

SECTION 1 — GENERAL SUBMISSION SUMMARY INFORMATION

Classification Name: Automated Blood Grouping and Antibody Test System

Common Name: Automated Blood Bank System

Trade/Proprietary Name: TANGO OPTIMO Automated Blood Bank Analyzer System

Establishment Registration Number: 9610824 Analyzer Manufacturer:
Biotest Medical Diagnostics GmbH
Dr. Rolf Vornhagen
Industriestrasse 1
63303 Dreieich
Germany
Phone: +49 (0) 6103 - 801 442

System Elements Classifications and Product Codes:

TANGO OPTIMO Automated Blood Bank Analyzer	21 CFR 864.9175 Class II 81 KSZ
Negative Control *Not a stand alone product, but integrated into the Erytype Strips	21 CFR 864.9650 Class II 81 KSF
Solidscreen II Control	21 CFR 864.9650 Class II 81 KSF
MLB 2 (Low Ionic Strength Solution)	21 CFR 864.9600 Class II (exempt) 81 KSG
Bromelin f. Erytype	21 CFR 864.9400 Class II 81 KSK
Erytype S ABD Rev. A ₁ ,B	21 CFR 864.9175 Class II 81 KSZ
Erytype S ABO Donor	21 CFR 864.9175 Class II 81 KSZ
Erytype S Rh Donor	21 CFR 864.9175 Class II 81 KSZ

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Erytype S Rh+K Type	21 CFR 864.9175 Class II 81 KSZ
Solidscreen II	21 CFR 864.9175 Class II 81 KSZ
Solidscreen II-control B	21 CFR 864.9650 Class II 81 KSZ
Solidscreen II negative Control	21 CFR 864.9650 Class II 81 KSZ
Alsevers Solution	21 CFR 864.9600 exempt, but part of the Analyzer System

OTHER ELEMENTS OF THE TANGO SYSTEM THAT ARE LICENSED BIOLOGICAL MATERIALS (LISTED HERE TO DEMONSTRATE COMPLETE TANGO SYSTEM)

For ABO/Rh Grouping

1. Biotest Medical Diagnostics Anti-A Blood Grouping Reagent
2. Biotest Medical Diagnostics Anti-B Blood Grouping Reagent
3. Biotest Medical Diagnostics Anti-A,B Blood Grouping Reagent
4. Biotest Medical Diagnostics Anti-D (two separate clones) Blood Grouping Reagent
5. Biotest Medical Diagnostics Reagent Red Blood Cells Erytypecell A₁, B
6. Medion Diagnostics Reverse-Cyte[®] Reagent Red Blood Cells A₁, B

For Rh Phenotyping and Kell Typing

1. Biotest Medical Diagnostics Anti-C Blood Grouping Reagent
2. Biotest Medical Diagnostics Anti-c Blood Grouping Reagent
3. Biotest Medical Diagnostics Anti-E Blood Grouping Reagent
4. Biotest Medical Diagnostics Anti-e Blood Grouping Reagent
5. Biotest Medical Diagnostics Anti-Kell Blood Grouping Reagent

For Antibody Screening, antibody identification, cross-matches and direct antiglobulin testing

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1. Biotest Medical Diagnostics Anti-Human Globulin Anti-IgG Solidscreen II
2. Biotest Medical Diagnostics Reagent Red Blood Cells: Biotestcell Pool, Biotestcell 1&2 and Biotestcell 3 for the antibody screening and Biotestcell I-8 and Biotestcell I-11 for antibody identification.
3. Medion Diagnostics Search Cyte® Reagent Red Blood Cells (Pooled, Duo, and Trio screen cells)

For weak D Testing

1. Biotest Medical Diagnostics Anti-Human Globulin Anti-IgG Solidscreen II
2. Biotest Medical Diagnostics Anti-D Blend Solidscreen II

Performance Standards:	None established under section 514 of the Food, Drug and Cosmetic Act
Labeling Material:	Labeling material of all already approved 510(k) reagents indicating the new intended uses and for the new 510(k) products is provided in section 9 of this submission.
Substantial Equivalence:	This modification is substantially equivalent to the predicate device identified in section 2 of this submission.
Safety and Efficacy:	In accordance with the Safe Medical Devices Act of 1990, safety and effectiveness information will be made available to any person upon request.

SECTION 2

2.1 PREDICATE DEVICE IDENTIFICATION

The following table identifies the predicate devices that were used in this comparison for ABO/Rh(D), Rh Pheno- and Kell typing and as well as the antibody screening, antibody identification, DAT, cross-matches and the weak D Testing. The Predicate Device 510(K) Clearance, FDA Biologic License Number, or device classification regulation that applies to the product, and the linkage between the predicate device and the elements that are discussed in this premarket notification submission is shown in the table below. The feature comparisons are presented in attachment 2.1.

