LEICA BIOSYSTEMS
STUDY SUMMARY

ACCURACY STUDY FOR THE BOND MMR ANTIBODY PANEL

STUDY SCOPE

The scope of the study was to compare the immunohistochemistry (IHC) profiles of an enriched cohort of 143 colorectal cancer (CRC) specimens against the molecular profiling data of the same samples using next-generation sequencing (NGS). The performance of the BOND MMR Antibody Panel consisting of our BOND MMR Ready-to-Use (RTU) antibodies MLH1, MSH2, MSH6 and PMS2 was compared to NGS molecular technology.

The overall intent of the study was to assess the performance of the BOND MMR Antibody Panel as an aid in the identification of cases that would benefit from additional genetic testing.

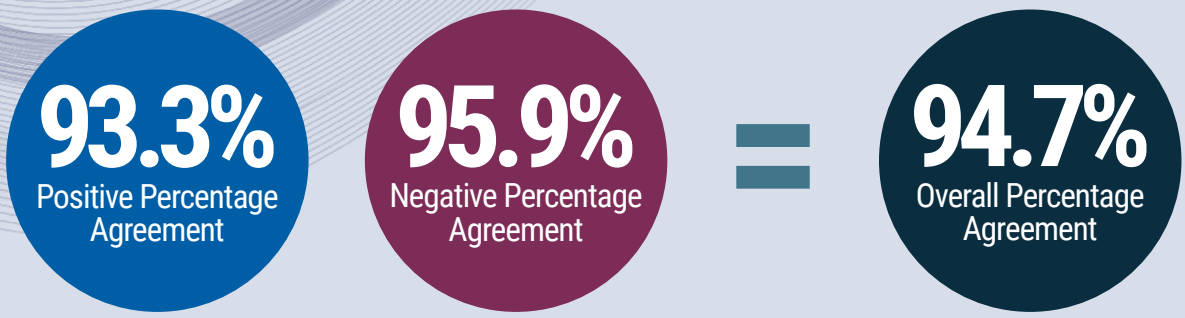
METHOD

The BOND MMR Antibody Panel is intended for use on the BOND-III or BOND-MAX fully automated systems with BOND Polymer Refine Detection (DS9800) for the qualitative identification of human mismatch repair (MMR) proteins MLH1, MSH2, MSH6 and PMS2 in formalin-fixed, paraffin-embedded (FFPE) CRC tissue sections by IHC staining.

For each of the four 7 mL BOND RTU primary antibodies, units from the same lot of product were used to stain 3 µm sections cut from each of the 143 genetically characterized FFPE CRC cases. Tissues were sectioned and stained per standard protocols.

RESULTS

Agreement of the BOND MMR Antibody Panel IHC Results and Molecular Analysis (Full Accuracy Cohort)



Point estimates for overall agreement between the 4 MMR RTU antibodies in the BOND MMR Antibody Panel and the molecular analysis data.

FOR IN VITRO DIAGNOSTIC USE

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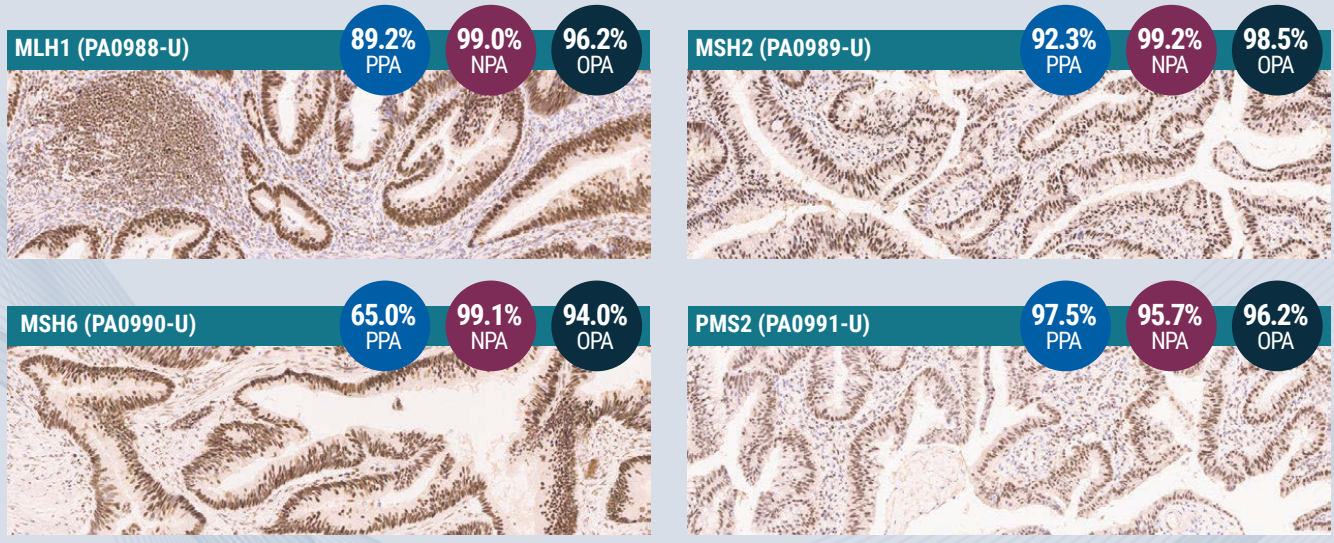
RESULTS

Concordance by Marker With Molecular Profiles



PPA Positive Percentage Agreement

NPA Negative Percentage Agreement

OPA Overall Percentage Agreement

DISCUSSION

The major drawback of microsatellite instability testing for mismatch repair is that it is expensive and can be performed only in selected laboratories. Moreover, it does not identify the specific MMR gene abnormality. IHC is now increasingly used in clinical practice for screening patients with possible mismatch repair protein presence or absence. This data supports the use of the BOND MMR Antibody Panel from Leica Biosystems to determine their expression of the corresponding protein.

The results of this study provide a comparison of the IHC staining profiles generated by the BOND MMR Antibody Panel and results of NGS analysis for a set of 137 CRC FFPE tissue samples. The BOND MMR Antibody Panel produced an OPA of 94.7% when compared against the NGS data as the reference for all the samples included in the study.

When each antibody was considered in isolation, the OPAs were; 96.2% for MLH1 (ES05) PA0988-U, 98.5% for MSH2 (79H11) PA0989-U, 94.0% for MSH6 (EP49) PA0990-U and 96.2% for PMS2 (EP51) PA0991-U.

This data supports the use of the BOND MMR Antibody Panel for the identification of proteins with MMR deficiencies and as a preliminary screening method for Lynch Syndrome.

Leica Biosystems is a global leader in workflow solutions and automation. As the only company to own the workflow from biopsy to diagnosis, we are uniquely positioned to break down the barriers between each of these steps. Our mission of "Advancing Cancer Diagnostics, Improving Lives" is at the heart of our corporate culture. Our easy-to-use and consistently reliable offerings help improve workflow efficiency and diagnostic confidence. The company is represented in over 100 countries. It has manufacturing facilities in 9 countries, sales and service organizations in 19 countries, and an international network of dealers. The company is headquartered in Nussloch, Germany. Visit LeicaBiosystems.com for more information.

221250 Rev C • 07/2023

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