QUALITY MANAGEMENT (QM) PROGRAM
Laboratory of Pathology: 2017

Purpose:

The Quality Management (QM) program is designed to continually evaluate the quality of clinical services generated throughout the Laboratory of Pathology (LP). This is accomplished by: monitoring and evaluating quality improvement indicators for the LP; ensuring continuous compliance with quality control and preventative maintenance policies by LP sections; addressing quality outliers and incident reports (addressing system issues); and ensuring all LP Clinical Sections are in compliance with the College of American Pathologists (CAP) standards and guidelines to ensure compliance with the Clinical Laboratory Improvement Amendments (CLIA-88) statutes that govern clinical laboratory medicine. The LP QM Committee oversees the program.

General Requirements

The QM program is an LP-wide initiative and quality indicators and reports cover all clinical areas. According to the College of American Pathologists, LabGEN Checklist, v. 8/17/2016, the laboratory must have a written quality management program to systematically ensure the quality of laboratory services. In laboratories that are part of a larger institution (e.g. a hospital), the laboratory quality management program must be integrated with the institutional program. In accordance with the CAP standards, GEN.13806, GEN.20100, GEN.20208, and GEN.20316, the laboratory has a written quality management program that covers the extent of all clinical services and establishes policies and procedures to identify and evaluate errors or issues that may interfere with patient care, and the QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.

A list of indicators is provided below. Some clinical sections can opt to devise additional QI plans to monitor and document a set of relevant indicators based on their section's regulatory standards (e.g. CAP standards for turnaround times). Indicators for individual sections' quality reports should include pre-analytical, analytical, and post-analytical variables.

QM Plan Overview

- All clinical sections are given the opportunity to report their section specific quality plans and subsequent end-of-year reports to QM Committee to share quality initiatives across clinical sections.

- In addition to the annual report for these sections, General Anatomic Pathology (AP): Autopsy and Histology Laboratory's QA Sheets, and LP and the Clinical Center's Environment of Care will be reviewed during each QM Committee meeting.

  (Histology is the primary clinical processing laboratory, therefore monthly monitoring of quality issues are important to report to QM committee).

– Improve identification, communication, and correction of errors in a timely manner. Specific criteria approved by QM Committee require that all sections establish and define any incidents/complaints to address, monitor and report to QM Committee on a monthly basis. The objective is to identify and resolve consistent or recurrent complaints or incidents that affect all LP clinical laboratories. Action items will be addressed by the QM Committee.

- The QM program must include a process to identify and evaluate errors, incidents and other problems that may interfere with patient care services (GEN.20208). LP staff have several mechanisms to identify and report any quality issues or concerns: a) LP currently participates in the Clinical Center's Occurrence Reporting System (ORS), which is a mechanism to report hospital-related incidents to Clinical Center clinicians, nurses, and allied health professionals; b) LP's internal Incident Reports, where LP staff reports internal and/or external quality concerns to the QM committee or Clinical Manager; and c) the Clinical Center has adopted a 'Morning Huddle' at 08:20 each weekday morning, which is attended by each clinical department, nursing units representatives, and support services representatives and is a forum for any healthcare professional to report on concerns that may benefit from other hospital departments.

Method of Implementation

The LP QM program will be devised and monitored by the QM committee. Indicators to be monitored and reported include: pre-analytical (number of cases without requisitions), analytical (turnaround time for SI and SB cases), and post-analytical (number of revised reports). Detailed specifications for the LP QM program and AP QI plan are listed below. The QM committee recommends that each laboratory/ section/ unit devise and monitor quality indicators specific to their discipline. The section's QM plan should improve patient safety and the quality of services provided by LP. Although a formal written and verbal report will not be required, updates on individual efforts to improve patient safety and quality of services will be requested by the QM committee.

The QM committee will monitor the process related to patient safety (CAP and JCAHO Laboratory Patient Safety Goals) on an annual basis. The committee will utilize several parameters in this process including the annual QM reports from the required LP laboratories/units/sections; outcomes of events reported to the QM committee via QI tracker/QI log or directly to either the QM committee chair or Clinical Lab Manager; participation of QM committee chair in the Surgical Administrative Committee (SAC); and reporting of relevant LP QM findings to Clinical Center/NIH office(s) involved in patient care and safety.

The QM committee will monitor the process related to occupational injury/illness in the LP at least on a quarterly basis. Each Unit/Section/Laboratory will submit all OMS reports to the Clinical Laboratory Manager. The OMS reports must not contain any personal identifiers. The OMS reports will be reviewed by the Clinical Laboratory Manager and reported to the QM committee to identify any common issues that could potentially impact other LP Units/Sections/Laboratories.

General Requirements of the QM Committee

The QM Committee will meet to review the effectiveness of the QM program and to follow-up on any corrective actions taken. Minutes of each QM Committee review will be generated to document the effectiveness of the QM program and to include any recommendations made to improve the QM program. However, overall review and approval of the QM program is the responsibility of the Laboratory of Pathology's Medical Director.

The QM Committee will include: (1) the Chief or Deputy Branch Chief of the Laboratory of Pathology; (2) the QM Committee Chairman (a physician representative), (3) the Clinical Manager, (4) the LIS Administrator, (5) a representative from each LP laboratory/unit/section, and (6) members of the AP residency and clinical fellowship programs.

All pathology residents onsite are expected to attend QM committee meetings for the purpose of providing educational experience and an opportunity to contribute to the ongoing improvement efforts of the QM committee. Hematopathology and Cytopathology fellows will attend the QM committee meetings as "guests" with the purpose of providing an educational experience with issues related to quality assurance, quality improvement and quality management.

PROCEDURE FOR IMPLEMENTATION OF QM PROGRAM
Laboratory of Pathology: 2017

Defined Laboratory/Unit/Section Head:

Medical Director – Frederic Barr
Autopsy - David Kleiner
Chromosome Pathology Unit – Svetlana Pack
Cytopathology – Armando Filie
Flow Cytometry - Maryalice Stetler-Stevenson
Hematopathology - Elaine S. Jaffe
Immunohistochemistry –Markku Miettinen / Armando Filie
Molecular Pathology - Mark Raffeld
Surgical Pathology – Markku Miettinen
Clinical Operations - Joseph Chinquee (Clinical Manager)
Histology - Michael Newford (Supervisor)

The Section Head, Technical Director or Chief Medical Officer for each LP laboratory/section/unit is responsible for establishing section-specific quality plans and for overseeing the section's overall quality plan and indicators. Each plan should include at least one pre-analytical, one analytical and one post-analytical indicator. Suggested indicators are listed below (indicators marked with [*] are related to patient safety). For each indicator monitored, the following should be documented:

(1) **Goal/Threshold**...What is the goal for the monitored indicator? For example specimen adequacy, what constitutes an adequate (or inadequate) specimen? An indicator for specimen adequacy might be *tissue viability*. The Goal/Threshold for an adequate specimen might be "viability of sample should exceed 40%."

