# 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**

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|---|---|
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| Date Summary Prepared: | April 10, 2019 |

**Name of Device**

| | |
|---|---|
| Trade or Proprietary Name: | TANGO infinity |
| Common Name: | Automated Blood Grouping and Antibody Test System |
| Classification Name: | Automated Blood Grouping and Antibody Test System |
| 510(k) number: | BK190312 |
| Device Class: | II |
| Product Code: | KSZ |
| Regulation number: | 21 CFR 864.9175 |

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

| | |
|---|---|
| Trade or Proprietary Name: | TANGO optimo |
| Common Name: | Automated Blood Bank System |
| Classification Name: | Automated Blood Grouping and Antibody Test System |
| 510(k) number: | BK080013 |
| Device Class: | II |
| Product Code: | KSZ |
| Regulation number: | 21 CFR 864.9175 |
| Clearance Letter: | July 23, 2008 |

## DESCRIPTION OF THE DEVICE

TANGO infinity is an automated instrument intended for the *in vitro* serological analysis of human blood specimens utilizing hemagglutination and solid phase methodology.
The analyzer is capable of automating the testing process from pipetting sequences of liquids (including diluting samples) through automated and standardized analysis of the end reaction. Process control features on the TANGO infinity include positive sample identification, automated recording of reagents (lot number, expiration date, onboard storage time tracking, sample dilutions, reagent addition and mixing, incubation (room temperature and 37°C), washing, centrifugation, re-suspension, and image analysis. Orders can be generated manually at the TANGO infinity or can be imported by a Laboratory Information System (LIS) interface.

This 510(k) summary applies to the addition of AHG crossmatch testing on TANGO infinity.

## DEVICE COMPARISON TABLE

**Table 1: Substantial Equivalence Comparison**

| Parameter | Predicate Device<br>Bio-Rad TANGO optimo | Subject Device<br>Bio-Rad TANGO infinity |
|---|---|---|
| Indications for Use Statement | Intended for use in ABO, Rh(D) (including weak D testing) and Rh Phenotype and Kell blood grouping for patient and donor testing, including on receipt, independent confirmation of donor unit labeling. The TANGO optimo Automated Blood Bank Analyzer System uses Anti-Human Globulin Anti-IgG Solidscreen II to detect human red blood cells sensitized with IgG alloantibodies and/or autoantibodies to include tests for antibody screening, antibody identification and the Direct Antiglobulin Test. Also, Blood Grouping Reagent Solidscreen II Anti-D is used to detect weak D and partial D (DVI and DVII) antigens.<br><br>The TANGO optimo automated system utilizes Blood Grouping Reagents and Anti-Human Globulin Reagents specifically formulated and manufactured by or for Bio-Rad Medical | The TANGO infinity automated blood grouping and antibody test system is an automated instrument intended for the in vitro serological analysis of human blood specimens. In the USA, TANGO infinity is "Rx only" and operates with TANGO infinity Software Version 1.5. It generates results from individual images that must be verified by visual inspection by a qualified person called a validator. In rare cases, where the software is unable to decide, manual editing may be necessary.<br>TANGO infinity utilizes Erytype S agglutination methodology for ABO (forward and reverse blood grouping), Rh(D), Rh Phenotype and Kell blood grouping.<br>TANGO infinity utilizes Solidscreen II solidphase methodology for weak D and partial D testing, antibody screening and identification of red cell alloantibodies, crossmatch, auto control and direct |

| Parameter | Predicate Device<br>Bio-Rad TANGO optimo | Subject Device<br>Bio-Rad TANGO infinity |
|---|---|---|
| | Diagnostics GmbH, and licensed and cleared exclusively for this system. | antiglobulin testing. The TANGO infinity uses reagents and microwell strips approved for the TANGO infinity. Operators of TANGO infinity must be trained by authorized personnel and must be familiar with the content of this TANGO infinity User Manual. The TANGO infinity User Manual is designed to serve as a reference manual for operations and troubleshooting, to assist writing institutional SOPs and to assist training. |
| Classification | II | Same |
| 510(k) Number | BK080013 | BK190312 |
| Product Code | KSZ | Same |
| Regulation Number | 21 CFR 864.9175 | Same |
| Common name | Automated Blood Grouping and Antibody Test System | Same |
| Tests Performed | • Blood Group and Rh(D)<br>• Antigen typing<br>• Antibody Screening<br>• Antibody Identification<br>• Direct Antiglobulin Test<br>• AHG crossmatch | Same<br>• Auto control |
| Primary components | • Analyzer<br>• Computer<br>• Software<br>• Printer | Same |
| Specimen Types | Plasma, Serum and Red Blood Cells | Same |
| Capability to process STAT samples | Yes | Same |
| QC procedures implemented | Yes | Same |
| Barcode Reading | Sample Identification, Reagent Lot No. and Expiration Date | Same |
| Manual Entry of Sample IDs or Reagent Data | Yes | Same |
| Sample Loading Random Access | Yes | Same |

