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Empowering Pathologists to Lead Immuno-Oncology (IO) Biomarker Testing in the Community

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BACKGROUND

As the landscape of immuno-oncology (IO) expands, there is a growing need to improve biomarker testing processes in the community. To educate and empower pathologists to lead in this area, the American Society for Clinical Pathology (ASCP) worked in collaboration with Q Synthesis to develop a peer-to-peer learning collaborative.

METHODS

ASCP recruited a group of 18 pathologists and laboratory professionals who made the commitment to participate in a 10-month program called IO ChangeMakers. Learners completed online modules covering scientific updates on IO biomarker testing. They went into small groups for case study discussions and reviewed operational challenges and opportunities to refine biomarker testing. Learners applied this knowledge to lead IO improvement projects at their own institutions.

The ASCP I-O ChangeMakers program included participants from the following organizations:

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- Alverno Laboratories
- AMITA St. Mary Elizabeth Medical Center
- Atlanta VA Medical Center
- Danbury Hospital
- Flagship Biosciences
- Memorial Hermann Health System
- Mills-Peninsula Medical Center Sutter Health
- University of Illinois Chicago
- University of Kentucky
- University of Minnesota
- University of Wisconsin Madison
- Urology Austin
- VA Greater Los Angeles Healthcare System
- VA Puget Sound - Seattle
- Versiti Blood Center of Wisconsin
- Yale School of Medicine

SUMMARY

- The landscape of immuno-oncology (IO) continues to grow and affect the treatment plans of many types of cancers
- Pathologists and laboratory professionals need to know how to navigate real-world challenges that impact IO biomarker testing
- The details surrounding PD-L1 testing continues to grow in complexity (eg, antibody clones, scoring criteria)
- Pathologists and laboratory professionals can demonstrate leadership around IO biomarker testing and optimize procedures to ensure the right patients are tested in a timely fashion

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RESULTS

Learners led improvement projects that addressed the following:

Reflex testing: Several developed or refined reflex biomarker testing processes to ensure that tissue was sent for PD-L1 testing at the time of cancer diagnosis. Pathologists established testing criteria with oncologists and implemented steps to reduce delays in testing.

Interobserver concordance: One learner identified a need to study interobserver concordance among pathologists diagnosing upper GI cancers and scoring PD-L1 using the combined positive score (CPS). After scanning over 100 gastric cancer slides, different pathologists were asked to provide CPS scoring on the digital images. Results from this study are still pending.

Tissue handling: Several identified ways to improve tissue processing and handling to preserve small amounts of tissue for biomarker testing. In cases where the quantity was not sufficient, pathologists asked the lab to prioritize PD-L1 testing and asked oncologists to order a liquid biopsy to look for molecular biomarkers.

Confusion around different PD-L1 antibody clones: Several aimed to reduce confusion regarding different PD-L1 antibody clones (eg, 22C3, SP142, etc.) and scoring criteria (eg, TPS ≥ 1%, CPS ≥ 10, TC ≥ 25%, etc.). They developed reference guides and education for staff to ensure that oncologists would order the right type of PD-L1 test based on the type of tumor, stage of disease, and intended treatment.

Test ordering to reporting: Most worked in hospitals where samples were sent out for PD-L1 testing. The use of different electronic systems (health record, lab information system) resulted in multiple inefficiencies when tests were ordered. They found ways to improve electronic test ordering, tracking status, and reporting results.

CONCLUSIONS

Pathologists can be empowered to lead improvement efforts in biomarker testing. As the use of IO expands into more cancers, there will be a growing need for more pathologists to demonstrate leadership in this area.