(2) **Events not meeting goal/threshold**...For each indicator, raw data is collected monthly and events not meeting goal/threshold may require further investigation. Using the above example, all samples with viability below 40% are documented.

(3) **Corrective action taken**...Corrective actions should include both **reactive** and **proactive** actions. Using the above example, contacting the physician who obtained the sample to report problems with viability would be a reactive action. A proactive action might include sending out an annual memo to physicians instructing them how to procure samples with the best possible viability.

Suggested QI Indicators

Section quality indicators should include pre-analytic, analytic, and post-analytic variables. Monitors should incorporate elements to identify areas for improvement with patient safety issues and improve the accuracy of results reported on our patients.

1. Specimen adequacy

To generate excellent data for patient care, specimens analyzed must be adequate and appropriate for analysis. Each chief/director should address the issue of what determines an adequate/appropriate specimen for his or her respective service (goal).

II. Appropriateness of test(s) ordered

When relevant, are the tests ordered appropriate? For example, a clinician ordering daily cytogenetics on bone marrow biopsies for the purpose of monitoring minimal residual disease is inappropriate.

*III. Turnaround time**

When relevant, what is the acceptable turnaround time for a given test/analysis?

*IV. Patient/Specimen Identification**

This indicator will include identification errors with specimens submitted by nursing/medical staff, labeling errors (or unlabeled specimens) received in the lab; misspelled or incorrect demographics on specimen or requisition labels; and laboratory labeling errors to include blocks, slides, or records.

V. Test Order Accuracy

Percent of test orders correctly entered into a laboratory computer.

*VI. Revised Reports**

Percent of reports that are revised - relative to the total workload. For example, total revised reports for routine small biopsies that impacted, or had the potential to impact patient care, are important to monitor.

VII. Quality Control / Preventative Maintenance Review

To ensure staff perform required test quality control procedures and preventative maintenance as required per standard operating procedure.

2017 QM Program - AP QI Plan
Method of Implementation:

Specific Requirements

The Quality Management program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases (GEN.20316). These indicators aim to monitor activities critical to patient outcomes or that may affect the patient care. Although the CAP does not mandate specific indicators, the LP QM program has adopted some of the key quality indicators that are commonly used to measure laboratory performance in a consistent manner and that are important to clinicians and patients as indices of care (e.g. specimen identification, customer satisfaction, and corrected reports).

The LP QM program also incorporates the AP QI plan to review and discuss the quality reports of at least 12, but no more than 20, Quality Indicators (QI) chosen by the committee and reviewed/approved annually for effectiveness by the Medical Director. The plan for each indicator is listed on the monthly reports and updated as necessary by the committee. Actions taken if goals are not met will be documented in the minutes. The following quality indicators have been approved by the QM committee as the 2017 Quality Indicators will be in effect from February 1, 2017 through January 31, 2018, and may be extended into the next calendar year if not revised by the QM committee and Medical Director.

The majority of indicators for the AP QI plan relate to the CAP Laboratory General and Section-Specific Checklists, or are derived from best-practice indicators for clinical laboratories:

Analytic:	1. Comprehensive Cytology (Medical and GYN Cytology TAT)
Analytic:	2. Small Biopsy TAT
Analytic:	3. Complex Cases TAT
Analytic:	4. Intraoperative (Frozen Section) TAT
Analytic:	5. Autopsy TAT (Final Autopsy Report)
Post-Analytic:	6. Intraoperative Correlation (Frozen Sections)
Post-Analytic:	7. Revised (Corrected) Reports
Pre-Analytic:	8. Patient Identification Error, Unlabeled Cases or Missing Patient Information
Pre-Analytic:	9. Requisitions Not Submitted
Pre-Analytic:	10. Molecular Diagnostics Specimen Adequacy
Analytic:	11. Molecular Diagnostics Turnaround Time
Pre-Analytic:	12. Chromosome Pathology Unit Specimen Adequacy
Analytic:	13. Chromosome Pathology Unit Turnaround Time (TAT)
Pre-Analytic:	14. Flow Cytometry Bone Marrow (BM) Specimen Adequacy
Pre-Analytic:	15. Immunohistochemistry Pre-Analytic Errors
Analytic:	16. Immunohisto Analytic Errors (Requests for Repeat Stains, QA issues)
Analytic:	17. Submitted Service (SS/SJ) TAT
Post-Analytic:	18. Medlegal & Return Material TAT

Being Evaluated for next year's QM Plan

Post-Analytic:	19. Lost/Misplaced Slides (continue from 2016 Evaluation)
Analytic:	20. Biomarker CAP Reporting (also a Resident Project)
Analytic:	21. Reporting of Research IHC in Pathology Report

1. Medical and GYN Cytology Comprehensive Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. A recent study collected data on TAT for medical (non-gynecological) cytology from 180 laboratories. Results showed that labs in the top 50 % of participants would have 90% of medical cytology cases with TAT (receipt to report) of 3 calendar days. It was not mentioned what types of laboratories participated in the study; however, it is likely that a large portion of participants were nonacademic labs. LP provides anatomic pathology services for the Clinical Center as well as 21 different Institutes of the National Institutes of Health (NIH). NIH is a large clinical/research institution where all patients participate in protocol studies for various diseases and disorders including rare syndromes and cancers. Only a minority of patients requires a primary diagnosis. A significant number of medical cytology cases require additional ancillary studies and/or further workup to confirm primary diagnosis exclude secondary malignancy/disorder or include additional studies mandated by protocol. Therefore, the process involved in signing out medical cytology cases at the NIH is more complex and does not reflect the medical cytology cases seen at more "conventional" cytology labs where primary diagnosis is often the main concern. In addition, the NIH LP is a teaching department with accredited residency and fellowship programs in anatomic pathology. These facts must be taken into consideration when defining a threshold for medical cytology TAT. As reported by ADASP for TAT in surgical pathology cases, extra time should be allowed for cases requiring recuts, immunohistochemistry, etc. The same principal is valid for medical cytology cases. The threshold established for medical cytology TAT was based on the above information and also in accordance with expectations of SAC. A prospective study on the TAT for gynecologic cytology specimens including 371 laboratories showed that half of the participating labs were able to sign out 90% of the cases within 8 calendar days. Typically these labs have a large volume of gynecologic cytology specimens. The number of gynecologic cytology cases seen at LP is low. Based on this observation and also in accordance with SAC expectations, the TAT for gynecologic cytology established by the committee is within the expected TAT for our patient population. The volume of GYN cases is limited; therefore, a more relevant quality monitor is the comprehensive turnaround times for Medical and GYN cases for the month.

Threshold: 90% of medical and gynecologic cytology cases signed out within 5 working days.

2. Small Biopsy Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. A recent study collected data on TAT for routine biopsy specimens (small biopsy) from 157 small private and public hospitals in the U.S. (153) and abroad. Results showed that approximately 86% of cases were signed out within 2 working days.5 LP provides anatomic pathology services for the Clinical Center as well as 21 different Institutes of the National Institutes of Health (NIH). NIH is a large clinical/research institution where all patients participate in protocol studies for various diseases and disorders including rare syndromes and cancers. Only a minority of patients requires a primary diagnosis. A significant number of biopsy cases require additional ancillary studies and/or further workup to confirm primary diagnosis, exclude secondary malignancy/disorder or include additional studies mandated by protocol. Therefore, the process involved in signing out biopsy cases at the NIH is more complex and does not reflect the biopsy cases seen at more "conventional" surgical pathology labs where primary diagnosis is often the main concern. In addition, the NIH LP is a teaching department with accredited residency and fellowship programs in anatomic pathology. These facts must be taken into consideration when defining a threshold for small biopsy TAT. As reported by ADASP for TAT in surgical pathology cases, extra time should be allowed for cases that needed recuts, immunohistochemistry, etc.3 Therefore, the threshold established for small biopsy TAT was based on the above information and also in accordance with expectations of SAC.

Threshold: 90% of small biopsy cases signed out within 7 working days.

3. Complex Cases Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. A study collected data on TAT for complex surgical pathology cases from 489 laboratories in the U.S. and abroad. Results showed that 60 % of complex special-handling cases were signed out within 2 working days. The median TAT was 2.6 days with a range of 0-13.5 days.6 LP provides anatomic pathology services for the Clinical Center as well as 21 different Institutes of the National Institutes of Health (NIH). NIH is a large clinical/research institution where all patients participate in protocol studies for various diseases and disorders including rare syndromes and cancers. Therefore, the LP surgical pathology complex cases are considered special handling complex cases. In addition, a significant number of complex cases require additional ancillary studies and/or further workup to confirm primary diagnosis, exclude secondary malignancy/disorder or include additional studies mandated by protocol. The NIH LP is also a teaching department with accredited residency and fellowship programs in anatomic pathology. These facts must be taken into consideration when defining a threshold for complex cases TAT. As reported by ADASP for TAT in surgical pathology cases, extra time should be allowed for cases requiring overnight fixation, resubmission, recuts, immunohistochemistry, etc.3 The threshold established for complex surgical pathology cases was based on the above information and also in accordance with expectations of SAC.

Threshold: 90% of complex cases signed out within 10 working days.

4. Intraoperative (Frozen Section) Turnaround Time

Frozen Section (IOC) is an essential tool for patients undergoing surgery to aid the surgeon with a rapid diagnosis; therefore, IOC turnaround time (TAT) might have direct impact on patient's therapy and safety during and after surgery. This indicator results from the CAP's Anatomic Pathology checklist question ANP.11820, supported by a CAP Q-Probe study of 32,868 frozen sections in 700 hospitals (Archives of Pathology Lab Medicine, 1997; 121:559-567) which suggests that 90% of frozen sections should be completed within 20 minutes. Twenty minutes is intended to apply to the typical single frozen section, and cases involving multiple sections on a single specimen or case (e.g., resection margins) should expect longer TATs. The threshold is established in accordance with the CAP standard and all outliers will be evaluated by the QM committee and recurring reasons will be addressed with the residents and faculty.

Threshold: 90% of frozen sections will be completed within 20 minutes average

5. Autopsy Turnaround Time

Autopsy reporting is an important part of the quality management of medical care. It may be the only tool for answering questions and is the gold standard for determining the cause of death. Autopsies serve to identify diseases that were unknown at the time of death. The NIH Clinical Center Medical Records Department, in line with JCAHO standards has set a goal for all final autopsy reports to be returned within 60 calendar days of the autopsy. The CAP's standard is set at 60 working days and requires ongoing review of cases failing to meet this deadline. Accordingly, the QM committee will review the TAT on all final autopsy reports, and assess possible resolutions to prevent similar future outliers.
Threshold: All autopsy Final Autopsy Diagnosis (FAD) must be signed out within 60 calendar days of the performance date of the autopsy. Outliers must have documentation to identify the reason for the delay, and an evaluation by the chief medical officer to determine future corrective actions to prevent similar delays.

Threshold: 100% within 60 working days

6. Intraoperative Correlation (Frozen Sections)

Discrepancies between frozen section and final diagnosis that significantly impact on patient's treatment and/or management (major discrepancies) will be tracked and reported to the committee. The QM committee will address major discrepancies and compliance with IOC review during each QM meeting. Through CAP's Q-Probe program, which survey 90538 ICs performed in 461 institutions and found a case disagreement rate of 2% when uncorrected for deferred cases. A recent study of IOC and final diagnosis looked at 2812 specimens, which had a 96.75% agreement. Findings from the CAP's W-Tracks and Q-Probes show those who monitor this as a quality indicator have a IC/FD disagreement rates close to 2% with improved performance over time.

Threshold: ≤2% of major discrepancies

7. Revised (Corrected) Reports

The number of revised reports for reasons that significantly impact on patient's care (major reasons) will be tracked for AP as well as for all other LP sections/units/labs and reported to the committee. In accordance with the CAP's 2008 National Laboratory Safety Goals, all inaccuracies will be documented and communicated as soon as an inaccuracy becomes known. Significant impact to patient care will be assessed by a pathologist, and in accordance with the CAP Safety Goals, the pathologist should discuss the matter with the physician who ordered the consultation to determine how best to communicate the result to the patient. Compliance of this quality indicator will be assessed by reviewing all corrected reports and documentation.

