

Prostate Cancer Misdiagnosis Identified by DNA Specimen Provenance Assignment Testing

BACKGROUND

This case involves the misdiagnosis of two prostate biopsy patients due to a specimen switching error. When Patient A's two positive prostate tissue samples were received for testing, it was discovered that neither sample matched the patient's DNA reference sample (collected via cheek swab at the time of his biopsy procedure) indicating that the tissues did not actually come from Patient A.



MATERIALS AND METHODS:

After the non-match report was issued for Patient A, samples were recut from the same block of cancerous paraffin-embedded tissue and submitted to Strand Diagnostics for retesting. The results of this second test were consistent with the original findings indicating a non-match.

Patient B was biopsied at the surgical center on the same day as Patient A and received a negative diagnosis. Tissues from the block used to render Patient B's diagnosis were cut and submitted to Strand for comparison with his reference sample, which also resulted in a DNA non-match.

Patient A's DNA reference sample was a match for the tissues submitted for Patient B, suggesting that a biopsy sample switch had occurred. New DNA reference samples were then collected for both patients, as well as additional tissues samples for final verification.

RESULTS:

DNA profiles obtained from the new buccal swabs matched those obtained from the original buccal swabs for each patient. It was then confirmed that the tissues in the block originally submitted for Patient A were a

match for Patient B and vice versa. Therefore, it was concluded that these patients' blocks were switched (evidently during the biopsy evaluation process), and thus the diagnosis of cancer ascribed to Patient A was actually meant for Patient B.

This biopsy testing process with these two patients involved multiple steps and processes (which is standard practice). For example: the DNA reference sample and biopsy samples were collected at the surgical center; the tissues were then sent to one lab to be cut; and then transferred to another for the pathology reading. Thus it is difficult to pinpoint the exact location where the error occurred.

CONCLUSIONS:

Through the use of the **know error® system**, this sample misidentification error was detected prior to any unnecessary treatment taking place for Patient A. DNA Specimen Provenance Assignment (DSPA) testing allowed the appropriate diagnosis to be assigned to each patient. Patient B was notified of his cancer diagnosis and proceeded with the recommended treatment.