

Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics-

College of American Pathologists

Request for Approval of New Data Collection

Supporting Statement B

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Appendices

- Attachment A. Authorizing Legislation
- Attachment B. Published 60-Day Federal Register Notice
- Attachment C. IHC Post-Dissemination Survey Paper Copy
- Attachment D. ALA Baseline Survey Monkey Screen Shots
- Attachment E. Privacy Act Checklist
- Attachment F. IHC Communication Materials
- Attachment G. ALA Communication Materials
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- Attachment J. Part I Worksheet
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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The College of American Pathologists will not perform any sampling for their IHC and ALA surveys.

2. Procedures for the Collection of Information

Overview of the Data Collection System

Immunohistochemistry Test Validation

The post survey for the immunohistochemistry (IHC) laboratory practice guideline includes questions about personal perspectives and preferences. The CAP will disseminate paper surveys (Attachment C) along with their PT mailings, to target all of the approximately 2885 laboratories already enrolled in the CAP Proficiency Testing (PT) program for any of the three PT modules they offer that involves immunohistochemistry testing, specifically, HER2 (human epidermal growth factor receptor 2 for breast cancer), the PIP (Performance Improvement Program in Surgical Pathology), and HQIP (HistoQIP Program for improving the preparation of histological slides). For these 2885 laboratories, the surveys will be included with the regular PT shipment and sent via the US postal system, with a fax-back mechanism.

CDC and CAP agreed that it will be desirable to also survey non-CAP-accredited laboratories that were not initially surveyed in order to better understand their awareness, perceptions, understanding, and uptake of the IHC LPG. The CAP will send a letter along with the paper copy of the IHC survey to invite this population to participate. (Attachment F- pg1) Therefore, an additional cohort of laboratories has been identified based upon their requests for reimbursement through Centers for Medicare and Medicaid Services (CMS) codes for Part B reimbursement, using any one of six Common Procedural Terminology (CPT) codes that represent IHC testing. Although 984 laboratories were initially identified as submitting at least one CPT reimbursement request, after the laboratories that were already known to CAP were removed, and a threshold of at least 9 reimbursement requests was used to remove laboratories that might have inadvertently used an incorrect CPT code, there were 450 remaining laboratories. This number is not intended to be a statistical sample; it represents all the non-CAP-PT customer accredited laboratories thought to be performing IHC testing. In other words, this additional cohort does not represent a sample of a larger population; it is inclusive of all laboratories thought to be performing IHC testing that are not currently CAP-PT customer accredited. No sampling or sampling statistics were necessary.

Acute Leukemia Algorithm

The baseline survey for the acute leukemia algorithm (ALA) laboratory practice guideline will be implemented electronically via Survey Monkey, their information collection software system (<http://www.surveymonkey.com/>). (Attachment D) The link to the baseline survey for the ALA guideline will be disseminated via email to 1100 pathologists who specialize in hematopathology. The CAP already has an internal database of pathologists who have indicated specialization in hematopathology. These hematopathologists who are CAP members represent the entire universe of

interest. The CAP will use a setting in Survey Monkey to accept only one response per computer Internet Protocol (IP) address.

3. Methods to Maximize Response Rates and Deal with No Response

The CAP and CDC will strive to ensure a high response rate for their IHC and ALA surveys. Prior to this CAP-CDC cooperative agreement, the CAP disseminated a mailing (Attachment F- pgs 2-3) to alert CAP-members who participated in the IHC baseline survey, that they will be sending out a post-dissemination survey and requests their participation. The CAP also plans to advertise it in CAP Today (Attachment F- pg4), a trade magazine that laboratories enrolled in the CAP PT Program, and some non-CAP-accredited laboratories, already receive. Similarly, the CAP plans to maximize response rates for CAP PT customer laboratories by sending reminders through the PT program. (Attachment F) The CAP will also try to maximize response rates for the ALA survey by advertising it in the CAP Pathology and Laboratory Quality Center quarterly newsletter (Attachment G- pg 2), the CAPconnect (its website for regular communications with members) (Attachment G- pg 3), the CAP website (Attachment G- pg 3), as well as through their CAP-member listserv (Attachment G- pg 1) and social media channels (Attachment G- pgs 2&4).

4. Tests of Procedures or Methods to be Undertaken

The IHC survey was pilot tested with 9 laboratory professionals representing a diverse spectrum of the kinds of pathologists, laboratory directors and laboratory managers who work in the types of laboratories that perform IHC testing, including hospital, independent (reference), and physician office laboratories (Attachment H). The ALA survey was pilot tested similarly on 7 laboratory professionals, but only the CAP list of hematopathologists will be used to identify representative pathologists. (Attachment I) In both cases, the CAP identified volunteers to take the survey and then, collected impressions concerning any ambiguities or other concerns and finally followed up with phone calls if necessary. While the CAP expects the IHC post-dissemination survey to take 20 minutes and the ALA baseline survey to take an average of 25 minutes to complete, the maximum times observed during pilot testing were 30 and 45 minutes, respectively. The CAP attempted to include a variety of geographical areas, including laboratories in smaller metropolitan areas, if possible. Results from the pilot tests were used to revise both surveys.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following provided consultation on survey design:

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Ms. Souers will also analyze survey data.