Histological Workflow

1. Physician collects the specimens using (carefully cleaned) surgical tools.6

2. Tissue samples are placed into the (properly) labeled specimen containers.3,4,6

3. Physician reviews reports for Patient’s Personalized Therapy

4. Cassettes are divided among several tissue cassettes.3,6

5. Pathologist removes the specimens and examines and describes the tissue grossly.15

6. Pathologist micro-dissects tissue for analysis and DNA/RNA extraction for biomarker results.

Biomarker Testing

1. Biomarker test ordered on cancer tissue(s), retrieve block/slide(s).

2. The thin wax slices are floated in a water bath where other patients’ wax slices previously floated.2,3,5

3. They are delivered to the pathologist for evaluation.3,5

4. All of the slides are assembled with the accompanying paperwork.3,4

5. Test report delivered to physician for assessment of treatment plan.

6. Physician reviews reports for Patient’s Personalized Therapy

Complications within the Diagnostic Testing Cycle

1. The following articles provide evidence of errors in the various stages of the biopsy evaluation process.

2. Bronner MP. DNA fingerprint analysis for specimen identification. Clinical and Translational Pathology Research. Division of Pathology and Laboratory Medicine, Cleveland Clinic. 2006;Fall:5-7.


7. Ford A. With AP specimen identification, the hero is zero. CAP Today. 2007.
The patented know error system® protects the entire diagnostic process, including histological workflow and biomarker testing.

**Histological Workflow**

1. Physician collects the specimens using (carefully cleaned) surgical tools.
2. Tissue samples are placed into the (properly) labeled specimen containers.
3. Containers are transported to the pathology lab.
4. Specimens are accessioned into lab computer system.
5. Pathologist removes the specimens and examines and describes the tissue grossly.
6. Tissue is dissected by clean instruments that have also been used with other samples.
7. Specimens are divided among several tissue cassettes.
8. Specimen containers are batched with many others.
9. Cassettes are labeled with the surgical pathology number and a unique block number.
10. Pathologist micro-discects tissue for analysis and DNA/RNA extraction for biomarker results.
11. All of the slides are assembled with the accompanying paperwork.
12. Pathologist sends the slides to the pathologist for evaluation.
13. The thin wax slices are floated in a water bath where other patients’ wax slices previously floated.
14. Flattened slices are transferred onto a hand-labeled, glass slide.
15. Laser micro-discection technician affixes a computer-generated label to the slides.
16. Hundreds of patients’ cassettes are placed in a chemical bath.
17. Tech uses forceps to pick up wax-infused tissue and place it in the final wax tissue block.
18. Another tech sections 5 µm slices on a razor blade affixed to a microtome.
19. Specimens are divided among several tissue cassettes.
20. Specimens are assigned unique ID numbers.
21. Specimens are bar-coded.

**Biomarker Testing**

1. Biomarker test ordered on cancer tissue(s), retrieve block/slide(s).
2. Transporting and accessioning of slides to pathologist.
3. Test report delivered to physician for assessment of treatment plan.
4. They are delivered to the pathologist for evaluation.
5. All of the slides are assembled with the accompanying paperwork.
6. Another tech sections 5 µm slices on a razor blade affixed to a microtome.
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**Transportation**

1. Swab.
2. Sample.
3. DNA Match.

**Laboratory**

1. The know error® system compares the DNA profiles of the patient swab to the patient biopsy sample.

**Medical Office**

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3. Containers are transported to the pathology lab.
4. Specimens are accessioned into lab computer system.
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