DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health
Laboratory of Pathology, NCI, CCR

MEMORANDUM

January 12, 2015

TO: Laboratory of Pathology Staff

FROM: J. Carl Oberholtzer, MD, PhD (Medical Director)

Armando Filie, MD (Quality Management Chair)

SUBJECT: **Annual Review of Efficacy of the Quality Management Plan for the Laboratory of Pathology, NCI**

In accordance with the College of American Pathologists' (CAP) Laboratory General Checklist GEN.16902, the Quality Management (QM) Plan must be implemented as designed and reviewed annually for effectiveness. The Laboratory of Pathology (LP) has identified several revisions to the CAP's most recent updated checklists requirements for QM (Attachment A), and the QM plan has been revised to address revisions to more relevant quality indicators and based on the CAP's 2014 checklist revisions. The 2014 LP QM Indicators included preanalytic, analytic, and post-analytic indicators for turnaround times, intraoperative correlations, corrected reports, patient identification events, and specimen errors.

Based on review of the relevance of our quality indicators based on relevance, industry recommendations, occurrence of incidents, and to be inclusive of LP's extent of services, the following revisions have been made to the 2015 Quality Management Plan:

REMOVE: It is the determination of the QM Committee that the analytic indicator to monitor the post-mortem provisional autopsy diagnosis (PAD) is no longer necessary because we have demonstrated more than two years of good performance.

REVISE: The CAP Checklist item ANP.33120 was revised to elaborate on the final autopsy diagnosis (FAD) turnaround time threshold is 60 working days in 90% of cases, considering that complex cases can be expected to exceed this threshold if external consultation is required.

NEW: Immunohistochemistry Patient Identification (Pre-Analytic)

According to CAP Checklist item ANP.21050, the identity of every specimen must be maintained through each step of tissue processing and block and slide preparation. This indictor in intended to monitor and address potential patient identification events, such as:

mislabeled slides, incorrect block cut, or incorrect slides pulled. Determining the threshold: In laboratory medicine, typical acceptable range for quality control is a +/- 2 std. deviation to allow a 95% confidence interval and in some cases, a 99.5% confidence for 1 standard deviation. As we implement this new quality indicator, we will use the 2 s.d. threshold of ≤5% allowable errors for patient identification events against total IHC cases stained for the month.

Threshold: There will be ≤5% patient identification errors out of all IHC requests per month

NEW: Requests for Repeat Immunohistochemical Stains (Analytic)

ANP.22900 requires immunohistochemistry stains be of acceptable technical quality, and this indicator aims to monitor and improve upon factors in processing and staining procedures that might lead to poor quality slides. Whether an IHC request for repeat is due to technical, clerical, or procedural error, the reasons for repeat stain requests should be reviewed for trends to determine if there is/are system errors that could/should be implement to prevent recurring quality failures that result in repeat stains. The IHC laboratory has developed a form that must be completed by Pathologists for each request for repeat (Attachment B) to document the reasons(s) for repeat stain requests, and an IHC QA tracking sheet (AttachmentC) will be used by Laboratory staff to monitor repetitive errors in order to identify system solutions to prevent potential future errors.

Threshold: There will be ≤5% of repeat requests for Immunohistochemical stains per month

MEMORANDUM

Attachment A

Material Referenced

COM.04000 Documented QM/QC Plan **Phase II**

The laboratory has a written quality management/quality control (QM/QC) program.

NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory's systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective/preventive action based on data from its QM system.

All QM requirements in the Laboratory General Checklist pertain to the laboratory.

Evidence of Compliance:

✓ Records reflecting conformance with the program as designed **AND**
✓ Results of quality surveillance

GEN.16902 QM Implementation **Phase II**

For laboratories that have been CAP accredited for more than 12 months, the QM plan is implemented as designed and is reviewed annually for effectiveness.

NOTE: Appraisal of program effectiveness may be evidenced by an annual written report, revisions to laboratory policies and procedures, or revisions to the QM plan, as appropriate.

Evidence of Compliance:

✓ Evidence that the plan has been implemented as designed requires all of the following:
- quality measurements/assessments specified in the plan are being substantially carried out;
- there is evidence of active review of quality measurements;
- if target performance levels are specified in the plan and the targets are not being met, there is documented follow-up action;
- any interventions/changes to operations that are specified in the plan have been carried out as scheduled, or the reason for delay documented; **AND**
- any communication of information that is required by the plan have taken place

GEN.20100 QM Extent of Coverage **Phase II**

The QM program covers all areas of the laboratory and all beneficiaries of service.

NOTE: The QM program must be implemented in all areas of the laboratory (e.g. chemistry, anatomic pathology, satellite, point-of-care, consultative services, etc.). The program must include all aspects of the laboratory's scope of care, such as inpatient, outpatient, and reference laboratory services.