ABO/RH, WEAK D AND RH PHENO- AND KELL TYPING		
Product	510(K), BLA, or CFR Classification	Predicate Linkage
Olympus PK7200™ Automated Microplate System	BK030009	TANGO OPTIMO Automated Blood Bank Analyzer Submission
Immucor® Blood Grouping Reagents (anti-A, anti-B, anti-A,B, anti-D)	U.S. LICENSE886	Erytype-S strips (including the cleared BLA products Anti-A, Anti-B, Anti-A, B, Anti-D), Anti-D Blend Solidscreen II, not part of this 510(K), but in submitted BLA)
Bioclone® Anti-C, Anti-E, Anti-c, Anti-e	U.S. License 1236	Erytype S Strips (including Anti-C, Anti-c, Anti-E, Anti-e, not part of this 510(K), but in submitted BLA)
Ortho Blood Grouping Reagent Anti-K	U.S. License 1236	Erytype S Strips (including Anti-K, not part of this 510(K), but in submitted BLA)
Immucor® Rh-Hr Control	21 CFR 864.9650	Negative Control
Ortho® Affirmagen® Reagent Red Blood Cells	U.S. LICENSE1236	Biotest Erytypecell A ₁ &B (not part of this 510(K), but in submitted BLA)
Immucor Referencecells® Reagent Red Blood Cells	U.S. LICENSE886	Biotest Erytypecell A ₁ &B (not part of this 510(K), but in submitted BLA)
Olympus PK™ Reagent Red Blood Cells	U.S. LICENSE 435	Biotest Erytypecell A ₁ &B (not part of this 510(K), but in submitted BLA)
Immucor® Automated Enzyme	21 CFR 864.9400	Bromelin f. Erytype S

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Antibody Screening / Antibody Identification / DAT / Cross-Matches		
Product	510(K), BLA, or CFR Classification	Predicate Linkage
Galileo [®] Automated Blood Bank Analyzer	BK040013	TANGO OPTIMO Automated Blood Bank Analyzer Submission
CAPTURE-R[®] READY SCREEN[®] POOLED CELLS	U.S. LICENSE886	Biotestcell Pool, Biotestcell 1&2, Biotestcell 3 (not part of this 510(k), but in submitted BLA)
Capture-R [®] Ready Screen [®] Strips containing dried red cell membranes	U.S. LICENSE886, BK960017	Biotestcell Pool, Biotestcell 1&2, Biotestcell 3 (not part of this 510(k), but in submitted BLA)
Immucor Panoscreen [®] Reagent Red Blood Cells	U.S. LICENSE886	Biotestcell Pool, Biotestcell 1&2, Biotestcell 3 (not part of this 510(k), but in submitted BLA)
Gamma [®] Red Blood Cells (Gamma Pool [™] , Gamma Duet [™] , Gamma Trio [™])	U.S. LICENSE 435	Biotestcell Pool, Biotestcell 1&2, Biotestcell 3 (not part of this 510(k), but in submitted BLA)
Ortho [®] Surgiscreen [®] Reagent Red Blood Cells	U.S. LICENSE1236	Biotestcell Pool, Biotestcell 1&2, Biotestcell 3 (not part of this 510(k), but in submitted BLA)
RRBCs 0.8% Resolve [®] Panel A	U.S. LICENSE1236	Biotestcell-I8, Biotestcell-I11 (not part of this 510(k), but in submitted BLA)
Search-Cyte [®] Pool for TANGO, Search-Cyte [®] Duo for TANGO, Search-Cyte [®] Trio for TANGO	U.S. License 1740	Biotestcell Pool, Biotestcell 1&2, Biotestcell 3 (not part of this 510(k), but in submitted BLA)
Immucor [®] Checkcell	21 CFR 864.9650	NA-The TANGO OPTIMO System has sensors built into the test method that ensure proper washing of cells during testing
Gamma-clone [®] Anti-Human Globulin Anti-IgG	U.S. License 886	Biotest Anti-Human Globulin Anti-IgG (not part of this 510(K), but in attached BLA supplement)
Immucor Capture [®] LISS	21 CFR 864.9600	MLB 2 (Modified LISS Solution)
Ortho [®] Antibody Enhancement Solution	K791791	MLB 2 (Modified LISS Solution)
Immucor ImmuAdd [™]	21 CFR 864.9600	MLB 2 (Modified LISS Solution)
MTS Diluent 2 Red Blood Cell Diluent	21 CFR 864.9600	MLB 2 (Modified LISS Solution)
Captur-R [®] Ready-Screen	21 CFR 864.9175	Solidscreen II strips
Immucor Capture [®] Positive Control Serum, Immucor Capture [®] Negative Control Serum	CFR 21 864.9650	Solidscreen II Control, Solidscreen II Control B, Solidscreen II negative Control
ORTHO Confidence System (ORTHO Confidence Antibody)	CFR 21 864.9650	Solidscreen II Control, Solidscreen II Control B
Immucor [®] Red Blood Cell Storage Solution	CFR 21 864.9600 exempt	Alsevers Solution