Platelet and Granulocyte Antigen and Antibody Testing Scenarios

Scenario

You are inspecting a hospital based HLA laboratory that is accredited for the areas of solid organ transplantation, deceased and live donor, and transfusion support. The laboratory is staffed with a director who serves as the technical supervisor and clinical consultant, a general supervisor and 4 technologists. The laboratory is a component of the hospital laboratories and as such is under the same CLIA number as most of the other hospital labs. The Chair of hospital laboratories is named as director on the CLIA certificate.

The laboratory performs low/intermediate resolution HLA Class I and II typing and platelet genotyping by SSP. The laboratory also performs platelet antibody screening using a commercially available, FDA cleared, ELISA assay that detects antibodies to common platelet antigens. This ELISA also detects antibodies to HLA Class I antigens but does not determine the specificity of the HLA antibodies. HLA antibody testing is also performed using a Luminex® bead array (both a screening assay and single antigen bead test. Typing and antibody tests are performed upon physician request. The laboratory report results electronically in the laboratory information system. For the workup of platelet refractory patients, the results of HLA/HPA genotyping and/or antibody testing are reported to the transfusion medicine service that is then responsible for using this information to obtain appropriate platelet units for refractory patients.

You begin your inspection with a meeting with the laboratory director, then a brief introductory meeting with the staff to outline the plan for the day. An audit based inspection is performed. After completing your audit, the inspection is ended with a summation for staff and representatives from the hospital and hospital laboratory administration.