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***REVISED** 07/29/2013*

GEN.20316 QM Indicators of Quality **Phase II**

The QM program includes monitoring key indicators of quality in the pre-analytic, analytic, and post-analytic phases.

NOTE: Key indicators should monitor activities critical to patient outcome and/or affect many patients. The laboratory must document evaluation of indicators by regularly comparing performance against available benchmarks. The number of monitored indicators should be consistent with the laboratory's scope of care. Special function laboratories may monitor fewer indicators; full-service laboratories should monitor multiple aspects of the testing process appropriate to their scopes of service.

While there is no requirement to monitor any specific laboratory monitor, the following key quality indicators listed below have been commonly used to measure laboratory performance in a consistent manner and are important to clinicians and patients as indices of care.

1. *Patient/Specimen Identification: Percent of patient wristbands with errors, percent of ordered tests with patient identification errors, or percent of results with identification errors*
2. *Test Order Accuracy: Percent of test orders correctly entered into a laboratory computer*
3. *Specimen Acceptability: Percent of specimens accepted for testing*
4. *Stat Test Turnaround Time: Collection-to-reporting turnaround time or receipt-in-laboratory-to-reporting turnaround time of tests ordered with a "stat" priority (e.g. emergency department or intensive care unit specimens), mean or median turnaround time, or the percent of specimens with turnaround time that falls within an established limit*
5. *Critical Value Reporting: Percent of critical results with documentation that results have been reported to caregivers; percent of critical results for which the primary clinician cannot be contacted in a reasonable period of time*
6. *Customer Satisfaction: Standardized satisfaction survey tool with a reference database of physician, nurse, or patient respondents*
7. *Corrected Reports – General Laboratory: Percent of reports that are corrected*
8. *Corrected Reports – Anatomic Pathology: Percent of reports that are corrected*
9. *Surgical Pathology/Cytology Specimen Labeling: Percent of requisitions or specimen containers with one or more errors of pre-defined type*
10. *Blood Component Wastage: Percentage of red blood cell units or other blood components that are not transfused to patients and not returned to the blood component supplier for credit or reissue*
11. *Blood Culture Contamination: Percent of blood cultures that grow bacteria that are highly likely to represent contaminants*

Performance of indicators should be compared with benchmarks, preferably from multi-institutional studies conducted within ten years of the laboratory's use of the monitor, where such surveys are available.

ANP.21050 Specimen Identity **Phase II**

The identity of every specimen is maintained through each step of tissue processing and block and slide preparation.

Laboratory of Pathology, CCR, NCI
Immunohistochemistry Laboratory
Room 2B58

Attachment B

REPEAT IMMUNOHISTOCHEMISTRY REQUEST

When you think that you received unsatisfactory or suboptimal immunostains, please bring original stains in question and completed form to the Surgical Pathology Office, 10/2B50. State a detailed reason for stain request, and kindly provide unstained slides for this purpose. All repeat stains must be approved by either Dr. Markku Miettinen, Head of the IHC Lab, or Dr. Armando Filie, Deputy Head of the IHC Lab. Do not bring requests directly to the IHC Lab without approval from the previously named pathologists. If repeat request is approved, another order for the repeat immunostain(s) must also be entered in SoftPath. Dr. Miettinen or Dr. Filie will bring the approved request to the IHC Lab, and a copy of the request will be retained in the QA files in that lab. If your request is not approved, you will be contacted directly.

Requesting Pathologist: _____

Date of Request: _____

CASE #(s): _____

Repeat Stain(s) Requested:_____

Reason for Repeat: _____

_____

_____

_____

_____

Appropriate number of unstained slides enclosed._____

Request approved_____ Not approved_____

_____ or _____

Dr. M. Miettinen Dr. A. Filie

Attachment C

Laboratory of Pathology, CCR, NCI
Immunohistochemistry Laboratory
Room 2B58

Immunohistochemistry Quality Monitoring

Month / Year: _____

Please complete an entry for each request for repeat stains that has been approved by the Technical Director, or if you identify a patient identification or quality control issue. This information is for Quality Management (QM) purposes only, and the only way to make the QM program effective is if everyone feels confident that this will only be used for QM purposes.

ERROR CODES:

PREANALYTIC

1. Mislabeled slides
2. Incorrect slides pulled from Histology
3. Incorrect block cut
4. Wrong control slide used
5. Incorrect stain ordered
6. Other identification error

ANALYTIC

7. Repeat stain required by pathologist request
8. Poor staining
9. Wrong stain performed
10. Incorrect protocol followed
11. Antibody diluted incorrectly
12. Other staining issue

Date of Incident	Accession #	Error Code	Issue and Corrective Action	Completed by (tech initials)

Supervisor Reviewed: _____ Date: _____ *(use back of form for more entries if needed)*

Date of Incident	Accession #	Error Code	Issue and Corrective Action	Completed by (tech initials)

Additional Comments: