7.0 510(k) Summary

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510(k) Owner

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Modified Device Information

Device Classification Name	Blood Establishment Computer Software And Accessories
Tradename	ImmuLINK (v3.0)
Device Name	Blood Establishment Computer Software And Accessories
Regulation Number	864.9165
Classification Product Code	MMH
Classification Advisory Committee	Hematology
Review Advisory Committee	Hematology

Predicate Device Information

Tradename	ImmuLINK, V.1.7
Company	Immucor, Inc.
510(K) Number	BK150333
Decision Date	11/19/2015
Regulation Number	864.9165
Classification Product Code	MMH

Tradename	Bio-Rad IH-AbID Integrated Antibody Identification
Company	Bio-Rad Medical Diagnostics GmbH Industriestrasse 1
510(K) Number	BK220769
Decision Date	12/7/2022
Regulation Number	864.9165
Classification Product Code	MMH

Device Description

ImmuLINK (ImmuLINK®|manage combined with ImmuLINK®|archive) is a software package designed to provide an interface between the operator, blood bank automated (and semi-automated) instruments and Blood Establishment Computer Software, such as the Laboratory Information System (LIS). ImmuLINK|manage, combined with ImmuLINK|archive, allows the integration of sample, donor, or patient data that has been collected from multiple sources and provides data management tools to create customizable reports from the diverse data.

ImmuLINK|manage, combined with ImmuLINK|archive, is configurable to interface with multiple instrument platforms including (but not limited to) Immucor's Galileo Neo, NEO Iris, Galileo Echo and Echo Lumena Blood Bank Systems, and BioArray's Array Imaging System (AIS) semi-automated instrument and associated products.

ImmuLINK|manage is used as a remote validation tool so that the result of a test produced by a testing platform can be validated prior to delivery to an LIS. This delivery is characterized by the transmission of an information package. The result validation requires an electronic signature for approval and can be performed remotely without having to be in the laboratory where the result was produced. Results can also be viewed and edited prior to the ImmuLINK|manage validation.

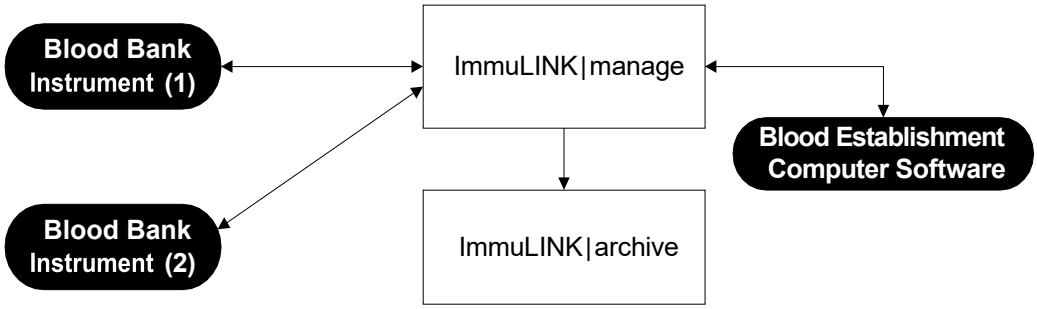
ImmuLINK|manage has bi-directional features, whereby test orders can be retrieved from the LIS and then transmitted to the appropriate instrument platform(s).

ImmuLINK|manage includes an Antibody ID feature which provides review of Master List for Capture-R products combined with instrument results and optional antibody exclusion (rule-out) capabilities.

ImmuLINK|archive is used to create and view result archives, which are stored in a secure environment.

Relationship between Instruments and ImmuLINK|manage

The diagram below summarizes the functional relationships between instruments and ImmuLINK|manage, using the example of two (2) blood bank instruments:



ImmuLINK Antibody ID Feature

Antibody ID (also referred to as Panel ID) allows viewing master list information, executing the Antibody ID algorithm evaluation, assigning an antibody to the result, and printing the results on a master list template.

The Antibody ID algorithm for applying rules as defined in AABB manual for rule out/in of antibodies in blood samples. The algorithm will provide user with suggested antibody assignments or antibodies that require additional investigation.

The algorithm available with Antibody ID is a first step in the antibody identification process. The algorithm will exclude using one double dose example of an antigen where the genetic background is known. The algorithm rules were derived using the *AABB Technical Manual, 18th Edition*, Chapter 16 – "Identification of Antibodies to Red Cell Antigens".

In cases like Lewis and P1 blood groups, the antigenic presentation cannot be determined. To accommodate this the algorithm will use either two or three antigen positive cells that do not react with the sample to exclude. Immucor personnel can configure ImmuLINK to use two or three cells according to customer policy or practice. In the presence of anti-D, C and E can be excluded on single dose cells (r'r, and r"r). This exclusion is included in the algorithm calculation of ImmuLINK.

Intended Use

ImmuLINK is software intended for use in a blood banking environment as an aid in interfacing and managing data between blood bank instruments, Blood Establishment Computer Software, and Laboratory Information Systems. ImmuLINK includes the following features and/or functions:

- It provides the ability to create and print reports of tests and results.
- It supports the ability to compare current results with previous results.
- It supports the automatic ordering of reflex tests.
- It provides a tool so that test results produced by a testing platform can be

remotely validated prior to delivery to an LIS. Results can also be viewed remotely and edited prior to delivery to an LIS.

- It provides bi-directional communication between an LIS and instrument platform(s).
- It provides a tool to assist with antibody exclusion for Capture-R results that is based upon the exclusion (rule-out) approach recommended in the *Technical Manual* (AABB).

