Histology Lab Stainer
Bath Contamination

Know the risks, see our solution
Histology lab risk is a real issue for healthcare providers and patients

Anatomical pathology (AP) labs can be a source of serious patient identification errors and risk, as high test volumes and manual processes create opportunities for sample misidentification, stainer bath cross contamination, and even false diagnoses.

As risk mitigation concerns take centre stage in the media, regulatory agencies, and our minds – we invite you to:

• Examine the evidence
• Learn the risks
• Explore the solutions that can help you immediately, and minimise risk in your lab

“Errors in the lab can be fatal. Anything that controls the process and removes the hands-on component is incredibly important.”

—BRENDA SMITH, RISK MANAGER, SELF REGIONAL HEALTH CARE, GREENWOOD, SC
What happens in a dip-and-dunk stainer bath?

Evidence suggests that as patient slides progress through the successive dip-and-dunk stainer baths, tissue fragments separate and float freely in the reagent baths. In addition to the possibility of false negative diagnosis caused by loss of diagnostic tissue, the fragments can float to adjacent samples, creating the possibility for a false positive diagnosis. This possibility is most elevated when malignant fragments float to adjacent slides containing the same tissue type.

**Tissue cross-contamination**

- Xylene-Deparaffinization
- 100% Alcohol
- 95% Alcohol
Examine the growing bank of evidence

Tissue cross contamination in the H&E linear stainer proves to be a significant risk for labs worldwide
Evidence 1: Extraneous Tissue in Surgical Pathology

PEER REVIEWED PUBLICATION
A College of American Pathologists Q-probes Study of 275 Laboratories
Gordon N. Gephardt, MD, Richard J. Zarbo, MD, DMD
(Arch Pathol Lab Med. 1996; Vol. 120)

• Study goal
  • To develop a multi-institutional reference database of extraneous tissue (contaminants) in surgical pathology microscopic slides

• Methods
  • 275 CAP Q-probes quality improvement program laboratories participated
  • Prospective and retrospective evaluations of extraneous tissue were performed over a 4 week period or until 1000 slides had been reviewed

• Conclusions
  • Study of extraneous tissue found in surgical pathology microscopic 275 labs
  • Of the slides reviewed retrospectively, 1,653 were found to contain extraneous tissue
  • Degree of diagnostic difficulty caused by the extraneous tissue was evaluated
    • Severe in 57 of slides reviewed retrospectively

“Even at an error rate of one in 1,000, the potential for patient harm is real. Our study certainly demonstrated that potential.”
Evidence 2: Tissue Floaters and Contaminants in the Histology Laboratory

PEER REVIEWED PUBLICATION
Eric Platt, BS; Paul Sommer; Linda McDonald, MT, ASCP; Ana Bennett, MD; Jennifer Hunt, MD
(Arch Pathol Lab Med. 2009;133:973–978)

- Recent increased attention to risks in the laboratory prompts study
  - Reduction of cross-contamination is an example of a patient identity issue for which process improvement exists

- Study goal
  - To assess for contaminants in water baths at cutting stations and in linear stainer baths
  - To assess tissue discohesion and carryover onto blank slides sent through the stainer

- Conclusions
  - Water bath contamination is very minimal in comparison to stainer bath; in the 13 water baths examined (195 litres of water), only 1 fragment of tissue was identified
  - Cross-contamination to blank slides at a rate of up to 25% in the late afternoon
  - Cross-contamination does occur on blank slides in the experimental setting

In the 13 water baths examined (195 litres of water), only 1 fragment of tissue was identified

Cross-contamination to blank slides occurred in the linear stainer baths at a rate of up to 25% in the late afternoon

“The potential for tissue contamination during the staining procedure may be much higher (relative to the water bath), because tissue is deparaffinised during the first steps in making an H&E stain”

—Jennifer Hunt, MD
(Arch Pathol Lab Med. 2009;133:973–978)
**Evidence 3: Ventana Stainer Bath Contamination Challenge results to date**

**GLOBAL, MULTI-CENTRE STUDY**

- **Study goal**
  - Measure stainer bath contamination and common mitigation strategies

- **Methods**
  - 80 sites volunteered for evaluating current process and instrumentation, all sites had contamination present
  - Evaluated contents of alcohol and xylene baths, based on the protocol developed in the Hunt study (Arch Pathol Lab Med. 2009;133:973-978)

