SECTION 5—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

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2. Device Name*:

Device Trade Name:	IH-A[b]ID
Common Name:	IH-A[b]ID Integrated Antibody Identification Software
Classification Name:	Blood Establishment Computer Software and Accessories
Product Code:	MMH
Regulation Number:	21 CFR 864.9165
Regulatory Class:	Class II

* IH-A[b]ID Integrated Antibody Identification Software is an optional software module for IH-Com V5.2. The IH-Com V5.2, product code KSZ: Automated Blood Grouping and Antibody Test System, is an FDA cleared device (BK190424) and has changes no substantial since the clearance in December 2019.

3. Identification of Legally Marketed Device (Predicate Device):

Device Trade Name:	ANTIGEN PLUS
Common Name:	Blood establishment standalone software
Classification Name:	Blood Establishment Computer Software And Accessories
510(k) Number	BK110045
Product Code:	MMH
Regulation Number:	21 CFR 864.9165
Regulatory Class:	Class II
Clearance Letter	May 25, 2012

4. Description of the Device:

IH-A[b]ID Integrated Antibody Identification Software is an optional software module for IH-Com that provides the user with guidance and information on the identification of antibodies to red blood cell antigens. It is an additional software module designed to be fully integrated with the existing IH-Com data management and result interpretation software.

Red blood cell antibody identification is used to determine the specificity after an antibody has been detected. The technique involves the interpretation of agglutination reactions obtained between patient serum/plasma and panel Reagent Red Blood Cells (RRBCs) with known antigenic composition for the major blood group systems. These phenotypes are presented in an antigen table. A process of antibody exclusion is followed based on the reactions between patient serum/ plasma and each individual panel cell.

IH-A[b]ID Antibody Identification Software graphically aids in the identification and ruling out of antibodies to red blood cell antigens, thereby automating the manual techniques of antibody identification used in blood transfusion laboratories. The software does not provide diagnostic interpretations of antibodies and the final decision remains that of the user.

Information about the related device:

The related device IH-Com v5.2 is an FDA cleared device (BK190424) and has no substantial changes since the clearance in December 2019.

IH-Com V5.2 is data management and result interpretation software used in immunohematology testing to analyze reaction images for blood samples that are tested on the IH-1000, IH-500 and IH-Reader 24 with IH-System reagents or the TANGO infinity® with reagents specifically formulated and manufactured by Bio-Rad Medical Diagnostics GmbH. It manages sample, patient, donor, QC and reagent data.

IH-Com can be used only in combination with Bio-Rad in vitro diagnostic device(s) and is regarded as an "Rx only" immunohematological diagnostic product, used by trained laboratory personnel in a blood banking environment.

The IH-Com software is designed to provide an interface between the user, Bio-Rad instruments and the Laboratory Information System (LIS). It transfers orders for patient or donor samples to a blood banking test system like the IH-500 and uses the image results for final test interpretation. The image results can be visually checked and verified in IH-Com before result validation and report printing or result transfer to LIS. IH-Com allows also the storage and management of patient, donor, QC, sample and reagent data.

5. Intended Use:

IH-A[b]ID Integrated Antibody Identification Software is an optional software module for IH-Com that provides the user with guidance and information on the identification of antibodies to red blood cell antigens subsequent to the immunohematology testing with the IH-system. For use by trained laboratory personnel, in a blood banking environment.

6. Technological Characteristics

Substantial Equivalence Comparison

Parameter	**Predicate Device** **ANTIGEN PLUS (Rowny Systems Inc.)**	**Subject Device** **Bio-Rad IH-A[b]ID Integrated Antibody Identification**
Indications for Use Statement	ANTIGEN PLUS is a software application intended for use by professionals in blood establishments. It is intended to aid the user in the identification of red cell antibodies	IH-A[b]ID Integrated Antibody Identification Software is an optional software module for IH-Com that provides the user with guidance and information on the identification of antibodies to red blood cell antigens subsequent to the immunohematology testing with the IH-system. For use by trained laboratory personnel, in a blood banking environment
Classification	II	same
Product Code	MMH	same
Regulation Number	21 CFR 864.9165	same
510(k) Number	BK110045	-
Common Name	ANTIGEN PLUS	IH-A[b]ID Integrated Antibody Identification Software
Tests managed	Antibody Screening Antibody Identification	same
User interface	Duplicates the existing antibody test procedures used in blood reference laboratories in a graphical electronic form.	same

