Expanding Histopathology Services For North Shore-LIJ Researchers



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Introduction

In an effort to encourage collaboration, improve efficiency, and minimize costs, the Department of Pathology at North Shore-LIJ is aiming to create a laboratory that will specifically provide histology and pathology services to researchers within the health system. Currently, the Pathology Department provides a wide range of clinical, molecular and diagnostic services to the entire health system to meet clinical needs. In the upcoming year, the department would like to expand in its ability to provide histology and pathology interpretive services to researchers at the Feinstein Institute by dedicating a new laboratory space and staff to this purpose. The goals of this new histology laboratory will be to provide high quality services for basic and clinical research (including animal experiments) that minimizes cost to researchers, while giving the opportunity to take advantage of in-system pathology expertise. At present, most investigators at Feinstein use external laboratories for histology. By bringing the work to an internal laboratory, the Department of Pathology hopes to achieve the following:

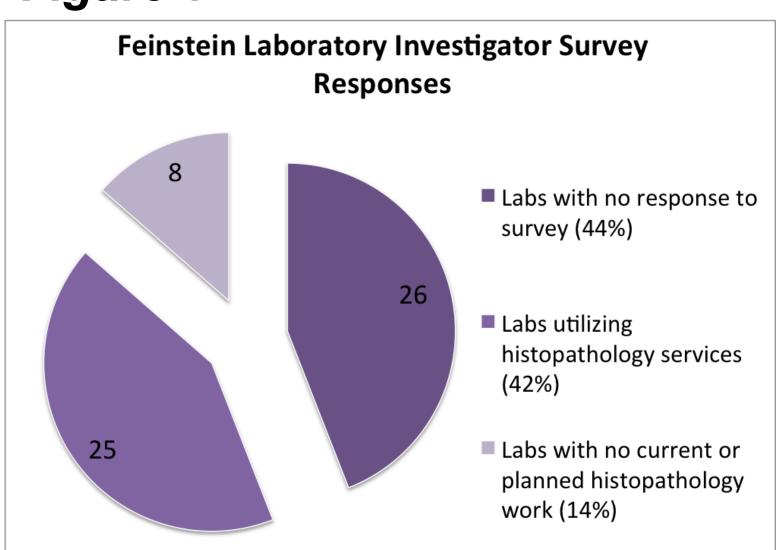
- Standardization of the specimen submission process
- Direct communication with histotechnologists and pathologists
- Competitive fee schedule/pricing list and rapid processing of requests
- Decreased shipping costs and minimal shipping risk by taking advantage of the existing Core Lab courier service offered by the department
- Scientific collaboration with in-house pathologists interested in expanding their research contribution
- Revenue grossed by laboratory work remains within the NS-LIJ Health System

In order to develop this research histology laboratory, several factors needed to be elucidated. First, the current utilization of histology services by the Feinstein institute had to be examined in order to estimate the scope of work that would be coming into the new lab. Because each investigator uses different histology service providers, accurate information would be impossible to obtain without contacting each laboratory at Feinstein. Secondly, the cost of pathology work performed by external histology laboratories had to be estimated for various types of projects. This data will help ensure that the new lab implements a competitive fee schedule and retains the Feinstein investigators as clients.

Survey Results

In order to determine the current and projected demand for histopathology services in the new laboratory, an email-based survey was developed to quantify the types of services currently requested by Feinstein researchers. The survey was sent to all principal investigators at the Feinstein Institute in July 2012 and responses were collected over several weeks. Out of a total of 59 laboratories, the survey assessed the number of laboratories that engage in at least some pathology work, as shown in Figure 1. In addition, the survey helped to determine the services that are utilized most often so that priority is given to setting up the equipment, supplies and staff for those services, as displayed in Figure 2.

