

3. 510(k) SUMMARY

3.1. Applicant Information

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3.2. Device Information

Trade Name: Hemo-QC

Common Name: Simulated Whole Blood Control

Classification Name: Quality Control for Blood Banking Reagents
(21 CFR 864.9650, Class II, Product Code
KSF)

3.3. Predicate Device

Alba Bioscience "AlbaQ-Chek Simulated Whole Blood Controls." The 510(k) cleared under BK070033 for use as ABO, RhD, and antibody screening controls for automated/semi-automated blood grouping systems using column agglutination techniques.

3.4. Performance Standard

No United States standard of potency exists. Hemo bioscience performs lot release testing using US FDA licensed blood bank reagents.

3.5. Device Description

Hemo-QC is supplied as a set of three (3), 7 mL tubes, each containing a 6 mL suspension of red blood cells in a preservative diluent containing bovine serum albumin. These red blood cells have been manufactured and prepared at a hematocrit of $15\% \pm 2$.

The diluent is a buffered solution containing antibiotics.

3.6. Intended Use

Hemo-QC is used to confirm the correct performance of ABO, RhD typing and antibody detection reagents.

3.7. Summary of Technological Characteristics

The contents of each tube have been manufactured to contain the appropriate ABO and Rh(D) blood group antigens as well as corresponding ABO blood group antibodies. Correct performance of ABO/Rh blood grouping reagents are confirmed when expected results are obtained with Hemo-QC. In order to confirm correct performance of antibody screening and identification systems, an anti-Fya and anti-D are contained in tubes 2 and 3 respectively of Hemo-QC.

Hemo-QC and the predicate device are identical in intended use as a control for automated, semi-automated and manual blood bank technologies.

3.8. Summary of Hemo-QC Performance and Stability Study

An external performance and stability study was conducted in three external blood bank laboratories using blood bank automation over a period of time with Hemo-QC product manufactured by Hemo bioscience according to SOP HB-MN-31 Manufacture of Hemo-QC. The study was also performed in-house using manual testing methods.

During the study, Hemo-QC was tested daily for appearance and reactivity. Daily appearance testing consisted of centrifuging a set of Hemo-QC controls and recording any appearance changes, such as color changes, hemolysis or turbidity. Daily reactivity testing required an ABO/Rh forward and reverse type along with an antibody screen to be run according to each laboratory's standard operating procedures. The testing was performed by three off-site laboratories using three different automated blood bank technologies: Immucor Capture Solid Phase, Ortho MTS Gel Test and Bio-Rad Solidscreen II. During the external performance and stability study, Hemo-QC was also being tested in-house using three different manual blood bank technologies (Capture Solid Phase, Ortho MTS Gel Test and tube testing). Results were evaluated in terms of appearance and reactivity throughout the studies.

3.9. Summary of Hemo-QC Reproducibility Study

In order to evaluate the lot to lot reproducibility of Hemo-QC, four different lots were manufactured by Hemo bioscience according to SOP HB-MN-31. Each lot was assessed by testing the ABO/Rh forward and reverse type, along with an antibody screen using three manual blood bank methods. Once testing was completed, the data from the four lots were compared.

3.10. Summary of Hemo-QC Neutralization Study

The neutralization study was performed to show that Hemo-QC can detect neutralized anti-human globulin (AHG) reagent when performing an indirect antiglobulin test (IAT).

3.11. Summary of Hemo-QC Enzyme Treatment Study

An enzyme treatment study was performed to evaluate the ability of Hemo-QC to detect if antibody screening cells have been exposed to a proteolytic enzyme. In the laboratory setting, this enzyme exposure could be due to enzyme treatment for antibody identification or bacterial contamination of the reagent red cells. When red cells are exposed to proteolytic enzymes, certain blood group antigens are modified. The target antigen system in this study is the Duffy blood group system, which is destroyed by proteolytic enzymes.

3.12. Summary of Hemo-QC Specificity Study

The specificity of Hemo-QC was evaluated by testing it with several different scenarios. An error could occur in the laboratory setting if the reagent vial contains improper contents, a reagent is mislabeled or typing reagents are accidentally switched during the testing process (most likely to occur with manual users).

3.13. Conclusion of Performance and Stability, Reproducibility, Neutralization, Enzyme Treatment and Specificity Studies

The above mentioned studies confirmed the satisfactory performance of the Hemo bioscience Hemo-QC and its suitability as a control reagent.