a blood or plasma unit that was the source of the sample if the sample contains reactive atypical antibodies.

In one aspect, there is provided a method for interdicting a blood or plasma unit in a blood products manufacturing process, the method comprising: (a) obtaining a sample of blood or plasma from a blood or plasma unit; (b) testing the sample and a control using any one or more of cellular agglutination, fluorescence microscopy, immunoprecipitation, immunodiffusion, immunofluorescence, ELISA, flow cytometry, FACS, or Western blotting; (c) comparing the sample and control testing results; (d) determining whether the sample contains atypical reactive antibodies that cross reacts with rabbit white blood cell antigens; and (e) interdicting the blood or plasma unit that was the source of the sample if the sample contains said atypical reactive antibodies.

Another aspect described herein is a method for identifying atypical reactive antibodies in a blood products manufacturing process, the method comprising: (a) obtaining a sample of blood or plasma; (b) testing the sample and a control using a cellular agglutination assay; (c) comparing the sample and control testing results; (d) determining whether the sample contains reactive atypical antibodies; and; (e) interdicting a blood or plasma unit that was the source of the sample if the sample contains reactive atypical antibodies.

Another aspect described herein is a method for identifying atypical reactive antibodies in a blood products manufacturing process, the method comprising: (a) obtaining a sample of blood or plasma; (b) testing the sample and a control using flow cytometry; (c) comparing the sample and control testing results; (d) determining whether the sample contains reactive atypical antibodies; and; (e) interdicting a blood or plasma

unit that was the source of the sample if the sample contains reactive atypical antibodies.

Another aspect described herein is a method for identifying atypical reactive antibodies in a blooda plasma products manufacturing process, the method comprising: (a) obtaining a sample of blood or plasma; (b) testing the sample and a control using Western blotting; (c) comparing the sample and control testing results; (d) determining whether the sample

contains reactive atypical antibodies; and; (e) interdicting a blood or plasma unit that was the source of the sample if the sample contains reactive atypical antibodies.

Another aspect described herein is a method for evaluating potential false positive pyrogen test results in a blood products manufacturing process, the method comprising: (a) obtaining a sample of blood or blood product; (b) testing the sample and a control using fluorescence microscopy, immunoprecipitation, immunodiffusion, immunofluorescence, ELISA, flow cytometry, FACS, or Western blotting; (c) testing the sample and a control using the Limulus Amebocyte Lysate (LAL) or similar assay; (d) comparing the sample and control testing results in both assays; (e) evaluating whether the sample gave a false positive pyrogen test result; and (f) interdicting a blood or plasma unit that was the source of the sample if the sample contains reactive atypical antibodies.

In another aspect, there is provided a method for evaluating potential false positive pyrogen test results in a blood products manufacturing process, the method comprising: (a) obtaining a sample of blood or blood product; (b) testing the sample and a control using fluorescence microscopy, immunoprecipitation, immunodiffusion, immunofluorescence, ELISA, flow cytometry, FACS, or Western blotting; (c) testing the sample and a control using the Limulus Amebocyte Lysate (LAL) or similar assay; (d) comparing the sample and control testing results in both assays; and (e) evaluating whether the sample gave a false positive pyrogen test result, wherein the sample containing atypical reactive antibodies that cross react with rabbit white blood cell antigens is indicative of false positive pyrogen test results.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1: Microscopy of Rabbit WBC Agglutination Assays. Donor X and control plasma were incubated with rabbit WBCs and then viewed using microscopy. Light (A, B) and phase contrast (C, D) photomicrographs of rabbit white blood cells incubated with Donor X plasma (A, C) or control plasma (B, D). Agglutination was observed with the Donor X plasma (A, C), but not with the plasma control (B, D).

Figure 2: Microscopy of Human WBC Agglutination Assays. Donor X and control plasma were incubated with human WBCs