Prostate Biopsy Kit Components

The know error® system for prostate biopsies contains all the necessary components to collect biopsy samples with the added benefit of confirming that the specimens being evaluated belong to the patient being diagnosed. It can be easily integrated within any pathology lab. All standard prostate biopsy kits contain the items pictured below.

A DNA Specimen Provenance Assignment (DSPA) report is issued for each patient to summarize the test results. A Know Error representative will contact the appropriate parties immediately if a complication is detected.
Core Features

The know error® system for prostate biopsies includes:

- **Unique Patient Identification Bar Code**
  Each biopsy kit features a unique patient identification bar code that is applied to the requisition and all kit components. This helps reduce SPCs that can occur during the collection, handling and processing of biopsy tissues.

- **Forensic Chain of Custody Principles**
  The know error® system incorporates forensic chain of custody principles, providing a strict means of control and documentation for the handling of samples.

- **DNA Specimen Provenance Assignment (DSPA)**
  Through the use of microsatellite analysis, DNA Specimen Provenance Assignment (DSPA) testing virtually eliminates diagnostic mistakes due to SPCs by verifying the patient's identity at the molecular level.

- **Detailed DSPA Report**
  Once the DNA test is complete, an electronic report—compatible with most EMR systems—is issued to summarize the findings. If a potential SPC is indicated, the appropriate parties are notified immediately to address the issue.

The Clinical Problem

The biopsy evaluation process requires nearly 20 steps and several medical professionals working in different locations. Each year, it plays a critical role in determining the diagnoses and corresponding treatments of millions of patients.

With such a complex process executed at a large scale, the risk of Specimen Provenance Complications (SPCs) is a serious concern for both physicians and patients. SPCs arise due to instances of specimen transposition, foreign cell contamination and patient misidentification that occur in clinical or anatomical pathology. If left undetected, they can lead to serious diagnostic mistakes and adverse patient outcomes.

The Innovative Solution

Through the use of bar coding, forensic principles and DNA matching, the know error® system brings new levels of diagnostic accuracy and patient safety to the biopsy evaluation process.

**How It Works**

Before the biopsy procedure, a reference sample of DNA is taken by swabbing the inside of the patient’s cheek. The swab is then sent to an independent DNA lab.

The patient’s biopsy tissue sample(s) are placed in bar-coded specimen containers from the biopsy kit and sent to the pathology lab for evaluation.

If the biopsy results come back positive for cancer (malignant), the DNA lab performs a DSPA test to compare the DNA profiles of the biopsy tissue and the reference sample. Concurrency of these profiles allows for absolute confirmation of patient identity.

With the know error® system, you can proceed confidently with treatment recommendations based on the patient’s lab results.

This innovative system dramatically reduces the incidence of SPCs and allows you to confirm that surgical biopsy samples being evaluated belong exclusively to the patient being diagnosed.
Prostate Biopsy Kit Components

The know error® system for prostate biopsies contains all the necessary components to collect biopsy samples with the added benefit of confirming that the specimens being evaluated belong to the patient being diagnosed. It can be easily integrated within any pathology lab. All standard prostate biopsy kits contain the items pictured below.

DSPA Report

A DNA Specimen Provenance Assignment (DSPA) report is issued for each patient to summarize the test results. A Know Error representative will contact the appropriate parties immediately if a complication is detected.
Core Features

Core features of the know error® system for prostate biopsies include:

- **UNIQUE PATIENT IDENTIFICATION BAR CODE**
  Each biopsy kit features a unique patient identification bar code that is applied to the requisition and all kit components. This helps reduce SPCs that can occur during the collection, handling, and processing of biopsy tissues.

- **FORENSIC CHAIN OF CUSTODY PRINCIPLES**
  The know error® system incorporates forensic chain of custody principles, providing a strict means of control and documentation for the handling of samples.

- **DNA SPECIMEN PROVENANCE ASSIGNMENT (DSPA) TESTING**
  Through the use of microsatellite analysis, DNA Specimen Provenance Assignment (DSPA) testing virtually eliminates diagnostic mistakes due to SPCs by verifying the patient’s identity at the molecular level.

- **DETAILED DSPA REPORT**
  Once the DNA test is complete, an electronic report—compatible with most EMR systems—is issued to summarize the findings. If a potential SPC is indicated, the appropriate parties are notified immediately to address the issue.
Core Features

• **Unique Patient Identification Bar Code**
  Each biopsy kit features a unique patient identification bar code that is applied to the requisition and all kit components. This helps reduce SPCs that can occur during the collection, handling and processing of biopsy tissues.

• **Forensic Chain of Custody**
  The **know error**® system incorporates forensic chain of custody protocols, providing a strict means of control and documentation for the handling of samples.

• **DNA Specimen Provenance Assignment (DSPA) Testing**
  Through the use of microsatellite analysis, DNA Specimen Provenance Assignment (DSPA) testing virtually eliminates diagnostic mistakes due to SPCs by verifying the patient’s identity at the molecular level.

• **Conclusive Report**
  Once the DNA test is complete, an electronic report—compatible with most EMR systems—is issued to summarize the findings. If a potential SPC is indicated, the appropriate parties are notified immediately to address the issue.

The Clinical Problem

The biopsy evaluation process requires nearly 20 steps and several medical professionals working in different locations. Each year, it plays a critical role in determining the diagnoses and corresponding treatments of millions of patients.

With such a complex process executed at a large scale, the risk of Specimen Provenance Complications (SPCs) is a serious concern for both physicians and patients. SPCs arise due to instances of specimen transposition, foreign cell contamination and patient misidentification that occur in clinical or anatomical pathology. If left undetected, they can lead to serious diagnostic mistakes and adverse patient outcomes.

The Innovative Solution

Through the use of bar coding, forensic principles and DNA matching, the **know error**® system brings new levels of diagnostic accuracy and patient safety to the biopsy evaluation process.

How It Works

The **know error**® system for prostate biopsies involves three simple steps and can be implemented with little disruption to the standard biopsy collection process.

1. **swab.** Before the biopsy procedure, a reference sample of DNA is taken by swabbing the inside of the patient’s cheek. The swab is then sent to an independent DNA lab.

2. **sample.** The patient’s biopsy tissue sample(s) are placed in bar-coded specimen containers from the biopsy kit and sent to the pathology lab for evaluation.

3. **dna match.** If the biopsy results come back positive for cancer (malignant), the DNA lab performs a DSPA test to compare the DNA profiles of the biopsy tissue and the reference sample. Concurrence of these profiles allows for absolute confirmation of patient identity.

With the **know error** system, you can proceed confidently with treatment recommendations based on the patient’s lab results.
The know error® system for prostate biopsies contains all the necessary components to collect biopsy samples with the added benefit of confirming that the specimens being evaluated belong to the patient being diagnosed. It can be easily integrated within any pathology lab. All standard prostate biopsy kits contain the items pictured below.

DSPA Report
A DNA Specimen Provenance Assignment (DSPA) report is issued for each patient to summarize the test results. A Know Error representative will contact the appropriate parties immediately if a complication is detected.