhD, A. J. Bredemeyer, PhD, C. E. Cottrell, PhD, H. J. Abel, PhD, E. J. Duncavage, MD.; Occult Specimen Contamination in Routine Clinical Next-Generation Sequencing Testing. *American Journal of Clinical Pathology,* October 2015; 144:667-674.

Strand Diagnostics Leadership Team

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

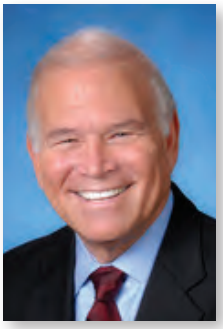
Dr. Knapp is Co-founder and Director of Strand Diagnostics LLC, and co-developer of the Know Error DNA Specimen Provenance Assignment (DSPA) test and kit used to improve diagnostic accuracy and patient safety in the evaluation of patient tissue specimens. Dr. Knapp is a practicing urologist involved in medical education, clinical research, product development, practice growth and clinical service line expansion for over 25 years. He holds multiple healthcare patents, has authored more than 30 articles and several book chapters, and served as principal investigator or sub-investigator on more than 50 clinical trials. Dr. Knapp is the past President of Urology of Indiana, a 35 physician urology group practice, and serves as Volunteer Clinical Associate Professor of Urology at Indiana University School of Medicine. He is Past President of the North Central Section of the American Urologic Association, Past President of the Large Urology Group Practice Association and remains active in the health policy and healthcare advocacy activities of both national organizations. Dr. Knapp has also served as consultant to other healthcare industry companies by providing strategic guidance on product development and application.

Dr. Knapp is a graduate of Indiana University and the Indiana University School of Medicine. He completed his general surgery internship and urology residency at the University of Michigan in Ann Arbor, Michigan. He is certified by the American Board of Urology and is a fellow of the American College of Surgeons.

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.

Strand Diagnostics Leadership and Executive Team

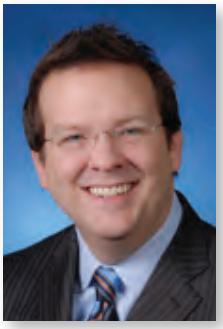


Theodore "Ted" Schenberg, *Co-founder & Chief Executive Officer*

Mr. Schenberg is a principal and co-founder of Caravel Ventures, a private equity group syndicating growth capital raises for lower middle market companies needing both financial and managerial support. Caravel's current portfolio includes Strand Diagnostics (an FBI and CLIA-accredited forensic and medical DNA testing lab) for which Mr. Schenberg has been the CEO since 2007, and Animated Dynamics (engaged in the biodynamic imaging of cancer tissues) for which Mr. Schenberg is also CEO.

Mr. Schenberg is a successful veteran businessman having founded and/or acquired several companies in the life-science, chemical, aerospace, construction, internet security, construction, and food processing industries. He has an extensive track-record of executive leadership as well as building value for stakeholders in his companies in partnership with his management teams. He has deep experience with start-ups, turnarounds, and merger/acquisition activities with a strong emphasis on commercialization activities. Three of the companies founded or purchased by Mr. Schenberg were subsequently sold to publicly-traded firms. He holds two patents and has taught courses on business and entrepreneurship at assorted venues including Indiana University Kelly School of Business from which he also holds a BS in Accounting and a Masters in Business Administration.

Mr. Schenberg is married to his wife of 45 years (Patty) with whom he has four children and seven grandchildren. He devotes a good deal of his civic time to 501C(3) public charities, and philanthropically donates money to a variety of medical research and patient advocacy groups.



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

After three years in the audit department of KPMG Peat Marwick focusing on lower middle market clients, Travis Morgan embarked on a successful career as a private equity investor and entrepreneur. As Co-founder and Managing Director of Caravel Ventures, Travis has been directly responsible for 18 capital infusions into 12 different operating companies, serving as the full-time President or CFO of 7 of those portfolio companies. His credits include securing over $103 million in funded capital transactions, including three liquidity events with publicly traded firms. 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 received an MBA with concentrations in entrepreneurship and international business from Babson. He is a certified Lean Six Sigma Greenbelt, and an alumnus of the Indianapolis Business Journal's "Forty under 40" list, recognizing the state's top business leaders under the age of forty (class of 2000).