| Parameter | Predicate Device<br>Bio-Rad TANGO optimo | Subject Device<br>Bio-Rad TANGO infinity |
|---|---|---|
| Sample loading capacity | 144 tubes simultaneously, 12 racks with 12 samples each | 120 tubes simultaneously, 10 racks with 12 samples each |
| Sample Barcode Type | • Coda-bar<br>• Code 39<br>• Interleaved 2/5<br>• EAN<br>• (isbt) Code 128 (Subset C) | Same |
| Reagent loading capacity | 18 positions<br>• 3 racks with 4 positions for Reagent Red Blood Cells<br>• 2 Racks with 3 positions for Diluents) | 27 positions<br>• 3 racks with 5 positions for Reagent Red Blood Cells<br>• 3 Racks with 4 positions for Diluents |
| Reagent Barcode type | Code 128 (Subset C) | Same |
| Reagent Red Cell Suspension | Yes | Same |
| Plate loading capacity | 10 Plates with 12 strips each | Same |
| Plate and Strip Transport System | Yes | Same |
| Pipettor | 2 independent pipettor arms | 1 pipettor arm |
| Aspirate Verification | For the whole strip before centrifuge step | After each aspirate step |
| Strip linear shaking system | Yes | Same |
| Incubator | Two independent temperature areas 37ºC and room temperature | Same |
| Incubator Temperature Tolerance | Incubator temperature specification at 37 ºC is ±2ºC | Same |
| Incubator capacity | 16 positions<br>• 5 position for RT<br>• 10 postions for 37 °C<br>• 1 position for balance strip | Same |
| Centrifuge | 1 Centrifuge; 4 strips capacity | Same |
| Centrifuge speed | The centrifuge speed is 30 to 900 g depending on the requirements of the test assay | Same |
| Centrifugation time | The centrifugation time depends on the requirements of the test assay | Same |
| Orbital shaker | 4 strip capacity | Same |
| Orbital shaking frequence | The orbital shaking frequency is depending on the requirements of the test assay | Same |

| Parameter | Predicate Device<br>Bio-Rad TANGO optimo | Subject Device<br>Bio-Rad TANGO infinity |
|---|---|---|
| Results reading | Yes. CCD camera and Digital Image Analysis. | Same |
| Test interpretation | Yes. According to predefined rules stated in a definition file. | Same |
| System solutions and waste containers | • System liqiud: DI water<br>• Wash buffer<br>• Liquid waste container<br>• Strip waste using conveyer belt | • System liqiud: isotonic saline<br>• Wash buffer<br>• Liquid waste container<br>• Strip waste using a bin |
| Total speed | 12 samples (ABO/ABS 3) per hour, including forward & reverse group | Same |
| Interfaces | Bidirectional with Laboratory Information System | Same |
| Useful life | 5 years minimum considering a normal function of 230 tests/day and 300 days/year | Same |
| Computer | TANGO optimo is supplied with a general purpose computer meeting the required specifications can be used | TANGO infinity is supplied with a general purpose computer meeting the required specifications can be used |
| Operating system | Window XP, Service Pack 3 | Windows 7 |
| IH-Com Connectivity | No | Yes |

## PERFORMANCE DATA PERCENT AGREEMENT TABLES

Performance Characteristics for crossmatch (Indirect Antiglobulin Test) on the TANGO infinity Analyzer

A multi-center clinical trial, which included testing at two different US clinical sites and an internal site, was conducted to evaluate the performance of Solidscreen II for AHG crossmatch testing on the TANGO infinity Analyzer. The clinical trial included testing of patient and donor samples. The positive and negative percent agreements were calculated for the Anti-Human Globulin Anti-IgG Solidscreen II for AHG crossmatch testing in comparison to the FDA licensed reference methods. Additional internal studies have been performed with well-characterized samples to evaluate the performance of the AHG crossmatch testing on the TANGO infinity Analyzer.
Results of the positive percent agreement and negative percent agreement, with the one-sided Exact 95% Lower Confidence Limit (LCL) are listed in the data table below.

| Test | Results from Clinical Trials | | | |
|---|---|---|---|---|
| | Negative Agreement | | Positive Agreement | |
| | N | Point Estimate (one-sided Exact 95% LCL) | N | Point Estimate (one-sided Exact 95% LCL) |
| IAT Crossmatch | 539 | 98.70% (97.57%) | 449 | 99.33% (98.28%) |

| Test | Results from In-House Study with well-characterized samples | | | |
|---|---|---|---|---|
| | Negative Agreement | | Positive Agreement | |
| | N | Point Estimate (one-sided Exact 95% LCL) | N | Point Estimate (one-sided Exact 95% LCL) |
| IAT Crossmatch | 344 | 100% (99.13%) | 320 | 100% (99.07%) |

Agreement between the methods does not imply which method obtained the correct result. The above results do not reflect any discrepancy resolution between the methods.

**CONCLUSION**

In support of this premarket notification a multi-center clinical study at three external sites and at Bio-Rad was performed to validate the use of Anti-Human Globulin Anti-IgG Solidscreen II on TANGO infinity for AHG crossmatching. The studies included a number of 1590 crossmatches.

The results obtained in the clinical trial support the conclusion that the testing of Anti-Human Globulin Testing using the Solidscreen II method on the TANGO infinity Analyzer is safe and effective. The yielded results demonstrate that end users, with proper training, could use the TANGO infinity Analyzer to perform crossmatching and that the testing with the specified reagents on the TANGO infinity Analyzer does generate results comparable to established FDA licensed reference reagents and FDA approved predicates.