

Be DNA Certain™
The know error® system

Information for Pathology



know error®



The Clinical Problem

The diagnostic testing cycle for cancer involves several medical professionals and nearly 20 complex steps, some of which are beyond your control as a pathologist. While your laboratory is closely regulated to comply with rigorous industry standards established by CAP and CLIA, other aspects of the process are not subject to the same quality controls and often lack standardized protocols to help ensure accuracy. If an undetected specimen transposition or contamination occurs prior to entering your lab, there is a risk of misdiagnosing your patient. When this happens, the patient with the false-positive diagnosis could receive unnecessary treatment, while the patient with the false-negative diagnosis would not receive the care she needs in a timely manner.

The Innovative Solution

According to federal regulations, a pathologist's responsibility for specimen integrity does not necessarily begin when a specimen is received at the lab.¹ **Expand your scope of quality control to all stages of the diagnostic testing cycle with the know error® system.** Available for a variety of specimen types, the **know error® system** uses bar coding, forensic principles and DNA matching to confirm that surgical biopsy samples being evaluated belong exclusively to the patient being diagnosed, arming clinicians with the critical information they need to proceed confidently with treatment recommendations.

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 prevent errors 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 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 biopsy misidentification by verifying patient 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 an error is detected, the appropriate parties are notified immediately to address the issue.

¹CFR §493.1232 Standard: Specimen identification and integrity. The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.



How It Works



swab.

Before the biopsy procedure (at treating physician's office), 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 laboratory.



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.



dna match.

If the biopsy results come back positive for cancer (malignant), the DNA lab performs a DNA Specimen Provenance Assignment (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.



Pathology Lab Components

The Pathology Laboratory's Role

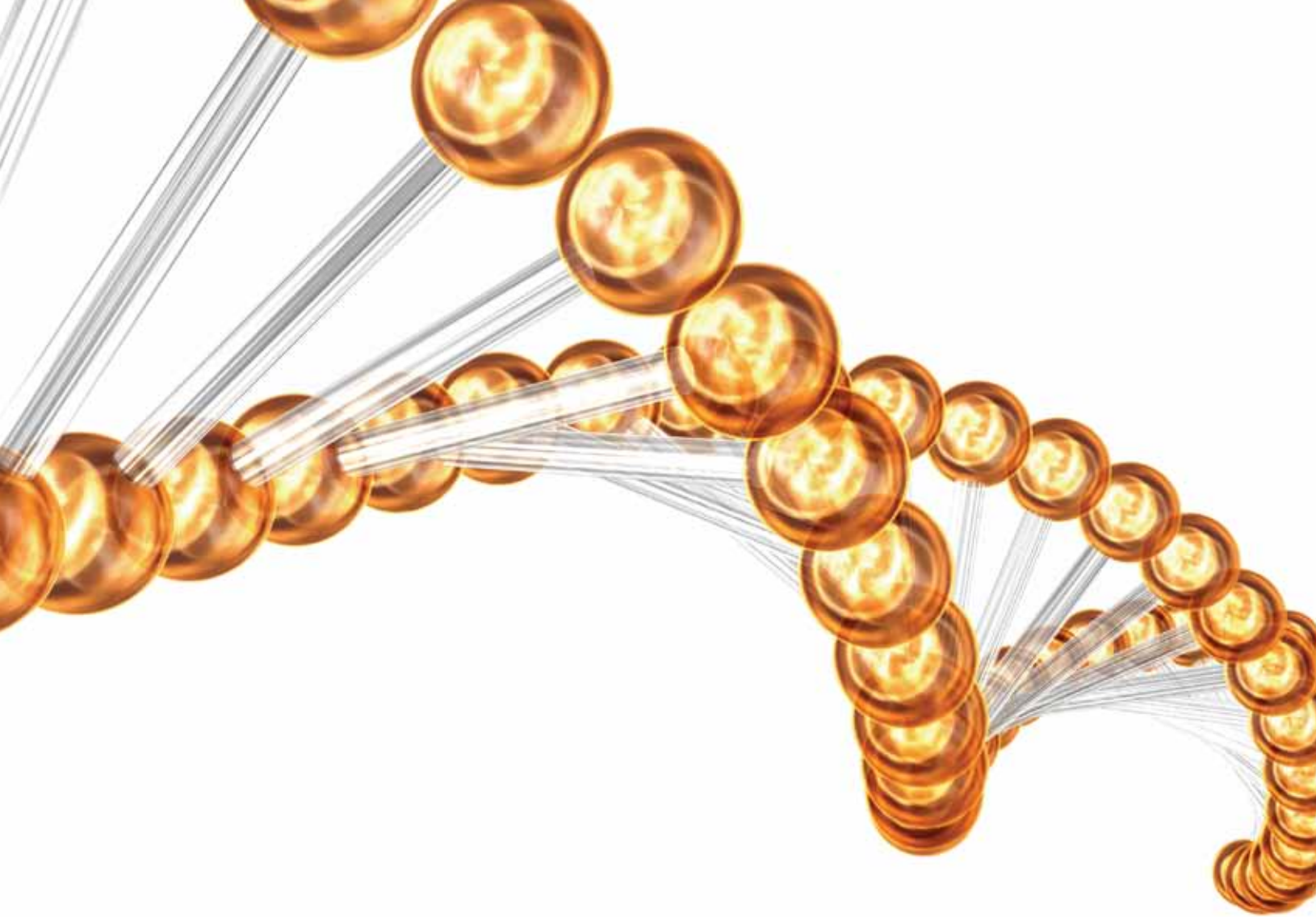
The DNA Specimen Provenance Assignment (DSPA) testing available through the **know error® system** is generally ordered by the treating physician. This send-out testing requires minimal disruption to your standard laboratory process.

Your role in implementation will simply be to oversee cutting and sending of the appropriate tissue scrolls for DSPA testing.

When a positive diagnosis is rendered, two 4-micron slices should be cut from the appropriate paraffin block(s) and sent to the DNA lab using the supplied transport vials. In some cases, unstained slides may be sent instead.

DSPA Testing Description

DNA is isolated from the reference sample (cheek swab) and positive specimen(s), and STR profiles are assessed across a multiplex panel of 16 genetic markers via PCR amplification and capillary gel electrophoresis. The loci consist of short, repetitive sequence elements of 20 to 300 base pairs in length which are highly polymorphic among the human population and provide predictive value in excess of 99.9%. The genotype of each positive specimen is compared with that of the reference sample to confirm specimen provenance. Concordant genotypes verify that the two samples are derived from the same patient, whereas differences in genotype may suggest that a transposition or contamination of specimens among patients has occurred.



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For more information about the **know error® system**, please visit:

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