Threshold: 0 with significant negative impact to patient care

8. Patient Identification Errors, Unlabeled Cases or Missing Patient Information

Another relevant CAP National Laboratory Safety Goal is to improve patient and sample identification at specimen collection, analysis, and reporting. LP staff documents identification errors with mislabeled specimens, slides, unlabeled cases, or reports and records with missing or inaccurate patient information. For 2010 quality indicators, SB (small biopsy) and SI (complex cases) for surgical pathology specimens will be tracked and system improvements addressed by QM Committee in partnership with section chiefs. A CAP study focused on 136 laboratories, with 427,255 reviewed cases where 0.4% (1811 cases) had some sort of mislabeling. The overall mislabeling rates per 1000 were 1.1 cases, 1.0 specimen, 1.7 blocks, and 1.1 slides. .00

Threshold: ≤ 5% of total SB/SI cases.

9. Requisitions Not Submitted for SB/SI cases

The number of small biopsy cases and complex cases that are submitted to the Surgical Pathology Section without a requisition will be tracked. The requisition should accompany the cases or should be forwarded to Surgical Pathology to prevent processing delays. According to CAP GEN.40700, All specimens are to be accompanied by an adequate requisition. Nakhleh & Fitzgibbons (CAP QM for AP, 2005) state that a requisition must accompany all specimens, and all identifying information on the request must match that on the specimen container. Further recommendation includes monitoring a subset of requisitions at least quarterly for completeness.

Threshold: $\leq 5\%$ of cases without a requisition for more than 24 hours.

10. Molecular Diagnostics Specimen Adequacy

The quality of services provided by the laboratory is related to the condition of the sample received and the receipt of correct documentation. The molecular diagnostics laboratory assesses the adequacy and documentation of all specimens received. Blood and bone marrow samples must be received with adequate anticoagulation and should not be clotted. All blood and bone marrow specimens must have at least 1 ml of sample. Unstained slides and paraffin blocks must contain sufficient tissue for analysis. The sample must be labeled with the patient's name or other clear identifier, and must be accompanied by a CRIS or Softpath order specifying the specific test.

Threshold: 0 specimen submission and processing errors

11. Molecular Diagnostics Turnaround Time

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. The Molecular Diagnostics laboratory continues to strive to improve and maintain satisfactory report time from specimen receipt through final report. There are currently no industry standards or norms for the turnaround time of Molecular tests. Based on our patient population (research based) and expectations of our medical staff, eleven working days is established as the initial threshold. As this indicator is monitored, future consideration to decrease the threshold will be considered.

Threshold: 90% of cases reported within 8 working days of receipt.

12. Chromosome Pathology Unit Specimen Adequacy

The quality of services provided by the laboratory is related to the condition of the sample received and the receipt of correct documentation. The Chromosome Pathology Unit assesses the adequacy and documentation of all samples received. In most cases, one H&E stained and four unstained slides per patient/sample are required. H&E stained should be reviewed by a pathologist who may designate tumor area(s) for analysis. Unstained slides must contain sufficient tissue for analysis. The sample must be labeled with the patient's name or other clear identifier, and all cases must be accompanied by a CRIS or Softpath order specifying the specific test.

Threshold: 0 specimen submission and processing errors

13. Chromosome Pathology Unit Turnaround Time (TAT)

The quality of services provided by a laboratory may be measured by the TAT of tests done by the lab. The Chromosome Pathology Unit (CPU) continues to make every effort to improve and maintain satisfactory report time from specimen receipt through the final report. The current industry standard for the turnaround time of FISH tests for formalin fixed paraffin-embedded (FFPE) tissues is 7 days [8]. Based on this observation, the TAT for the FFPE FISH established by the QM committee is within the expected TAT for our patient population.

Threshold: 90% of cases reported within 7 working days of receipt

14. Flow Cytometry Bone Marrow (BM) Specimen Adequacy

Optimal specimen quality is vital for successful flow cytometric immunophenotyping. Clotted specimens may result in loss of the cells of interest and may compromise test result accuracy. The technologist performs gross inspection on all specimens to detect non-optimal specimen conditions. Clots in all specimens are noted upon specimen receipt in the Softpath Specimen Source Modifier field during accessioning on in the Gross Section of the Final Report. The QM committee will monitor the number of clotted specimens received by Flow Cytometry.

Threshold: $\leq 5\%$ of BM specimens received with clots

15. Immunohistochemistry Pre-Analytic Errors (e.g. Patient Identification, Processing issues)

A 1994 Q-Probes study involving over one million cases from 417 institutions documented identification and accessioning deficiencies in 6% of total cases accessioned, with a median deficiency rate of 3.4%. Errors related to specimen identification accounted for 9.6% of these deficiencies, discrepant or missing information were present in 77%, and 3.6% involved specimen handling[6]. This quality indicator was established in CY2015, and the initial threshold established for allowable errors for pre-analytic variables (e.g. patient identification, processing, and handling events) measured against total IHC cases stained for the month was consistently less than 5 percent. CAP checklists (GEN.40490), (ANP. 11950), (ANP. 11950) establish a standards for Patient Identification.

Threshold: $\leq 0.5\%$ of all IHC stains ordered per month will have no pre-analytic errors. This is a preliminary threshold, and will be reassessed for possible 99% confidence interval mid-year.

16. Immunohistochemistry Analytic Errors (e.g. Requests for Repeat IHC Stains, QC issues)

An inadequate immunohistochemical stain may be the result of less than optimal tissue fixation, selection and/or processing, antibody failure, or technical factors. It is important that the lab document all requests for repeat stains, the reason for the request, the corrective action performed, and final outcome[6]. Whether an IHC request for repeat is due to technical, clerical, or procedural error, the reasons to repeat stain requests should be reviewed for trends to determine if there are system errors that should/could be implement to prevent recurring quality failures that result in repeat stains. The IHC laboratory has developed a tracking sheet to document. CAP checklist (ANP.21450) Special Stain quality, all immunohistochemical stains should be of adequate quality, and daily controls are demonstrated on each day of use for the tissue components or organisms for which they were designed. Some examples of common problems include: high background, periphery staining, no or weak staining, and tissue detachment. All analytic errors and repeat requests will be reported and assessed.

