

Euroimmun IFA mosaics cleared with EuroPattern

October 2018—PerkinElmer announced that its Euroimmun ANCA IFA and Europlus Granulocyte Mosaic assays for use with its EuroPattern microscope have received 510(k) clearance from the FDA. The Euroimmun IFA Granulocyte assays are designed as indirect immunofluorescence tests for the qualitative or semiquantitative determination of antineutrophil cytoplasmic antibodies of immunoglobulin class IgG in human serum. The Europlus Granulocyte Mosaic EuroPattern assay allows for additional monospecific detection of anti-PR3, anti-MPO, and anti-GBM IgG antibodies. These IFA mosaics, together with the FDA-cleared EuroPattern microscope, are used to aid in the diagnosis of ANCA-associated vasculitis. The multiplexing capabilities of the assays, in combination with Biochip technology, allow for complete ANCA screening in a single well.

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