know error®

Incidence of Errors in the Diagnostic Testing Cycle

As a pathologist, you are dedicated to maintaining meticulous operating protocols to ensure your laboratory produces accurate results. However, Specimen Provenance Complications (SPCs)[1] occurring within those steps of the diagnostic testing cycle taking place outside of your controlled lab environment can undermine your investment in quality processes and pose serious patient safety and medical-legal risks.

A recent study[2] conducted by researchers at Washington University School of Medicine in St. Louis examined the rate of occult SPC occurrence through prospective analysis of approximately 13,000 prostate biopsies performed as part of routine clinical practice. A variety of settings were evaluated, including physician-owned labs, independent reference labs, hospital labs, third-party managed labs and environments where the technical and professional components were split. Each patient in the study cohort had been putatively diagnosed with cancer by a pathologist with no indication of a Specimen Provenance Complication. All specimens were collected using the **know error® system**, and therefore benefited from the forensic chain of custody principles and patient-specific bar codes designed to reduce errors. Nonetheless, DNA Specimen Provenance Assignment (DSPA) testing results confirmed the presence of occult SPCs characterized as either a **Type I Error** (complete transposition of specimens between patients) or **Type II Error** (contamination of the patient's tissue with one or more unrelated patients). The study's key findings and clinical implications are summarized below:

	Type I Error: Specimen Transposition	Type II Error: Specimen Contamination
Mean Incidence of Occult SPCs Among Positively Diagnosed Patients	**0.26%** among all lab types Type I Errors have **no statistical correlation to clinical setting,** and no particular setting type is immune from the problem.	**0.72%** among physician-owned labs **3.14%** among independent reference labs Type II Errors are **highly correlated to clinical setting**, implying that higher volume labs (with more specimens in simultaneous circulation) experience higher rates of contamination.
Clinical Significance	The patient with the false-positive diagnosis could receive unnecessary treatment (radiation, chemotherapy, surgical procedures, etc.), while the patient with the false-negative diagnosis would not receive timely access to potentially life-saving care.	If unidentified foreign cells are known to exist in the tissue block, the provenance of specific cells on which the diagnosis was made cannot be verified without micro-dissection and repeat DSPA testing. Although some "floaters" are obvious and can be excluded from the diagnosis by the pathologist, studies suggest that: **[a]** fewer than 21% of foreign cell contaminations are prospectively identified, **[b]** extraneous tissue is located near diagnostic tissue in nearly 60% of contaminated specimens, and **[c]** the degree of diagnostic difficulty caused by extraneous tissue is severe in 0.4% of slides overall.[3]
Potential Causes of SPCs	• Incorrect registration of patient during biopsy procedure • Misidentification of patient on pathology requisition • Mismatch of requisition and specimen jars in physician office • Mislabeling of cassettes, blocks or slides in pathology lab	• Improper specimen handling procedures in surgical suite • Combination of tissues at microtome blade, water bath or cassette processor

1 Complete transposition of a biopsy sample between patients or a contamination of one patient's tissue with another
2 Pfeifer JD, Liu J. Rate of occult specimen provenance complications in routine clinical practice. *Am J Clin Path.* 2013;139(1):93-100.
3 Gephardt GN, Zarbo RJ. Extraneous tissue in surgical pathology: a College of American Pathologists Q-Probes study of 275 laboratories. *Arch Pathol Lab Med.* 1996;120:1009-1014.

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