



Use of the Know Error® System Prevents Two Patients from Having Incorrect Treatments

BACKGROUND

A large urology group practice uses the **know error®** system (which includes DNA Specimen Provenance Assignment “DSPA” testing) as **part of routine clinical practice** to identify otherwise occult (hidden) specimen provenance errors which can lead to patient harm.



SUMMARY:

Buccal swabs (included in the know error collection kit) were received by Strand Diagnostics for two patients, Patient A & Patient B. Both had prostate biopsies at the same practice, on the same day whereby the **know error®** biopsy kits and protocol were utilized. Pursuant to the practice’s protocol, tissue samples for Patient A, who was putatively diagnosed with cancer, were sent to Strand Diagnostics for DSPA testing. When Strand Diagnostics accessioned the tissues for Patient A it was noted that, though the patient names matched, the barcode on the tissues did not match the bar code on the buccal swab.

Due to this discrepancy, DSPA testing was not performed and the client was immediately notified. The practice believed the tissues were indeed those of Patient A and instructed Strand Diagnostics to test “name to name” (i.e. ignore the bar codes). **The DSPA test resulted in a complete DNA non-match.** Strand Diagnostics recommended that Patient A be re-swabbed and that new tissues be cut from the blocks labeled for Patient A. It was also suggested to submit the tissues for Patient B in an attempt to confirm the provenance of Patient B’s tissues (even though Patient B was diagnosed as “negative for cancer”).

RESULTS:

The second round of DSPA testing on Patient A ALSO resulted in a complete DNA non-match. The DNA from both of the buccal swabs from Patient A DID match each other suggesting that it was the tissues that were mislabeled. Further, it was confirmed that the buccal for Patient B as compared to the tissues labeled for Patient B was also a complete DNA non-match. Further analysis proved that the tissues labeled for Patient A actually belonged to Patient B and vice versa. The original pathology reports for the patients were the reciprocal and had to be revised to show the correct diagnosis for each patient.

CONCLUSIONS:

In a timely fashion (a 4 day turn-around-time for the initial report), Strand Diagnostics’ **know error®** system was able to prevent a mislabeled (false-positive) cancer-free patient from having unnecessary prostate surgery and likewise a mislabeled (false-negative) cancer patient from going untreated. Without the use of the **know error®** system and DSPA testing, the error might not have been found until after radical prostatectomy; and an undetermined length of time might have passed before treatment of the patient with cancer. This client continues to use the **know error®** system as part of their routine clinical practice providing their physicians with increased diagnostic accuracy and their patients with the highest level of safety.