Technological Comparison to Predicate Devices

Below is a summary of the technological characteristics of modified device compared to the predicate devices.

Characteristic / Feature	Predicate Device: ImmuLINK (v.1.7)	Modified Device: ImmuLINK (v3.0)
Classification	II	SAME
Product Code	MMH	SAME
Regulation Number	21 CFR 864.9165	SAME
Multi-Instrument Connectivity	Capable of interfacing with more than one instrument at a time	SAME
Thin-client	A computer or a computer program which depends heavily on some other computer (its server) to fulfill its traditional computation	SAME
Multiple, Concurrent Users	More than one end user	SAME
LIS Backup	Continuous results production while your LIS is unavailable	SAME
Integrated QC	Customer is able to perform the qc using the same run controls and software will check the status of the qc for each instrument	SAME
Data Storage	Able to store data	SAME
Data Retrieval	Able to retrieve data	SAME
Data Mining	Able to turn data into information through analysis	SAME
Serology Results	Capable of displaying serology based results	SAME
Molecular Results	Capable of displaying molecular based results	SAME
Regulatory Compliance	Documentation control for better regulatory compliance	SAME
Specimen Routing	Sample processing for better turnaround time	SAME
User-defined rules	Customer customizable rules based on workflow and lab practices	SAME
Rules-based decision processing	Yes	SAME

Characteristic / Feature	Predicate Device: ImmuLINK (v.1.7)	Modified Device: ImmuLINK (v3.0)
Real-time delta checking	Current results are checked against previous results (when available) in real time	SAME
Reflex ordering	Automatic ordering of follow-up test based on previous results	SAME
Previous results	Allow for storage of prior results	SAME
Color coding using rules logic	Ability to display information in various colors based on outcome of predefined rules	SAME
Filtering	Ability to display information based on end user profile	SAME
Reactions Images Storage	Storage of result images	SAME
Images Review	Provides viewing of result images	SAME
Instrument Log details	Captures and displays logs from instruments	SAME
Intended Use	ImmuLINK is software intended for use in a blood banking environment as an aid in interfacing and managing data between blood bank instruments, Blood Establishment Computer Software, and Laboratory Information Systems. ImmuLINK includes the following features and/or functions: • It provides the ability to create and print reports of tests and results. • It supports the ability to compare current results with previous results. • It supports the automatic ordering of reflex tests. • It provides a tool so that test results produced by a testing platform can be remotely validated prior to delivery to an LIS. Results can also be viewed remotely and edited prior to delivery to an LIS. • It provides bi-directional communication between an LIS and instrument platform(s).	ImmuLINK is software intended for use in a blood banking environment as an aid in interfacing and managing data between blood bank instruments, Blood Establishment Computer Software, and Laboratory Information Systems. ImmuLINK includes the following features and/or functions: • It provides the ability to create and print reports of tests and results. • It supports the ability to compare current results with previous results. • It supports the automatic ordering of reflex tests. • It provides a tool so that test results produced by a testing platform can be remotely validated prior to delivery to an LIS. Results can also be viewed remotely and edited prior to delivery to an LIS. • It provides bi-directional communication between an LIS and instrument platform(s). • It provides a tool to assist with antibody exclusion for Capture-R results that is based upon the exclusion (rule-out) approach recommended in the *Technical Manual* (AABB).

Characteristic / Feature	Bio-Rad IH-AbID Integrated Antibody Identification	Modified Device: ImmuLINK (v3.0)
Classification	II	SAME
Product Code	MMH	SAME
Regulation Number	21 CFR 864.9165	SAME

Characteristic / Feature	Bio-Rad IH-AbID Integrated Antibody Identification	Modified Device: ImmuLINK (v3.0)
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
Use environment	Blood bank software used by reference laboratories and transfusion services—an application with functionality specifically for blood establishments	SAME
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
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
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
Results management	The software's results are repeatable so a reviewer may check the technologists' work and decisions.	SAME
Audit trail	Audit trail of processing steps and user actions	SAME

Characteristic / Feature	Bio-Rad IH-AbID Integrated Antibody Identification	Modified Device: ImmuLINK (v3.0)
Intended Use	IH-AbID 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	ImmuLINK is software intended for use in a blood banking environment as an aid in interfacing and managing data between blood bank instruments, Blood Establishment Computer Software, and Laboratory Information Systems. ImmuLINK includes the following features and/or functions: • It provides the ability to create and print reports of tests and results. • It supports the ability to compare current results with previous results. • It supports the automatic ordering of reflex tests. • It provides a tool so that test results produced by a testing platform can be remotely validated prior to delivery to an LIS. Results can also be viewed remotely and edited prior to delivery to an LIS. • It provides bi-directional communication between an LIS and instrument platform(s). • It provides a tool to assist with antibody exclusion for Capture-R results that is based upon the exclusion (rule-out) approach recommended in the *Technical Manual* (AABB).

Basis for Claim of Substantial Equivalence

The modified ImmuLINK is substantially equivalent to the predicate devices relative to technological characteristics of the software devices.

This Traditional 510(k) is submitted to modify legally a marketed, predicate device. Fundamental scientific technology of the proposed device is unchanged from the legally marketed, predicate. There are no significant differences between the modified device and the predicate as related to the Intended Use or Principle of Operation, except for the addition to the Intended Use statement that it provides antibody exclusion (rule-out) capabilities for Capture-R results [with the Antibody ID feature].

Immucor concludes, based on the indications for use, technological characteristics, and performance testing, that modified ImmuLINK with Antibody ID is safe and effective for the intended use described above.