

## A SUMMARY OF THE PATENTED KNOW ERROR® SYSTEM

Strand Diagnostics' patented **know error® system** includes a biopsy kit that incorporates DNA testing (a buccal swab-to-biopsy tissue comparison) to make certain that the biopsy results are free from contamination and belong to the patient being evaluated. The DNA test is referred to as DSPA (DNA Specimen Provenance Assay). Through the use of bar-coding, forensic principles and DNA matching, the **know error® system** brings a higher level of diagnostic accuracy and patient safety to the biopsy evaluation process. The average turn-around time (TAT) from the time our laboratory receives a positive biopsy testing sample is 3 days for prostate biopsy samples and 2 days for breast specimens.



1

### Swab

The patient's DNA sample is taken by gently swabbing the inside of the cheek.



2

### Sample

The patient's biopsy tissue sample(s) are placed in bar-coded specimen containers and sent to pathology.



3

### DNA Match

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



## WHY DNA MATCHING IS NEEDED

The diagnostic testing cycle can involve 18 different steps:<sup>1</sup> patient misidentification, specimen transposition, and foreign cell contamination can occur. Published literature indicates that up to 3.5%<sup>2</sup> of prostate biopsies may be subject to undetected (occult) specimen errors which could lead to a cancer diagnosis being assigned to the wrong patient. These hidden Specimen Provenance Complications (SPCs) can pose serious patient safety and medical-legal risks. The costs associated with misdiagnosis due to SPCs is estimated at \$880 million per year.<sup>3</sup>

## MARKET ACCEPTANCE<sup>4</sup>

- Since 2010, over 275,000 patients protected
- Over 2,100 physicians utilize the patented **know error® system**
- Over 400 Laboratories throughout the US and Canada process tissue for Strand Diagnostics
- 12% of all prostate biopsies performed using the **know error® system** for DNA confirmation
- 1% of all breast biopsies performed using the **know error® system** for DNA confirmation

## THE BENEFITS OF USING KNOW ERROR

- **Increased Patient Safety:** Be DNA Certain™
- **Increased Practice Safety:** Protects practice reputation
- **Increased Practice Growth:** Practice differentiator

## THE COST OF USING KNOW ERROR

- **To the practice:** There is no cost related to practice adoption of the **know error® system**. (The collection kits are provided along with prepaid shipping.)
- **To health care:** *The Journal of Urology®* reports that the use of the **know error® system** saves healthcare over \$880 million per year.<sup>3</sup>
- **To the patient:** Strand Diagnostics bills the patient's insurance company, handles any appeals, and once the claim is exhausted the patient will owe no more than \$295 (with flexible payment terms). Medicare patients are not "balanced billed."

(continued on reverse)

## TRAINING AND IN-SERVICE

- Staff training is provided by Strand Diagnostics at the convenience of the practice, clinic, and/or laboratory setting.
- While hundreds of outside laboratories process Know Error samples, if there is an outside laboratory that currently is not, Strand Diagnostics will reach out to partner with any laboratory.
- Quarterly “Scorecards” are provided to each practice, laboratory and/or clinic providing a comprehensive summary of all essential statistics including: utilization, positivity rates, along with description of the match/non-match and contamination reports.
- The integration with the clinic’s EHR allows for the bidirectional exchange of ordering and reports.

## OTHER USES FOR DSPA TESTS

Healthcare centers that have not adopted the prospective use of the patented **know error® system** can order DSPA testing from Strand Diagnostics whenever a specimen misidentification is suspected or when the treating physician or patient wants the peace of mind to know that the biopsy belongs to the patient.

**Special kits are provided by Strand Diagnostics to assist in these instances. Client Services can be reached at: 1-888-924-6779, option 2.**

### References

1. Bronner MP. DNA fingerprint analysis for specimen identification. *Clinical and Translational Pathology Research*. Division of Pathology and Laboratory Medicine, Cleveland Clinic. 2006;Fall:5-7.
2. Pfeifer JD, Liu J. Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path*. 2013;139(1):93-100.
3. 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.
4. Data on file through May 2017. Strand Diagnostics, LLC.

## About Strand Diagnostics

Strand Diagnostics, privately owned and located in Indianapolis, Indiana, was formed as a forensic DNA testing crime lab in 2005 and maintains its FBI-accreditation and processes crime-scene samples for a number of public police agencies throughout the United States. Since 2008, Strand Diagnostics has maintained its CLIA and New York State accreditations and has processed prostate and breast biopsy collection samples from over 275,000 patients.



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