November 21, 2019

Part B Policy
PO Box 100238 (JM) and
PO Box 100305 (JJ)
AG-315
Columbia, SC 29202
MolDX@palmettogba.com

RE: MolDX: Erythrocyte Molecular Antigen Typing (DL38240)

Dear Dr. Bien-Willner,

Thank you for the opportunity to review and comment on Palmetto's proposed coverage policy for Erythrocyte Molecular Antigen Typing DL38240. The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

The College of American Pathologists (CAP) is the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs. The CAP serves patients, pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

Members of AMP and the CAP appreciate the willingness by Palmetto to offer limited coverage for molecular typing of red blood cell antigens using both FDA-approved tests and laboratory developed tests that meet the criteria outlined in the proposed policy. Given the level of evidence at this time our organizations agree with the limited coverage that is outlined in the proposed policy.

Thank you again for the opportunity to review and comment on this proposed policy. If you have any questions please direct your correspondence to Tara Burke, AMP Senior Director of Public Policy, at tburke@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@cap.org. Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@cap.org.


Sincerely,


Association for Molecular Pathology
College of American Pathologists