



**Premarket Notification 510(k)
ALBAcheck® - BGS Reagent Control for Anti-D**

Appendix 3

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92" on behalf of

Alba Bioscience Limited, 21 Ellen's Glen Road, Edinburgh EH17 7QT, Scotland, United Kingdom.
Tel. +44 (0)131 536 5907
Contact : Ian Carmichael, Quality and Regulatory Affairs Director
Date: May 30th, 2008

Name of Device: ALBAcheck® - BGS Reagent Control for Anti-D
The assigned 510(k) number is: BK

ALBAcheck® - BGS Reagent Control for Anti-D is classified as a Quality Control Kit for Blood Banking Reagents under the classification number: 864.9650 as Product Code: KSF.

ALBAcheck®- BGS Reagent Control for Anti-D is intended for use as a negative control in conjunction with Alba Bioscience monoclonal Anti-D reagents.

ALBAcheck®- BGS Reagent Control for Anti-D is formulated in a similar manner as Alba Bioscience's monoclonal Anti-D reagents (Product No's: Z031, Z036, Z039, Z041). The reagent also contains 7.46 g/L EDTA and 1g/L sodium azide.

ALBAcheck®- BGS Reagent Control for Anti-D is substantially equivalent to another currently marketed predicate the Immucor Monoclonal Control. The intended use of these two devices is the same.

ALBAcheck®- BGS Reagent Control for Anti-D is designed for the control of reagents used in slide and tube techniques whereas the Immucor Monoclonal Control is designed for use in slide, tube and microplate testing. The technological characteristics are similar as the Immucor Monoclonal Control is a phosphate buffered saline solution which contains glycine, EDTA, bovine albumin, gelatin and sodium azide in concentrations similar to that found in Immucor monoclonal blood grouping reagents and ALBAcheck®- BGS Reagent Control for Anti-D contains the same components as a monoclonal reagent without the antibody.

Conclusions

From clinical, non-clinical tests and available data sources and comparison of the results presented at 4.1, it is possible to conclude substantial equivalence between the ALBAcheck®- BGS Reagent Control for Anti-D and the Immucor Monoclonal Control.

ALBAcheck®- BGS Reagent Control for Anti-D is as safe, as effective and is substantially equivalent to the legally marketed predicate device the Immucor Monoclonal Control.



**Premarket Notification 510(k)
ALBAcheck® - BGS Reagent Control for Anti-D**

Appendix 4

PERFORMANCE TESTING

4.1 Comparator Study Summary

ALBAcheck®- BGS Reagent Control for Anti-D, Product Code Z271

The comparator study was undertaken to demonstrate Substantial Equivalence (SE) between ALBAcheck®- BGS Reagent Control for Anti-D and the legally marketed predicate the Immucor Monoclonal Control, 510(k) number BK070013.

ALBAcheck®- BGS Reagent Control for Anti-D has the same intended use as the predicate device the Immucor Monoclonal Control. ALBAcheck®- BGS Reagent Control for Anti-D is designed for the control of reagents used in slide and tube techniques whereas the Immucor Monoclonal Control is designed for use in slide, tube and microplate tests. The technological characteristics are similar as the Immucor Monoclonal Control is a phosphate buffered saline solution which contains glycine, EDTA, bovine albumin, gelatin and sodium azide in concentrations similar to that found in Immucor monoclonal blood grouping reagents and ALBAcheck®- BGS Reagent Control for Anti-D contains the same components as a monoclonal Anti-D reagent without the antibody.

Tests of both kits were carried out according to the manufacturers recommended methods by suitably trained Alba Bioscience Staff. All results obtained were acceptable and demonstrated that the respective products were fit for their intended purpose as a negative control for the respective manufacturers Anti-D monoclonal blood grouping reagents by both tube and slide techniques.

Comparison of the two kits using the same methods indicated substantive equivalence between the ALBAcheck®- BGS Reagent Control for Anti-D and the US legally marketed predicate Immucor Monoclonal Control Reagent.