Threshold: $\leq 0.5\%$ of repeated IHC stains

17. Submitted Surgical Pathology Cases (SS & SJ) Turnaround Time (Analytic)

An integral component of the LP clinical service is review of submitted surgical materials for patients being considered for an NIH research protocol. Additionally, LP pathologists are considered experts in certain disciplines, and their consultative services are requested by non-NIH institutions for the rendering of a second opinion. Variables to consider while assessing issues with the submitted service turnaround times include: Identifying the purpose for the Consult (e.g. some second opinion rather than protocol-driven); The type of Consult - Is the patient being considered for protocol – is it a personal consultation or second opinion for a specific pathologist; were there additional documents requested from submitting facility (NIH staff or submitted outside source) that is not within the scope of control of LP staff; or consideration if the submitted case for patient protocol review was received without accompanying paperwork from the submitting clinic. This indicator is implemented in order to determine if there are system errors, or specific variables, that contribute to extended turnaround times, that might be addressed.

Threshold determination: According to Volmar, K., et. al., (2015), median turnaround times in government institutions was 6.06 days for complex surgical specimens (based on a 2012 CAP Q-Probes Study of 56 Institutions reported on 2,763 large or complex cases). Considering there are potential processing issues, such as requesting additional material or missing paperwork, and also considering this includes routine consults that are less time-critical are mixed with consults for protocol consideration. Initially, 90% within 10-days was evaluated, similar to the turnaround time indicator for complex surgicals; however, initial data demonstrates that 90% within 7 days is a more effective threshold. This, and all thresholds, are reviewed periodically by the QM Committee and the Medical Director, and can be revised to strive for further improvement.

Threshold: $\geq 90\%$ within 7 days

18. Medicolegal and Return Material Turnaround Time (Post-Analytic)

LP's Surgical Pathology service routinely receives requests to have non-NIH submitted patient material (stained, unstained slides recut or whole blocks (less frequently)) returned to the submitting facility or forwarded on to another facility at a patient's request if that patient is being treated or being considered for another protocol in that facility. It's an important responsibility that LP staff process patient requests to forward pathology material to other facilities. Additionally, patients who are on multiple protocols in various health care organizations routinely ask that their material be returned to the submitting facility so that they can send on to other facilities. Historic customer satisfaction surveys provided feedback that having material sent to other facilities may take too long, so this indicator was created to monitor the turnaround times for return material requests.

Threshold determination: Numerous factors can contribute to the time it takes from receipt of a request for material until the time it is mailed to the requesting facility. A formal requisition is needed, determination if and/o how much material can be released to that facility, availability of the material (time to recut if necessary), release by the attending pathologist, and administrative staff availability to process the paperwork and physically mail the material. For the purpose of evaluating an initial threshold, we referenced Giannini et al. (2011), of the Mayo Dept of Lab Medicine and Pathology, which esablished expected return of their submitted material at 14 days for clinical cases and 6 months for materials requsted for research or education. A focus on the clinical expectation, and based on LP's initial QM data which suggests that 7 to 10 days from receipt of request would be a more appropriate target, the Medical Director has requested setting the threshold at the lower limit and eventually strive to improve even that threshold.

Threshold: ≥90% withing 7 days

Indicators Being Evaluated for 2018

19. Lost Slides (Post-Analytic)

LP has a significant archive of past patients' surgical slides, both for in-house cases and slides received for the submitted service. There are routine requests from the submitting facility to return the slides for continuum of their patient care, and there are requests by the patient or submitting NIH investigator for additional material to be sent to other facilities for additional research. Because of the department's research and academic functions, there are occasions that slides may be removed from the slide storage system and this creates some effort to identify where these slides are located. In other situations, the slides are not located and recutting the block is the solution. In the worst-case scenarios, no slides or blocks are available. As a result of the critical nature of patient slides in the continuum of patient care, the QM committee requested the evaluation of lost or misplaced slides as a quality indicator.

Threshold: Being evaluated for 2017

20. Biomarker CAP Reporting (Analytic)

CAP's Checklist Standard ANP.12350 Cancer Protocols: data elements required in applicable CAP Cancer Protocols are included in at least 90% of the surgical pathology reports from definitive resection specimens with an invasive malignant histologic diagnosis, as well as cases of ductal carcinoma in situ of the breast, with an audit performed annually to ensure that all required elements are included.

Plan: Initial data collection q1 year to determine compliance, and document potential limiting factors. Clinical Residents, an Attending Mentor, and IHC Technical Staff to develop plan of action based on data.

Threshold: Being evaluated for 2017

21. Reporting of Research IHC in Pathology Report (Analytic)

In addition to the clinical antibodies that have been developed, validated, implemented and have routine proficiency testing performed, the Laboratory of Pathology has a developmental Immunohistochemistry service with the objective to evaluate new IHC antibodies for clinical applications or to support research protocols. CAP Lab GEN.41350 references research testing: For laboratories subject to US regulations: for tests in disciplines covered by CLIA, specimens and materials for testing must be referred only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. With respect to patients on research protocols, whose tests are referred to a research laboratory: if those test results are used for patient management decisions, the research laboratory must be CLIA-certified, or meet equivalent requirements as determined by CMS.

This indicator is established to ensure antibodies developed for research use or research protocol that have not yet been *validated and implemented for clinical use* are not referenced in the diagnostic line of the pathology report and that the report contains the appropriate note regarding these antibodies.

Threshold: Being evaluated for 2017

ANNUAL QUALITY MANAGEMENT PROJECTS – REGULATORY COMPLIANCE (RC)

RC-I. Biennial Customer Satisfaction Survey – GEN.20335 (due November 2017)

The Laboratory of Pathology measures the satisfaction of healthcare providers with laboratory services every two years. Satisfaction metrics are important for understanding the needs of clients (physicians, patients, referring laboratories, nurses, etc.) to improve laboratory services. Experience has shown that surveys are more informative if they are conducted anonymously and allow for open ended comments. The sample size should be adequate. A numeric satisfaction scale allows for calculation of statistics.

RC-II. Quality of Water – GEN.41500 (due March / October 2017)

The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and recorded at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be recorded if water does not meet acceptability criteria. LP conducts biannual PMs and tests for maximum microbial content (CFU/mL) <10.

RC-III. Biennial Report Format and Content Review (due October 2017)

The laboratory director (or a designee who meets CAP qualifications for laboratory director) must review and, at least every two years, approve the content and format of laboratory patient reports (whether paper or computer screen images) to ensure that they effectively communicate patient test results, and that they meet the needs of the medical staff (GEN.41067).