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),which includes switching and contamination errors, 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 Assay (DSPA) confirms specimen purity and verifies patient identity at the molecular level by comparing the genetic profiles obtained from the patient's biopsy tissues and a DNA swab 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.
- A study published in *The Journal of Urology* documents healthcare and legal costs associated with misdiagnosis because of specimen provenance complications to be estimated at $880 million[2] per year.
- The **know error® system** is patented in the United States and Australia. It employs unique patient-specific bar coding and forensic principles for the purpose of reducing provenance errors and preventing misdiagnosis resulting in adverse patient outcomes.
- Simplified, the **know error system** involves three 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 the bar-coded specimen containers and sent to the pathology lab for analysis.

  3. DNA match: If the biopsy results are positive for cancer (malignant), A DNA test compares the (1) swab sample with the (2) biopsy tissue sample to ensure a (3) DNA match.
- Once the DSPA test is complete a report is issued for each patient to summarize the results. If the test determines that the DNA profiles do not match or if the specimen is contaminated, the laboratory is contacted and further testing might be required to properly identify the positive biopsy. The average turn-a-round time for DSPA is 2 to 3 days.
- The patented **know error system** is widely used for breast and prostate biopsies; however, bladder, cervical, endometrial and colon tissues are commonly tested. Additional tumor types can be requested for further investigate to determine clinical feasibility on a case-by-case basis. 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 routinely 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 the laboratory or 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.

1. Pfeifer J.D., Liu J.; Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path*. 2013;139(1):93-100.
2. Wojno, K., Hornberger, J., Schellhammer, P., Dai, M., Morgan, T.; The clinical and economic implications of specimen provenance complications in diagnostic prostate biopsies, *The Journal of Urology* 2015 Apr;193(4):1170-7.

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, over 1.6 million new cancer cases are expected to be diagnosed in 2017.[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 patented system uses unique patient-specific bar codes and forensic principles for the purpose of reducing errors, and DNA testing (also known as DNA Specimen Provenance Assay or DSPA) for the purpose of identifying errors before adverse patient outcomes occur. DSPA 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 are free from contamination and 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.

The costs associated with misdiagnosis because of specimen provenance complications is estimated at $880 million per year as documented in a 2015 study[7] from *The Journal of Urology*.

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. Hundreds of physicians in a variety of specialties, including urology, radiology, GI and oncology, are using the patented **know error system** as a routine standard of care for diagnosing patients with cancer.

1. American Cancer Society. Cancer Facts & Figures 2017. Atlanta: American Cancer Society; 2017.
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 J.D., Liu J.; Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path*. 2013;139(1):93-100.
7. Wojno, K., Hornberger, J., Schellhammer, P., Dai, M., Morgan, T.; The clinical and economic implications of specimen provenance complications in diagnostic prostate biopsies, *The Journal of Urology* 2015 Apr;193(4):1170-7.

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
At the time of the biopsy a DNA sample is taken by gently swabbing the inside of the patient's cheek.

2 Sample
The biopsy tissue sample(s) are placed in bar-coded specimen containers and sent to a pathology lab for evaluation.

3 DNA Match
A DNA test compares the (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
At the time of the biopsy a DNA sample is taken by gently swabbing the inside of the patient's cheek.

2 Sample
The biopsy tissue sample(s) are placed in bar-coded specimen containers and sent to a pathology lab for evaluation.

3 DNA Match
A DNA test compares the (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 smaller kit size 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 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.

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
At the time of the biopsy a DNA sample is taken by gently swabbing the inside of the patient's cheek.

2 Sample
The biopsy tissue sample(s) are placed in bar-coded specimen containers and sent to a pathology lab for evaluation.

3 DNA Match
A DNA test compares the (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

Please use the email address below to request media coverage opportunities, coordinate interviews and answer a variety of questions regarding press releases, images and company information.

Linda Tuttle
ltuttle@knowerror.com

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