

**510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance to requirements of SMDA 1990 and 21 CFR §807.92.

**Submitter's Details**

Name: Bio-Rad Medical Diagnostics GmbH  
Address: Industriestrasse 1, 63303 Dreieich, Germany  
Establishment Registration Number: 9610824  
Contact Person: Dr. Rolf Vornhagen  
Telephone number: +49 (0) 6103 3130-442  
Fax number: +49 (0) 6103 3130-646  
Date of Summary: January 31, 2018

**Device Information**

Trade / Device Name: IH-Com V5.0  
Common Name: IH-Com Data Management and Results Interpretation Software  
Classification Name: Automated Blood Grouping and Antibody Test System  
Device Class: II  
Product Code: KSZ  
Regulation number: 21 CFR 864.9175

**Identification of the Legally Marketed Device (Predicated Device)**

Trade / Device Name: IH-Com V5.0  
Common Name: IH-Com Data Management and Results Interpretation Software  
Classification Name: Automated Blood Grouping and Antibody Test System  
510(k) number: BK170021  
Device Class: II  
Product Code: KSZ  
Regulation number: 21 CFR 864.9175  
Clearance Letter: September 26, 2017

## Description of the Device

IH-Com V5.0 is a data management and result interpretation software designed only for immunohematological diagnostic purposes. IH-Com V5.0 can be used only in combination with a Bio-Rad in vitro diagnostic device and is regarded as “Rx only”. IH-Com V5.0 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-1000 or TANGO infinity and uses the image results for final test interpretation. The image results can be visually checked and verified in IH-Com V5.0 before result validation and report printing or result transfer to LIS. IH-Com V5.0 allows also the storage and management of patient, donor, QC, sample and reagent data.

The main functions of IH-Com V5.0 are:

- Interpretation of results
- Validation of results (user interface)
- Data management (patient, donor, results, users, etc.)
- Documentation (tracing of events, lot numbers, etc.)
- Bi-directional communication with connected instruments and the LIS
- Back-up and archiving of data
- Quality Control management

There are no specific environmental requirements for IH-Com V5.0. Hardware requirements are as follows:

- PC with INTEL or AMD CPU
- Dual-Core or Quad-Core
- Frequency  $\geq 2\text{GHz}$
- Memory  $\geq 2\text{GB}$
- Hard disk  $\geq 100\text{GB}$  (rpm  $\geq 7200$ )

## Intended Use

IH-Com V5.0 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 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 V5.0 may be used with:

- a standalone IH-1000, with multiple IH-1000 systems;
- a standalone TANGO infinity® or multiple TANGO infinity® systems;

or connected to a Laboratory Information System.

IH-Com V5.0 should only be operated by trained personnel and is not intended for use in a direct patient environment. In the USA IH-Com V5.0 is “Rx only”.

### Comparison to Predicate Device

The predicate device for this Traditional 510(k) submission is IH-Com V5.0, reviewed by the FDA under BK170021 and determined substantially equivalent on May 2017. The substantial equivalence comparison of the subject and predicate device is presented in Table 1 below.

Table 1 Substantial Equivalence Comparison

Parameter	Predicate Device Bio-Rad IH-Com V5.0 Software	Subject Device Bio-Rad IH-Com V5.0 Software
Indications for Use Statement	<p>IH-Com V5.0 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 with IH-System reagents. It manages sample, patient, donor, QC and reagent data. IH-Com V5.0 may be used with a standalone IH-1000, with multiple IH-1000s, or connected to a Laboratory Information System.</p> <p>IH-Com V5.0 should only be operated by trained personnel and is not intended for use in a direct patient environment. In the USA IH-Com V5.0 is “Rx only”.</p>	<p>IH-Com V5.0 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 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.</p> <p>IH-Com V5.0 may be used with:</p> <ul style="list-style-type: none"> <li>• a standalone IH-1000, with multiple IH-1000 systems;</li> <li>• a standalone TANGO infinity® or multiple TANGO infinity® systems;</li> </ul> <p>or connected to a Laboratory Information System.</p> <p>IH-Com V5.0 should only be operated by trained personnel and is not intended for use in a direct patient environment. In the USA IH-Com V5.0 is “Rx only”.</p>

<b>Parameter</b>	<b>Predicate Device Bio-Rad IH-Com V5.0 Software</b>	<b>Subject Device Bio-Rad IH-Com V5.0 Software</b>
Classification	II	same
Product Code	KSZ	same
Regulation Number	21 CFR 864.9175	same
510(k) Number	BK170021	-
Common Name	IH-Com V5.0	same
Tests managed	ABO and Rh typing Rh phenotyping Antibody Screening Antibody Identification AHG Crossmatch Direct Antiglobulin Test Auto Control	same
Primary components	<ul style="list-style-type: none"> <li>• Computers</li> <li>• Software with license dongle</li> </ul>	same
QC procedures implemented	Yes	same
Overall test interpretation	Software algorithm analyzes and combines image results and generates final test results	same
Reports	<ul style="list-style-type: none"> <li>• Daily journal</li> <li>• Sample result protocols</li> <li>• Patient result protocols</li> <li>• QC reports</li> <li>• Sample work list</li> </ul>	same
Interfaces	<ul style="list-style-type: none"> <li>• Bidirectional with Laboratory Information System (LIS)</li> <li>• Additional IH-Web interface for user access from outside locations</li> <li>• IH-1000 Connector</li> </ul>	<ul style="list-style-type: none"> <li>• Bidirectional with Laboratory Information System (LIS)</li> <li>• Additional IH-Web interface for user access from outside locations</li> <li>• IH-1000 Connector</li> <li>• TANGO Infinity Connector</li> </ul>
Operating System	Windows 7 Ultimate SP 1	same
Programming Language	Microsoft VB.NET (Visual Basic "Dotnet")	same

## **Conclusion**

This Traditional 510(k) is submitted to allow for a connection of IH-Com V5.0 to TANGO infinity. The verification and validation activities for IH-Com V5.0 have been completed and the results have been found satisfactory to confirm the system is meeting the software requirements. The fundamental scientific technology of the proposed device is unchanged from the predicate (BK170021).

Bio-Rad concludes, based on all information submitted and described in this submission and this summary that IH-Com V5.0 is safe, effective and substantially equivalent to the predicate device.