RC-IV. Patient Confidentiality QM Review (due March 2017)

In order to satisfy the CAP revised standard GEN.41303, Patient Confidentiality QA, the Laboratory of Pathology will conduct an annual audit of compliance with the NIH and LP patient confidentiality policies. LP policies dictate that: 1) requests for release of patient reports must be initiate from the NIH Clinical Center's Medical Records department, or based on the distribution list provided by the submitting clinician for consultative and submitted cases; and 2) any report released electronically will be encrypted when released to internal NIH health care providers, and/or password protected file(s) when submitting reports to the patients' non-NIH health care provider(s).

RC-V. Pending Supplemental Reports (due March 2017)

Because of the nature of LP's patient workload, there are occasions that supplemental reports are added to case(s) without having been signed out. Examples of reasons can include: duplicative orders; the result was reported with an associated clinical case (e.g. Molecular result reported with the Surgical case); or the supplemental could have been delayed for sign-out. Because the supplemental reports do not show up on pending lists, the QM program will review pending supplemental pathology reports at least annually. Pending supplemental reports will be resolved as soon as identified. However, if recurring issues are demonstrated or if there is the potential to impact patient care based on the annual review, the project could potentially become a recurring quality indicator.

RC-VI: Intradepartmental-Observer Variability – Predictive Markers

For immunohistochemical and FISH/ISH tests that provide independent predictive information, the laboratory at least annually compares its patient results with published benchmarks, and evaluates inter-observer variability among the pathologists in the laboratory. NOTE: Individuals interpreting the assay must also have their concordance compared with each other and this concordance should also be at least 95%. (Reference: ANP.22970)

With specific reference to estrogen and progesterone receptor studies: in general, the overall proportion of ER-negative breast cancers (invasive and DCIS) should not exceed 30%. The proportion is somewhat lower in postmenopausal than premenopausal women (approximately 20% vs. 35%). The proportion is considerably lower in well-differentiated carcinomas (<10%) and certain special types of invasive carcinomas (<10% in lobular, tubular, and mucinous types). The proportion of PgR-negative cases is 10-15% higher than for ER-negative in each of these settings. Investigation is warranted if the proportion of negative cases is significantly lower in any of these settings.

RC – VII: Patient Confidentiality QA

In order to satisfy the College of American Pathologists' (CAP) revised standard GEN.41303, Patient Confidentiality QA, the Laboratory of Pathology will conduct an annual audit of compliance with the NIH and LP patient confidentiality policies. LP policies dictate that: 1) requests for release of patient reports must initiate from the NIH Clinical Center's Medical Records department, or based on the distribution list provided by the submitting clinician for consultative and submitted cases; and 2) any report released electronically will be encrypted when released to internal NIH health care providers, and/or password protected file(s) when submitting reports to the patients' non-NIH health care provider(s).

In order to satisfy the annual audit, LP staff will:

Review no less than 5 random Medico-legal requests from the previous calendar year to ensure that there is proper patient authorization to release the patient's repot to the requested provider or facility. The quality reviewer will ensure: a) Medicolegal request includes the patient signed authorization; b) The pathology report was submitted to the intended audience (e.g. patient's own request, submitting health care provider, and/or facility); c) The transmission of the pathology report was secure encrypted and/or password protected file if transmitted electronically; and d) If possible, contact the facility to ensure the report was received securely.

Review no less than 5 random submitted surgical (SS) cases with distribution that included at least 1 internal NIH provider and at least 2 external facilities. The quality reviewer will ensure: a) Ensure the name(s) and address(es) of the distribution list is correct by reviewing the original submitted case documents; b) Ensure the internal NIH email was encrypted (the reviewer can print the sender' sent email file as evidence); and c) The distribution to the external health care provider or facility was encrypted and/or password protected and password did not accompany the same email as the report. This review can also be done via reviewing the Surgical Pathology Patient Care Coordinator's sent emails.
All evidence (emails and reports) will be submitted to the Clinical Manager, and the results of the audit will be submitted to the Quality Management Committee and Medical Director with appropriate investigations and corrective actions if necessary.

RESIDENT & CLINICAL FELLOW PROJECTS (CFP)

The LP QM program will also incorporate "projects" that will address specific CAP checklist requirements and areas that need further monitoring and improvement based on the results of indicators monitored in CY2017 and based on recurring issues in LP's sections that may pose a risk to quality management.

Areas previously identified as potential projects to be adopted by the QM committee include: determining common causes of >10 day outliers, delays in autopsy, missed CAP cancer reporting, and clotted bone marrow samples. As of the close of CY2016, the autopsy service was consistently in compliance with the 60-day turnaround time standard. By the close of CY2017, the bone marrow clotted samples project resulted in compliance with the threshold.

As our clinical residents and fellow train to be future pathology lab directors, all are required to participate in at least one resident/fellow QM Project. In addition to the LP Quality Indicators, the QM Committee engaged the in-training pathology physicians (residents and fellows) to implement three projects for 2017. These projects were selected because they involve recurring quality issues affecting LP and require monitoring and corrective action.

Guidelines for Residents/Fellows QM Projects

- Identify an issue or area of LP's clinical services that require process improvement
- Suggestions might include examples such as:
  Pre-analytic Variables – specimen collection, requisitions, transport, receiving
  Analytic Variable – turnaround times, grossing, procedures, strains, interpretations, reporting
  Post-Analytic Variables – supplementals, customer complaints, corrected reports, physician notification of abnormal reports
- Discuss the issue(s) with the sections' technical staff or director
- Develop a plan: Identify metrics, data sources, how to report, how to address system issues
- Coordinate with a mentor – e.g. Lead Technologists, Medical Officers, Clinical Manager
- Implement the Plan(s), Monitor Metrics, Quarterly Reports to LP QM Committee
- The most important consideration when developing your Project Plan: there MUST be an end to the project – there must be a SOLUTION

2017 PROJECTS

CAP Cancer Protocols Review (continued from previous year):

To address CAP Anatomic Pathology Checklist requiring that all data elements required in applicable CAP Cancer Protocols are included in the surgical pathology report.

SS case patient ID/accession errors:

The General Surgical Pathology service receives numerous cases from outside facilities on a daily basis with requests for LP's Pathologists to review previous diagnoses for patients being considered for protocol (inclusion criteria), as well as patient cases submitted to LP's pathologists for consultation based on their discipline and expertise. The clinical residents have proposed that there are clerical errors that result from accessioning, and the residents propose to identify system issues and propose solutions to prevent these types of errors.