Figure 1

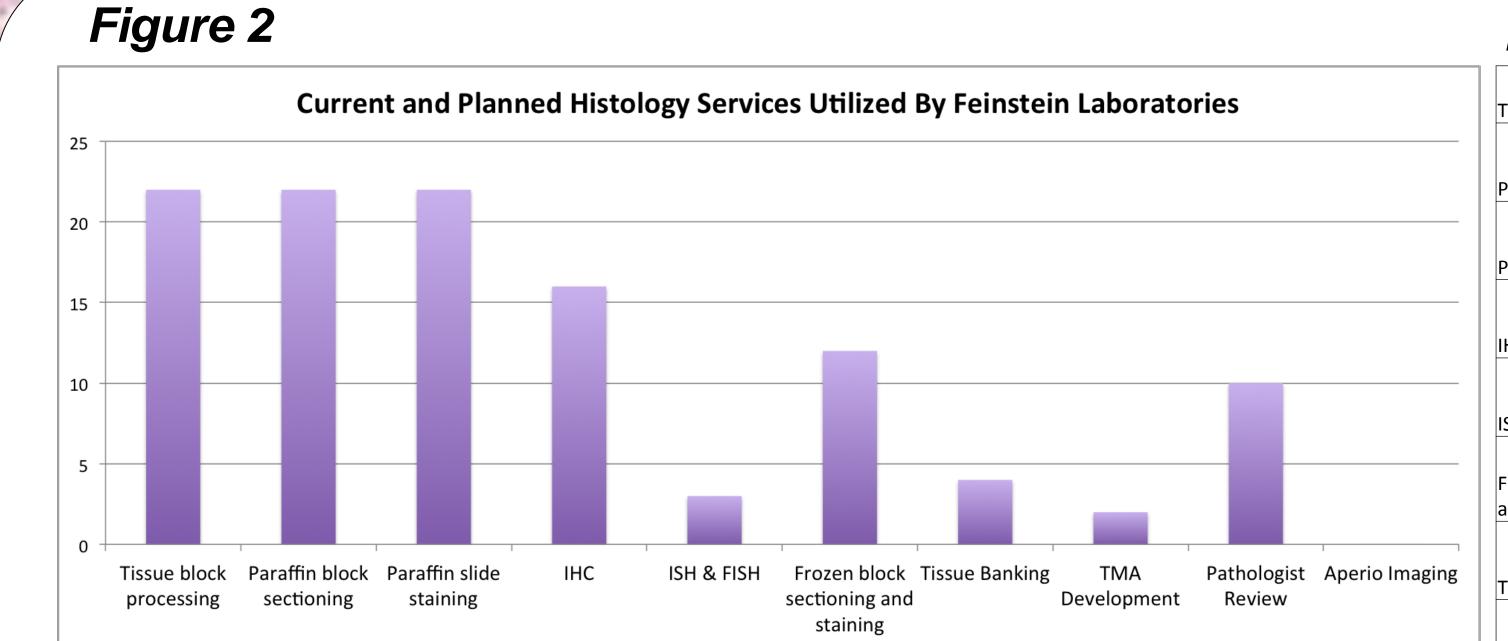


Services most in demand by researchers include tissue block processing and paraffin embedding, paraffin slide sectioning and staining, and immunohistochemistry. Few investigators reported the need for in-situ hybridization and tissue microarray development, so it was determined that building the infrastructure to perform these techniques can be delayed until the more basic services are established.

The next step in development of the histology laboratory was to estimate the incoming volume of specimens and develop a working budget based on projected revenue. Many investigators were interviewed in order to establish a baseline number of samples sent per year for histology services. Each laboratory varies in its histology sample numbers year to year based on the quantity and nature of experiments performed. In order to account for this variability, an average of these estimates from several Feinstein labs was determined as shown in Table 2.

A fee schedule, or pricing list for services, was developed by comparing several external histology laboratories currently used by Feinstein investigators (Table 1). These include AML Labs, Albert Einstein Histotechnology Facility, NCI Cooperative Human Tissue Network, and University of Floriday Molecular Pathology Core. The cost of supplies and labor for each process were also taken into account.

