# CAP 2023 Predictive Marker Testing Updates

October 7, 2022

**Venus Brady:**

For 2023, the College of American Pathologist Laboratory Accreditation Program has made changes to proficiency testing requirements for laboratories performing predictive marker testing using immunohistochemistry. These changes reflect the need to assess the quality of predictive marker testing more broadly due to their importance in treatment decisions for patients with cancer. Today, Dr. Lisa Stempak, chair of the CAP's Continuance Compliance Committee has joined us to share more about the new requirements, the activity menu, changes for predictive markers, upcoming checklist changes, and the rationale for these updates. Welcome Dr. Stempak. Can you introduce yourself?

**Dr. Lisa Stempak:**

Thank you. Yes. My name is Lisa Stempak, and I'm the System Director of Clinical Pathology at University Hospitals in Cleveland, Ohio.

**Venus Brady:**

Thanks for joining us. So what changes are the laboratory accreditation program making around predictive marker testing?

**Dr. Lisa Stempak:**

In 2023 laboratories that perform both staining and interpretation of immunohistochemistry and in situ hybridization for predictive markers must participate in CAP accepted proficiency testing when it's required per the lab's activity menu, in addition to estrogen receptor and HER2 in breast cancer, which PT has been required for many years, high sensitivity ALK in small cell lung cancer, and HER2 and gastroesophageal adenocarcinoma will be required in 2023. Additional details can be located in the 2022 edition of the accreditation program checklist. This is COM.01520, which will be published in October of 2022 for all other predictive markers tested by these methods for which CAP doesn't require proficiency testing. Alternative performance assessment is required, at least semi-annually. Alternative performance assessment, at least semi-annually, is also required for labs that perform stain only or interpretation only components of testing for predictive markers. CAP has revised the activity menu to provide clear guidance regarding if proficiency testing or alternative performance assessment is required for protective markers based on the checklist modifications.

**Venus Brady:**

You mentioned that the activity menu changes were to make things a little clearer. Can you share a little bit more about why these changes are necessary?

**Dr. Lisa Stempak:**

Yes. These changes were made due to the significant implication that staining procedures and the interpretation of predictive markers have on patient treatment. It's critical to properly perform the staining technique and accurately interpret the results to ensure the correct targeted therapies are available to cancer patients. Since so much depends on a single test result, it's extremely that laboratories are performing testing well since high sensitivity, ALK and gastric, HER2 are known to be two of the more challenging tests to perform. The decision was made to require proficiency testing for these predictive markers in 2023 as correct results are crucial for therapeutic decision making.

**Venus Brady:**

Sounds like very important updates, but what about the laboratories? How will they benefit from this update?

**Dr. Lisa Stempak:**

Yeah, there's a couple benefits to the laboratories. Most importantly, by performing proficiency testing, laboratories will have an external assessment of the test performance of the predictive markers they're performing and how they compare to their peers. Acceptable proficiency testing performance provides an additional level of reassurance. The laboratory is reporting accurate results that will result in patients receiving the best therapy to treat their cancer. If laboratories are identified as doing suboptimal testing, we want to make them aware of issues in predictive marker performance and provide them with resources to improve. The goal is not necessary to have laboratory cease testing, but rather work to improve the predictive marker testing that is performed to result in accurate diagnoses and correct therapeutic options for patients. Finally, with the new structure for proficiency testing for predictive markers, labs that perform interpretation only will not be required to enroll in formal proficiency testing, which in the past has been burdensome and expensive. In a typical hubs spoke model where slides are stained and interpreted at the central laboratory or the hub, the stain slides are also sent to peripheral labs for ation known as the spokes, and now proficiency testing will only be performed for the central hub laboratory spoke, or peripheral laboratories that perform interpretation only can instead perform another form of quality assurance such as alternative performance assessment. And CAP is exploring new educational programs to meet this need.

**Venus Brady:**

So what should laboratories be prepared to do?

**Dr. Lisa Stempak:**

The first thing I recommend is for laboratories to carefully review the updates for proficiency testing of predictive markers in the 2022 edition of the accreditation program checklist. In particular item COM.01520. Then laboratories should update their activity menu for predictive markers accordingly. High sensitivity ALK and small cell lung cancer and HER2 in gastroesophageal adenocarcinoma will now be discrete items that should be selected. If the laboratory performs any of the various aspects of testing based on if the laboratory performs staining and interpretation, staining only or interpretation only, there will be clear guidance on the proficiency testing required. If the laboratory is performing staining and interpretation, they must enroll in CAP accepted proficiency testing for laboratories, doing stain only, interpretation only, or performing testing other predictive markers. In addition to the four that require CAP accredited proficiency testing, these labs should develop alternative performance assessment to be completed semi-annually to meet the checklist requirements for predictive markers.

**Venus Brady:**

And you mentioned that there are some new resources on the way, but do we currently have any resources available for laboratories to help navigate these changes?

**Dr. Lisa Stempak:**

Yes. In addition to the details in the accreditation program checklist and the test menu guidance, CAP does have a number of high quality resources to assist laboratories in making the necessary changes. I encourage labs to register and participate in two upcoming focus on compliance webinars to learn more about the changes to predictive markers and other checklist updates. The first is October 19th, and it's a webinar entitled 2022 CAP Accreditation Checklist Updates, changes That Matter. And then in November, there's a webinar on November 16th titled Update on CAP Accreditation Programs, how it Started, how it's going. In addition, for those that are attending the 2022 annual CAP meeting, there will be an onsite 90 minute session on October 9th titled "Tips and Tools for Quality Planning, Predictive Marker Monitoring and Performance Improvement by IHC." This session will discuss the elements of an IHC laboratory quality plan. It will explain the requirements for monitored IHC predictive markers. It will present case-based studies for process improvement of selective markers, and talk about strategies that can be applied to additional markers such as PD-L1 in the future. Also recommends labs to check out the article titled What's Required in 2023 for Predictive Marker Tests in the September edition of CAP Today. And then as always, laboratories can reach out to CAP directly by phone or email if they have any questions on activity, menu options, or PT requirements for predictive marker testing.

**Venus Brady:**

You're right, there are a lot of great resources available. Well, I'd like to thank you again for joining me today. For more information on PT requirement and activity menu changes for predictive marker testing using IHC methods, visit cap.org and search predictive marker testing by IHC.