Parameter	**Predicate Device** **ANTIGEN PLUS (Rowny Systems Inc.)**	**Subject Device** **Bio-Rad IH-A[b]ID Integrated Antibody Identification**
Use environment	Blood bank software used by reference laboratories and transfusion services—an application with functionality specifically for blood establishments	same
Primary components	Installed on a PC workstation or on the server of a local area network (LAN)	Installed on a PC workstation (integrated in IH-COM software)
Minimal Operating System	Windows Vista	Windows 7
Interpretation	Makes no decision about which antibodies are present. It helps the technologist select the best red cells for testing, analyze which antibodies are ruled out and decide which antibodies are present.	same
Results import	Manual import of analyzer results	Results automatically imported from connected Bio-Rad analyzers
Reagent data	Reagent data is updated by the submitter from data sheets provided with each new lot of reagent cells distributed by the original manufacturers.	same
	Manufacturers reagent data to be downloaded from website	Bio-Rad IH-Reagent Red Blood Cell data scanned from 2D barcode from antigen tables supplied with each lot of cells.

Parameter	**Predicate Device** **ANTIGEN PLUS (Rowny Systems Inc.)**	**Subject Device** **Bio-Rad IH-A[b]ID Integrated Antibody Identification**
	Reagent data is available for query in retained files.	same
	Allows the technologist to select the best cells to rule out the remaining antibodies	same
Displayed results	Shows which antibodies are ruled out based on negative test results for both homozygous and heterozygous positive antigens on reagent cells, and displays a count of these rule-outs.	same
	Displays reagent cell antigens in the various antigen display orders used by the manufacturer, for ease of comparison and verification of the data	same
	Results displayed in fixed columns	Columns can be sorted by probability (option)
	Not possible to see microwell images sent from analyzer	Mouse over reaction strength displays the image sent from analyzer
Results management	The software's results are repeatable so a reviewer may check the technologists' work and decisions.	same
Comments	The software allows for explanatory notes for each saved custom worksheet.	same
Probability calculation	p-Value not calculated	p-Value calculation (optional) associated to each antibody specificity

Parameter	**Predicate Device** **ANTIGEN PLUS (Rowny Systems Inc.)**	**Subject Device** **Bio-Rad IH-A^{b}ID Integrated Antibody Identification**
Audit trail	No audit trail for sample processing and verification	Audit trail of processing steps and user actions
Additional tests	Additional tests need to be manually requested on the analyzer	Additional tests are automatically requested on the connected analyzer
Identified antibodies	Identifies antibodies against 28 principal antigens	IH-A^{b}ID identifies antibodies against 37 principal antigens:

7. Conclusion

In support of this premarket notification, a clinical study was performed based on the written feedback from the FDA (BQ190436; dated January 29, 2020).

The clinical testing was done to evaluate the performance of IH-A[b]ID Integrated Antibody Identification Software V1.0 for IH-Com with end users in a clinical setting. The objective of the study was to demonstrate that the labelling, training, and graphical user interface support the safe and effective use of the software.
The performance of the IH-A[b]ID Integrated Antibody Identification Software V1.0 for IH-Com was evaluated by a total of three intended use operators between two US sites. The antibody determination was performed manually, using AABB standard practices, and with IH-A[b]ID Integrated Antibody Identification Software. The results between the two methods were compared for concordance.

The data generated during this performance evaluation support the conclusion that the results obtained using the A[b]ID Integrated Antibody Identification Software V1.0 are comparable to results obtained using standard antibody identification practices with manually completed worksheets by an experienced user and that the labeling, training, and graphical user interface support safe and effective use of the software when used as a tool for assisting in antibody identification.

Bio-Rad concludes, based on the indications for use, technological characteristics and performance testing, that IH-A[b]ID Integrated Antibody Identification Software V1.0 is safe and effective for the intended use described above.