Based on these estimations of sample numbers and the price of each service, the revenue per month for the new research histology lab would be between \$8,600 and \$11,350, if all Feinstein business was captured.



Definitions

Fresh tissue specimens are fixed in formalin, dehydrated and embedded in paraffil that cuts 4-6um thick tissue slices that are adhered Paraffin block sectioning to glass slides Paraffin sections on glass slides are stained with various reagents (i.e.. hematoxylin and eosin) for imunohistochemistry is the use of antibodies or antisera to identify patterns of antigen distributior n situ hybridization or fluorescent in situ acid sequences with specifically developed probe that can then be stained without requiring fixation Standardized collection and storage of frozen or ixed tissue and clinical data to be used for future Tissue microarrays incorporate cores from multiple ssues into a single block or section to be analyzed perio imaging system provides high resolution

Conclusion

Several factors need to be considered moving forward with the research histopathology laboratory.

- First, because this laboratory will be handling research specimens only, government certification is not required. However, in order to support research which might undergo FDA review, the department may want to strive for Good Laboratory Practices (GLP) certification.
- Development of an accessioning system should be considered for incoming specimens, in order to have the highest standards for specimen tracking and to reduce the likelihood of error. This will be especially important if specimens are stored on site for any period of time or if the laboratory begins to expand its services to include tissue banking.
- Advertising the new laboratory's capabilities will be essential in the coming months in order to attract clients at Feinstein. Laboratory space and some of the most costly equipment has already been dedicated to the new histopathology laboratory. The success of this project will depend on identifying highly skilled clinical histotechnologists who can provide high quality results and the willingness of department pathologists to participate in these studies.

Table 1. Basic Fee Schedule

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Cross Discostion (into acceptant)	¢ (
Gross Dissection (into cassettes)	\$6.50	per specimen
Processing and Embedding	\$5.50	per cassette
Unstained Paraffin Slide	\$2.00	per slide
Unstained Paraffin Slide for DNA/RNA extraction	\$3.00	per slide
H&E Stained Paraffin Slide	\$4.00	per slide
Unstained Frozen Slide (1st slide)	\$10.00	per first slide
Unstained Frozen Slide (serial)	\$5.00	per following slide
H&E Stained Frozen Slide	\$12.00	per slide
Special Stain (Level 1*)	\$10.00	per slide
Special Stain (Level 2**)	\$15.00	per slide
Immunohistochemistry	\$30.00	per slide
Multiple sections per slide (paraffin)	\$0.75	additional per slide
Multiple sections per slide (frozen)	\$2.00	additional per slide

*Level 1 Stain: Giemsa, Periodic acid-Schiff, Masson's Trichrome, Oil Red O, Congo Red, Prussian Blue, AFB, Alcian Blue, Verhoeff's, Colloidal Iron, Gram **Level 2 Stain: Various silver stains
Pathologist review will be provided by request if a pathologist is not currently

Table 2. Projected Budget Estimation

	Tissue block dissection, processing & paraffin embedding	FFPE sectioning	FFPE staining (H&E and special stains)	IHC	ISH & FISH	Frozen block sectioning and staining
Number of labs using each service	22	22	22	16	3	12
Sample number by service per year from each lab	250	250	100	100	20	20
Total samples utilized by all labs by service	5500	5500	2200	1600	60	240
Total samples utilized by labs by service per month	458	458	183	133	5	20
Average cost per sample	\$6 - \$12	\$2	\$4	\$30	TBD	\$10
Total revenue per month	\$2750 - \$5,500	\$917	\$733	\$4,000	TBD	\$200

*Cost of tissue block dissection, processing and paraffin embedding is a range between six and twelve dollars per sample based on the complexity of request and extent of dissection required.

Cost of in-situ hybridization services will be determined on a case to case basis.

Acknowledgements:

associated with the study. Rates may vary by scope of work.

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