Compliance with Immunohistochemistry Daily Quality Control (QC) review:

IHC control slides and QC must be completed daily and slides and paperwork returned to Immuno daily. ANP.21395 For special stains, including histochemical stains, and studies using immunologic and ISH methodology, positive and negative controls are verified and recorded as acceptable prior to or concurrent with the reporting of patient results and records maintained. NOTE: Controls must be verified and recorded as acceptable by a pathologist or designee (provided the designee meets high complexity testing qualifications).

Delayed CRIS Orders (to be developed 2017)

Requested by the Medical Director to be a Resident project because we have been unsuccessful with attempting to consistency with receiving requisitions with all biopsies or surgical specimens received in the Histology accessioning. According to CAP GEN.40700, all specimens are to be accompanied by an adequate requisition, but specimens are routinely received in the laboratory while waiting for a surgeon to complete a procedure or attending to enter the CRIS order.

Accuracy of CRIS orders to actual specimen(s) received (to be developed 2017)

The Medical Director has requested that a Resident, under the supervision of a surgical pathologist, develop a Resident QM Project to identify: the problem; the number of incidents involved in CRIS order differences; types of incidents (wrong site, wrong procedure, used the wrong CRIS order); contributing factors; develop and monitor metrics (from standards, cited best practices, publications); how outliers are addressed; and a proposed outcome.

CAP Cancer Protocols Reporting Project

I. Issue: All data elements required in applicable CAP Cancer Protocols should be included in the surgical pathology report. Violation of this rule is phase II deficiency. (References: College of American Pathologists. Practicing Pathology: Cancer Protocols http://www.cap.org/cancerprotocols/protocols/intro.html)

CAP cancer reporting protocols should be incorporated in the final surgical pathology report for those cases that such protocols exist and are made available by CAP. Anatomic Pathology CAP Checklist # ANP.12350

A retrospective review of surgical pathology reports for tumors that required the CAP cancer protocol showed that the majority of the reports did contain the CAP protocol. However, there are a few cases that did not include the required CAP protocol.

II. Project Plan Objective: The objective is to have 100% compliance with the reporting of CAP cancer protocols for those tumors that such protocol exist and should be included in the final surgical pathology report. In order to achieve this goal the proposed plan would include:

III. Materials and Methods: Final, supplemental and/or revised reports of all cases with large specimens received by and grossed at NIH Laboratory of Pathology (SI cases) are retrieved from SoftPath and are checked one by one for followings:

1) Whether those are tumor cases that need data elements required in CAP Cancer Protocols (Yes or No)
2) If 1) is Yes, then check whether applicable data elements required in CAP Cancer Protocol is included in the pathology report (Yes or No), regardless of whether each element is spread throughout the report in diagnosis line, note, comment, clinical information and gross examination, or entered in a summarized form of CAP checklist template.

The following data is obtained for reporting:
1) Total cases reviewed for this project each month of 2016 and 2017
2) Number of cases that need data elements required in CAP Cancer Protocols
3) Number of cases that need data elements required in CAP Cancer Protocols, but do not have the elements completely, and % of 2)/3)
4) Brief description of cases that falls in 3)

IV. Monitoring and corrective action: Review of all SI cases in each month is performed within 2 weeks in following month. The summary data is reported in monthly QM meeting. For non-compliant cases, the residents and attendings who initially signed out the reports issue supplemental reports with the appropriate CAP checklist.

V. Solutions to improve compliance
1) Provide a table listing all tumor types requiring the reporting of CAP cancer protocols to residents and attendings
2) Incorporate CAP checklist requirements into educational seminars
3) Regular detailed review of patient history prior to signing out SI cases

VI. Expected outcome
1) Familiarizing residents and attendings with the CAP cancer protocol reporting checklist and to alert them to the need of having the cancer protocol reporting incorporated in applicable cases
2) As the monitoring of compliance with CAP Cancer Protocol is on monthly basis, corrective action (supplemental report) can be taken early.

SS case patient ID/accession errors

I. The issue: Clerical errors on cases, namely submitted cases. These reports affect patient care and are legal documents. It is important to have basic accessioning information correct.

II. Quality Plan Objective: Residents will prospectively collect quantifiable data to identify causes of delay at specific points in the autopsy evaluation and report preparation. Residents will keep a log of dates corresponding to several check points. Actionable:

a. Bring awareness to errors and address where common mistakes are made
b. Enforce that everyone records errors
c. Issue amendments if necessary

Data / Statistics:

a. Each month collect data pertaining to errors int:
    - Name of patient
    - Gender of patient
    - Date of birth of patient
    - Outside case number and collection date
b. Each month we will record:
    - Date case was accession / error caught
    - Case number
    - What the issue / error is
    - Those involved including resident
    - How it was corrected
    - Any other pertinent details including explanations for error

III. Expected outcome: Identify system errors that contribute to accessioning clerical errors, and implement processes to prevent these errors from recurring.

IV. Future Plan of Action: how to prevent recurrence

a. Continue to emphasize the importance of tracking this information
b. Include mistakes noticed / made by histology in data
c. Possibly adding the merging of patients
d. Reassess in 6 months

Ensuring Compliance with IHC Daily QC

I. Issue: IHC control slides and QC must be completed daily and slides and paperwork returned to Immuno daily. There are days that IHC controls are not documented. The objective is to have 100% compliance with the Control Slide Review item. In order to achieve this goal the proposed plan would include the following changes:

A. Controls are delivered to the hot seat resident by IHC lab staff. The arrangement of control slides matches the order on the QC sheet that is filled out with legible handwriting.
B. Hot seat previews controls and starts filling out QC sheet flagging questionable stains.
C. All controls are evaluated together with the surgical pathology on service attending at the same time when hot seat trays (biopsies, frozen controls) are being shown. For new or rarely used stains the opinion of the pathologist ordering the stain should be sought.
D. Attending takes responsibility of control slide review by signing QC sheet.
E. Controls are left in sign-out room by hot seat and QC sheets are handed to IHC lab.
F. Attendings (surgical pathology, hematopathology, cytology), IHC lab staff, and residents on service should be notified promptly of inadequate control slides by the hot seat resident via email.

ANP.21395 For special stains, including histochemical stains, and studies using immunologic and ISH methodology, positive and negative controls are verified and recorded as acceptable prior to or concurrent with the reporting of patient results and records maintained. NOTE: Controls must be verified and recorded as acceptable by a pathologist or designee (provided the designee meets high complexity testing qualifications).

