

## Use of Digital Pathology to Drive Revenue to Labs

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Received: August 12, 2019; Accepted: August 21, 2019; Published: August 28, 2019

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### Abstract

This paper presents the practical use of digital pathology (DP) as a tool to drive revenue. A regional dermatopathology laboratory developed and patented a digital pathology software system called Clearpath™ featuring a touch-enabled viewer that allows dermatologists to read digital slides remotely and generate pathology reports on their own patients. The laboratory realized over \$1M in additional revenue in less than a year primarily through the technical component (TC) slide processing of referred skin biopsies. Additionally, the lab benefited from “pull-through” requests for consults and global reads. Now with the introduction of Artificial Intelligence (AI) algorithms applied to image analysis, laboratories implementing digital pathology systems will realize even greater return on investment of this technology.

**Keywords:** Digital pathology; Laboratory revenue; Dermatopathology; TC/PC model

### Introduction

To date, the primary value proposition of digital pathology systems in clinical laboratories has centered on efficiencies. Efficiencies in digital pathology include error reduction, turnaround time improvement, flexibility in slide sharing, and digital storage of archived specimens. Expenses related to the implementation of a digital pathology laboratory are often cited as the cost of doing business. With the recent advancement of FDA approved scanning systems for use in primary diagnosis, the use cases for digital pathology are growing and the metrics to substantiate their purchase are becoming evident. However, there has been little attention focused on how digital pathology can increase the top line revenue for the laboratory. This is the case of a large midwestern dermatopathology laboratory utilizing the tools of digital pathology to increase slide referrals and revenue, while providing dermatologists an efficient means to read their own patient's slides.

### Objectives

Provide dermatologists an efficient workflow solution to remotely read their own patient's biopsies using the advantage of digital pathology. Note that dermatologists are trained in residency to interpret dermatopathology slides and are allowed to diagnose cases under Clinical Laboratory Improvement Amendments (CLIA) guidelines at a CLIA approved location [1].

Improve laboratory revenue by increasing the number of referral skin biopsies for technical slide processing, special stains and immunohistochemistry (IHC) orders, increased numbers of second opinion consultation requests, and requests for full global reads for complex cases and vacation coverage.

### Methods

Clearpath™ laboratory information software developed over a 2-year period with input and beta testing by laboratory dermatopathologists and selected referring dermatologists.

Laboratory dermatopathologists publish results of largest dermatology specific validation study (499 cases) showing equivalency between Whole Slide Imaging (WSI) diagnoses and traditional glass slide reads [2].

Interested new client dermatologists buy Clearpath™ software license and independently purchase recommended tablet for viewing images (Apple's Ipad Pro most popular). Client dermatologists are provided instructions for WSI validation following the latest guidelines from the College of American Pathologists (CAP) for reading WSI for primary diagnosis [3].

Referring dermatologists send skin biopsies to lab for technical component (TC) slide processing followed by generation of 20X or 40X magnification WSI scan. WSI is immediately available to remote dermatologists via the Clearpath™ viewer. Glass slides are also sent back to the referring physicians for confirmation as part of recommended protocol.

Referring dermatologists have 24/7 secure access to their own slide images on the Clearpath™ server and a workflow-efficient solution literally held in their hands. Clearpath™ software allows image rotation, zooming, lesion measurement, and reporting of diagnosis by means of a touch-enabled screen. Special stains, IHC and second opinions can be ordered from the tablet and the physician can share the diagnosis with the patient while showing the digital slide image in the exam room.

The laboratory bills for the TC component and the referring dermatologist bills for the PC component. Additional requested stains and consultations are billed by the provider of the service, most often the laboratory.

## Results

The Table 1 below shows the revenue and related expenses associated with the digital TC/PC model resulting in an additional \$1M of lab revenue within the first year of launching the program. The revenue represents a blend of TC billed, additional stains ordered, and some global and consulting requests. Fixed expenses for the slide scanner and annual maintenance, and addition of two FTE for IT support and customer service are not included in the analysis. As slide referrals increase, the economies of scale dramatically impact both the fixed and some variable costs. In addition, as more WSI systems are FDA approved for primary diagnosis, shipping costs associated with slides sent back for confirmation will be eliminated. Shipping costs currently represent almost 18% of the total variable cost.

Variable expense	\$ Cost/slide	Revenue/slide	Gross margin
Technical prep	\$8.57		
Logistics/shipping	\$4.28		
Billing	\$0.78		
Sales	\$0.97		
Scanning	\$0.5		
Other	\$1.75		
Total	\$16.85	\$26-\$32*	35%-47%

**Table 1:** The revenue and related expenses associated with the digital TC/PC model. \*Based on blended rate of global and TC reimbursement codes.

## Discussion

Laboratories are in a unique position to gain significant revenue in the digital TC slide market. Digital pathology provides laboratories the ability to centralize operations to further decrease slide production costs as digital slides are stored on servers and accessed from anywhere, anytime.

This laboratory was successful in recruiting dermatologists who were typical early adopters, education-oriented, rural or remotely located, or tech savvy physicians seeking to integrate more parts of their practice. While many were looking to make extra income through reading their own slides, the majority expressed control of their cases and turnaround time (TAT) as the primary motivator. As digital pathology gains acceptance in the industry with more systems approved for primary diagnosis, the number of physicians reading their own slides will likely increase significantly.

With the number of validation studies showing equivalence of WSI to glass slides, along with the recent FDA clearances of two whole slide scanning devices for primary diagnosis (Phillips Intellisite Pathology Solution (PIPS) in April 2017 and Leica's Aperio AT2 DX in May 2019) [4,5], followed by the rush of FDA submissions from numerous slide scanner manufacturers, physician acceptance that WSI is equal to glass slides is certain.

Implementation barriers for laboratories interested in moving into digital pathology services include the upfront capital and integration into their existing laboratory information system (LIS). However, the revenue potential in acquiring new clients as TC/PC or simply from

expansion using remote pathologists will quickly offset these costs. In addition, the introduction of AI specific workflow tools for assisted diagnosis in pathology will also improve efficiencies in both the upfront slide tray creation for pathologists as well as the diagnostic accuracy of end users. On June 19, 2019, the first specific AI application for dermatology was introduced by Proscia, Inc., as a tool to improve efficiency and quality in the dermatopathology lab [6-8].

## Conclusion

Digital pathology provides a number of benefits to the medical community. We present a revenue-generating opportunity for the forward-thinking laboratory and referring physicians eager to utilize digital pathology to gain value in terms of ease of use, improvement of turnaround, access to specialists for difficult cases, ability to engage the patient in viewing slides, as well as the realization of additional revenue potential by both the laboratory in performing the Technical Component (TC) and the physician performing the Professional Component (PC). Certain TC/PC specialties make sense for digital pathology applications including dermatology, gastroenterology, urological pathology, gynecologic pathology, and general pathology.

The future of digital pathology is now. Artificial intelligence and machine learning algorithms are directing the creation of computer-aided diagnosis applications to support pathologists. With this digital transformation comes the expanded use of CPT codes 88360 and 88361 along with potential new insurance billing codes. Biorepositories are being created for pharmaceutical research and enhanced medical knowledge. The first step in digitizing glass slides for diagnosis represents the tip of the iceberg and those who see the value of this technology will be at the head of the line as the opportunities abound.

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