### Be DNA Certain

DNA testing that brings patient safety and diagnostic accuracy to the biopsy process.



# Patient Information & Insurance Coverage



The **person** in personalized medicine.®

www.stranddiagnostics.com www.knowerror.com



# Did you know that **biopsy specimen errors** can occur outside the control of your doctor?

There are up to 18 different steps<sup>1</sup> in the diagnostic testing cycle from the time your biopsy specimen is taken. The **know error® system** created by Strand Diagnostics increases both patient and practice safety, safeguarding you.



Data published in *The Journal of Urology* indicate that 1 in 200² prostate biopsy patients may be subject to undetected specimen transposition or contamination which could lead to a cancer diagnosis being assigned to the wrong patient. When this happens, patients with a false-positive diagnoses could receive unnecessary treatment, while patients with a false-negative diagnoses would not receive needed care in a timely manner.

- 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.
- 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.



## Understanding how the **know error**® **system** works to protect patients

#### Be DNA Certain\*

The patented **know error® system** brings a higher level of diagnostic accuracy and patient safety to the complex biopsy evaluation process allowing you and your physician to proceed with a personalized treatment for YOUR diagnosis.

The **know error® system** is a simple process during the time of your biopsy that includes DNA Specimen Provenance Assay (DSPA) commonly known as the Know Error test.



- **1. Swab.** A reference sample of DNA is taken by gently swabbing the inside of the patient's cheek.
- 2. Sample. The patient's biopsy specimen sample(s) are placed in barcoded specimen containers included in the biopsy kit and sent to the pathology lab for evaluation.
- 3. DNA Match. If the biopsy results come back positive for cancer (malignant) a test is performed at Strand Diagnostics' comparing DNA fingerprints of the (1) swab reference sample to the (2) biopsy specimen sample in evaluation for a (3) DNA match and for specimen purity.





# Common questions about the know error® system

Why do you need my DNA?

Your DNA plays an important part in the biopsy evaluation process. With a reference sample of DNA (taken via cheek swab at the time of your procedure), physicians using the **know error® system** can confirm that any biopsy specimens used in your diagnosis are, in fact, your specimens and are free from contamination.

- Will my DNA information be confidential?
  - Your DNA will ONLY be used for the **know error**® test or other tests ordered by your doctor (i.e. Strand's UroSeq® hereditary DNA repair gene panel for prostate patients). Further, all of your personal information is protected by the Health Insurance Portability and Accountability Act (HIPAA). To review our comprehensive privacy policy, please refer to www.knowerror.com/privacy.
- Where can I find more information?

Additional information can be found by visiting our website at www.knowerror.com.

If you have know error® testing questions please contact Strand client services at 1-888-924-6779, option 2.



### **Billing and insurance coverage** questions about Know Error

• Is Strand Diagnostics an "in network" lab which participates with my health insurance?

Strand Diagnostics is an out-of-network laboratory which allows Strand to work directly with a patient to limit out-of-pocket expenses. Some insurance companies will cover Strand's Know Error test.

#### If your insurance does cover the Know Error test:

- Strand will bill your insurance company.
- You will receive an Explanation of Benefits (EOB) from them.
  - o This EOB will explain how they have processed your charges and it may mention a "Patient Responsibility" portion.
  - o Please disregard that amount because their EOB is not the same as Strand's bill. Strand Diagnostics will not bill you for any more than \$295. If needed, Strand will work with you to establish a payment plan that works for you.

#### If your insurance company including Medicare does not cover the Know Error test:

- The maximum you will be billed by Strand is \$295. If needed, Strand will work with you to establish a payment plan that works for you.
- What if my insurance sends me the check?

If you receive a check from your insurance related to the services provided by Strand Diagnostics, please do not cash the check. Instead, contact Strand at 1-888-924-6779, option 1 for instructions regarding how to handle and where to forward the check.

• What if I do not have any health insurance?

The price for anyone uninsured will be \$295.

• Does Strand offer payment plans?

Yes, we are happy to work with you to make a payment plan that works for you.

For any additional billing related questions, please contact Strand at 1-888-924-6779, option 1.



#### **Your Trusted Partner**

An Advocate in Patient & Practice Safety

Strand Diagnostics has a long history as a comprehensive provider of identity confirmation testing services. We solve complex problems and help doctors accurately diagnose and ensure patient safety by utilizing the patented **know error® system**.



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Patented system. Patient Information Brochure 11-2019.