II. Project Plan Objective: The objective is to have 100% compliance of daily IHC quality control reviewed daily and results documented, prior to patient cases, and slides be made readily available for all pathologists for cases reviewed throughout the day.

IV. Monitoring and corrective action: Monitoring of compliance of Control Slide Review will be performed on an ongoing basis together with IHC lab staff and results will be reported to the QM committee monthly. Monitoring should be continued over at least the next 6 months since there is now more responsibility on the hot seat residentThe IHC laboratory reviews daily compliance and reports outliers to the Clinical Manager. Cumulative reports are submitted to the Medical Director and QM Committee.

V. Solutions to improve compliance
The Residents have taken on the task of including IHC QC review as a project. A clinical resident will review IHC controls with the surgical pathology on service each morning and report the results to the IHC laboratory. Slides will remain in the Signout Room to be accessible to all pathologists throughout the day.

VI. Expected outcome
It's expected that the residents ensure consistent compliance with daily IHC QC review, documentation and reporting to the laboratory. The added benefit is this becomes another learning opportunity for the residents as they review the controls with various attendings. The expected outcome is close to 100% compliance in Control Slide Review. Residents and attendings are expected to familiarize themselves with Control Slide Review requirements. A better integration into the daily routine should lead to a timely and reliable fulfillment of this important CAP requirement.

Senior residents should have an educational opportunity by reviewing slides with attendings and have IHC interpretational questions answered. It would also prepare them for their future practice in which they might have the responsibility of reviewing laboratory testing and at a minimum would have to review IHC controls either in batch testing or on a case by case basis.

Projects Being Considered for CYs 2017-2018

Proposal 1 – The Medical Directed requested the QM committee conduct a biannual review of all pending supplemental reports in SoftPath, to determine if the supplemental reports were added erroneously or if these cases still require sign out and were missed. The Medical Director will consult the QM committee chair to determine if there is a need to include this as a quality indicator in CY2018.

Proposal 2 – Accuracy of CRIS orders to actual specimen(s) received: While reviewing the incidents of cases received without CRIS orders, the Histology technicians and residents indicated that there are occasions that a CRIS order (placed by the treating clinician) doesn't always match the actual specimen received in Histology (will also be different in Softpath). Additional resources in Attachment A: Referenced Material. Plan: The Medical Director has requested that a Resident, under the supervision of a surgical pathologist, develop a Resident QM Project to identify: the problem; the number of incidents involved in CRIS order differences; types of incidents (wrong site, wrong procedure, used the wrong CRIS order); contributing factors; develop and monitor metrics (from standards, cited best practices, publications); how outliers are addressed; and a proposed outcome.

Proposal 3 – Delayed CRIS orders continues to be an issue for the clinical residents as their work is delayed as they wait for attending clinicians to place CRIS orders. There are considerations that some cases will have delayed orders if the surgeon is still in the Operating Room, but there are cases that it's unclear who is responsible for entering the CRIS orders. It has been recommended by the QM committee that a resident take on a QM project to identify the issues, investigate, evaluate, report, and propose solution(s) to the delays in receiving CRIS orders with specimens.

References

1. College of American Pathologists (CAP) Accreditation Checklists: Laboratory General (GEN); All Common (COM); and Anatomic Pathology (ANP) Checklists, 8/17/2016 version.

2. Jones BA, Novis DA. Nongynecologic cytology turnaround time: a College of American Pathologists Q-Probes study of 180 laboratories. Arch Pathol Lab Med 2001;125:1279-84.

3. Association of Directors of Anatomic and Surgical Pathology. Recommendations on Quality Control and Quality Assurance in Anatomic Pathology. Am J Surg Pathol 1991;15:1007-9.

4. Giannini, C., et al.,. (2011, March). Maintaining Clinical Tissue Archives and Supporting Human Research: Challenges and Solutions. Arch Pathol Lab Med; 135, 347-353.

5. Jones BA, Valenstein PN, Steindel SJ. Gynecologic cytology turnaround time. A College of American Pathologists Q-Probes study of 371 labs. Arch Pathol Lab Med 1999;123:682- 6.

6. Novis DA, Zarbo RJ, Saladino AJ. Interinstitutional comparison of surgical biopsy diagnosis turnaround time: a College of American Pathologists Q-Probes study of 5384 surgical biopsies in 157 small hospitals. Arch Pathol Lab Med 1998;122:951-6.

7. Nakhleh, R.E., Fitzgibbons, P.L: Quality Management in Anatomic Pathology, Promoting Patient Safety Through Systems Improvement and Error Reduction. College of American Pathologists (CAP); 2005.

8. Nakleh, R.E., Idowu, M.O, Souers, R.J., Meier, F.A., & Bekeris, L.G. (2011, Aug). Mislabeling of Cases, Specimens, Blocks, and Slides: A College of American Pathologists Study of 136 Institutions. Arch Pathol Lab Med 2011; 135, 969-974

9. White, V.A., & Trotter, M.J. (2008). Intraoperative Consultation / Final Diagnosis Correlation: Relationship to Tissue Type and Pathologic Process. Arch Pathol Lab Med; 132, 29 – 39.

10. Wagar, E., Stankovic, A., Raab, S., Nakhleh, R., & Walsh, M. (2008, Oct). Specimen Labeling Errors: A Q-Probe Analysis of 147 Clinical Laboratories. Arch Pathol Lab Med; 132, 161 –1622.

11. Idowu, M., Bekeris, L., Raab, S., Ruby, S., Ruby, S., & Nakhleh, R. (2010). Adequacy of Surgical Pathology Reporting of Cancer: A College of American Pathologists Q-Probes of 86 Institutions. Arch Pathol Lab Med; 134, 969-947

12. American College of Medical Genetics, E.6.5.3.2 (2009).

13. Volmer, K., Idowu, M., Souers, R., Karcher, D., & Nakhleh, R. (2015). Turnaround Time for Large or Complex Specimens in Surgical Pathology: A CAP Q-Probes Studey of 56 Instituions. Arch Pathol Lab Med; 139, No. 2, pp. 171-177.

14. Zembowicz, A., Ahmad, A., & Lyle, S. (2011) A Comprehensive Analysis of a Web-Based Dermatopathology Second Opinion Consultation Practice. Arch Pathol Lab Med: March 2011, Vol. 135, No. 3, pp. 379-383.