- **Conclusions**
  - Blank patient simulator slide contamination – up to 36%
  - Stainer bath contaminants (only first xylene, 100% alcohol and 95% alcohol) – up to 3,018 fragments
  - Stainer bath contaminants tissue types in those baths – up to 18 different types
  - 100% of participating labs showed contamination in reagent baths

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80 sites participated globally, studies are ongoing

**36%**

- Up to 36% contamination on patient simulator slides
- Up to 3,018 contaminants in the xylene and alcohol baths
- Up to 18 tissue types in the xylene and alcohol baths

“A single misdiagnosis could be catastrophic to the patient and laboratory alike. For the patient, exposure to unnecessary treatment or a delay in the start of lifesaving therapy are both possible outcomes of a misdiagnosis. For the laboratory, such outcomes also pose the risk of expensive lawsuits.”

—JOHN B. CARPENTER, MD, PATHOLOGIST, PACIFIC PATHOLOGY PARTNERS SILVERDALE, WA
Evidence 4: Risk of misdiagnosis due to tissue contamination may be higher for certain tissue types

VENTANA SPONSORED WHITE PAPER
John B. Carpenter, MD,
Pacific Pathology Partners Silverdale, WA
The Dark Intelligence Group

Most contaminants, often called “floaters” by laboratory staff, are easily recognised as such. However, depending on the tissue being evaluated and the clinical circumstances, contamination can be problematic for the pathologist.

Biopsy from the lower oesophagus showing a fragment of gastric cardia-type mucosa (A) and several detached fragments of columnar mucosa with goblet cells (B). Adjacent tissue levels did not show the fragments of intestinal-type epithelium.

A diagnosis of Barrett’s oesophagus was initially rendered on the basis of this field, but later reconsidered given the possibility of slide contamination. The patient will be undergoing increased surveillance due to the appearance of this slide.

“Even when the pathologist is able to confirm that a suspected floater is really a contaminant, the additional analytical time and need for additional tissue sections decreases productivity of the entire lab.”

—JOHN B. CARPENTER, MD, PATHOLOGIST,
PACIFIC PATHOLOGY PARTNERS SILVERDALE, WA
Risk by the numbers

Surprising statistics on patient identification risks and improvements in Anatomical Pathology labs

1,653 slides in 275 labs contained tissue contaminants¹
57 slides presented severe diagnostic difficulty²
18 different contaminants found on slides³

Is a 99% quality rating a GOOD thing?
For a lab that processes 250,000 slides/year, 99% quality means:

275 errors/year

23 errors/month

6 errors/week

1 patient at risk every day for misdiagnosis

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¹ A College of American Pathologists Q-probes Study
² A College of American Pathologists Q-probes Study
³ Stainer Bath Challenge, 2009 to present
Discover the solution for lower-risk anatomical pathology lab processes
The fully integrated VENTANA solution

A global leader in tissue-based cancer diagnostics, Roche innovates fully integrated staining and workflow platforms that deliver total confidence in the AP lab’s ability to deliver the right patient results. The Roche integrated solution enables risk mitigation through positive patient ID, barcoded sample tracking, individual slide staining, exceptional test quality, and improved efficiency.

Better together

**H&E staining**
The SYMPHONY H&E staining platform stains every patient’s sample individually, protecting against tissue cross-contamination that can occur when slides are manually dipped and dunked into shared reagent baths. Automation, individual slide staining, sample barcoding, high-definition stains, and efficient test runs all work together to help labs deliver prompt, personalised patient results.

“Even in instances where the risk of misinterpretation is unlikely, loss of productivity as a result of contamination is a serious issue.”

—JOHN B. CARPENTER, MD, PATHOLOGIST,
PACIFIC PATHOLOGY PARTNERS SILVERDALE, WA

**Laboratory workflow management**
The VANTAGE workflow management system guides the anatomical pathology process along the right path with error-reducing touch-screen technology and real-time operations dashboards that empower lab managers to run safer, more efficient operations. The VANTAGE system tracks a single patient’s slide anywhere in the lab, at any time, for complete chain of custody – even during peak volumes.

“I like the VENTANA VANTAGE because slides are scanned throughout the process, so I feel more comfortable that the right tissue is on the right slide.”

—DR. PATRICK BOGARD, MD, PATHOLOGIST,
ALEGENT HEALTH OMAHA, NE
Learn more and read the publications cited online:

www.ventana.com/symphony/cc

Talk to your local Roche Diagnostics representative about solutions to protect against cross contamination and to run safer, more efficient operations in the AP lab.