tech guide

Microbiology Systems

	Randox Biosciences Crumlin, UK +44 (0)28 9442 2413 www.randox.com	Randox Biosciences Crumlin, UK +44 (0)28 9442 2413 www.randox.com	Roche Diagnostics Corp Indianapolis (800) 428-5076 usdiagnostics.roche.com
1. What is the brand name of your company's microbiology system?	Respiratory pathogen (RP) multiplex array	Sexually transmitted infection (STI) multiplex array	Cobas *C. diff* assay for use on the Cobas 4800 system
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark, 2016.	CE mark, 2013.	CE mark, 2013; FDA 510(k), 2015.
3. What is the intended use or primary function of the product?	In vitro diagnostic using a multiplex polymerase chain reaction (PCR)-based biochip array; simultaneous detection of 22 viral and bacterial infections of the upper and lower respiratory tracts.	In vitro diagnostic using a multiplex polymerase chain reaction (PCR)-based biochip array; simultaneous detection of 10 STIs from a single patient sample.	An automated, qualitative in vitro diagnostic test for the direct detection of the toxin B gene of toxigenic *Clostridium difficile* (*C. difficile*).
4. What types of specimen/sample does the product employ?	Bronchoalveolar lavage, nasopharyngeal swab, saliva, and sputum.	Urine and urogenital swab.	Unformed (liquid or soft) stool specimens obtained from patients suspected of having *C. difficile* infection.
5. What types of diseases, conditions, or analytes does the system detect?	Respiratory pathogen (viral and bacterial) nucleic acid targets.	STI (viral and bacterial) nucleic acid targets.	*C. difficile*
6. Which methodology or clinical standard of care does the product use?	Biochip microarray-based approach using simple chemiluminescent chemistries similar to enzyme-linked immunosorbent assay.	Biochip microarray-based approach using simple chemiluminescent chemistries similar to enzyme-linked immunosorbent assay.	Real-time polymerase chain reaction testing.
7. What are the product's maximum specimen capacity and throughput under ideal conditions?	A maximum of 54 multiplex tests in a single EI imaging run.	A maximum of 54 multiplex tests in a single EI imaging run.	The instrument can run up to 96 tests at a time (94 samples and 2 controls) in under 4 hours.
8. Briefly describe any automation or connectivity features or options that pertain to the product.	Multiplex PCR reactions performed on separate thermal cycler; amplicon hybridization and conjugation steps automated using EI analyzer package thermoshakers.	Biochip array chemiluminescent signatures are automatically detected by charged-coupled device camera on the EI platform and reported in approximately 3 minutes.	Simplified sample preanalytics; automated sample preparation; automated amplification and detection; laboratory information system connectivity; ability to parallel process multiple analytes (MRSA/MSSA, *C. difficile*, herpes simplex virus 1 and 2).
9. What is the typical training time for the product?	3 days to complete Randox accredited standards.	3 days to complete Randox accredited standards.	n/a
10. What types of technical support are available?	Remote diagnostics available globally; gold, silver, and bronze service packages include annual preventive maintenance visits.	Remote diagnostics available globally; gold, silver, and bronze service packages include annual preventive maintenance visits.	Directly through Roche Diagnostics.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Simultaneous detection of routine and frequently requested bacterial and viral infections; EI allows throughput flexibility; 3–54 tests (1188 results) in a single run; multiple protocol stop points to harmonize with laboratory workflow; EI performs protein and nucleic acid multiplex tests; suitable for a multidisciplinary pathology laboratory.	A comprehensive biochip-based test, including primary, secondary, and asymptomatic coinfections for a complete sexual health profile; simple, easy-to-interpret, and fully traceable result report with zero posttest data analysis.	Flexibility to adapt to variable testing volumes while maintaining optimal workflow and cost efficiency; broad strain coverage validation for detection confidence.

Roche Diagnostics Corp	**Roche Diagnostics Corp**	**Roche Diagnostics Corp**	**Thermo Fisher Scientific**
Indianapolis (800) 428-5076 usdiagnostics.roche.com	Indianapolis (800) 428-5076 usdiagnostics.roche.com	Indianapolis (800) 428-5076 usdiagnostics.roche.com	Waltham, Mass (800) 255-6730 www.thermofisher.com
Cobas MRSA/SA assay for use on the Cobas 4800 system	Cobas Strep A assay for use on the Cobas Liat system	Cobas influenza A/B assay for use on the Cobas Liat system	Thermo Scientific Sensititre ARIS 2X system
CE mark, 2013; FDA 510(k), 2015.	CLIA waived, 2015; FDA 510(k), 2014.	CLIA waived, 2015; FDA 510(k), 2015.	FDA 510(k), year n/a.
A qualitative in vitro diagnostic assay for the direct detection of methicillin-resistant *Staphylococcus aureus* (MRSA) and S. aureus (SA) DNA.	A qualitative in vitro diagnostic test for the detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*, Strep A) in patients with signs and symptoms of pharyngitis.	Automated multiplex assay for the rapid in vitro qualitative detection and discrimination of influenza A virus and influenza B virus RNA in patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.	Automated organism identification and antimicrobial susceptibility testing (AST).
Nasal swabs.	Throat swabs.	Nasopharyngeal swabs.	Antimicrobial susceptibility and identification of bacterial, fungal, and mycobacterial isolates.
MRSA and SA.	*Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*, Strep A).	Influenza A and influenza B viruses.	Bacterial identification (ID) and AST.
Real-time polymerase chain reaction testing.	Real-time polymerase chain reaction testing.	Real-time polymerase chain reaction testing.	Fluorescence technology detection; broth microdilution.
The instrument can run up to 96 tests at a time (94 samples and 2 controls) in under 4 hours.	The instrument can conduct one test at a time with a turnaround time of 15 minutes.	The instrument can conduct one test at a time with a turnaround time of 20 minutes.	64 minimum inhibitory concentration (MIC), breakpoint, or identification plates, for a combination of a possible 192 tests on one instrument.
Direct sample vial loading; automated sample preparation; automated amplification and detection; laboratory information system connectivity; ability to parallel process multiple analytes (MRSA/MSSA, *C. difficile*, herpes simplex virus 1 and 2).	Health Level Seven International enabled connectivity.	Health Level Seven International enabled connectivity.	Automatically incubates and reads microtitre plates to identify organisms and report susceptibility results with laboratory information system connectivity; customizable expert system; quality control module; automated reports/alerts; and optional epidemiology module.
n/a	Waived status under the Clinical Laboratory Improvement Amendments of 1988; no training required.	Waived status under the Clinical Laboratory Improvement Amendments of 1988; no training required.	3 days.
Directly through Roche Diagnostics.	Directly through Roche Diagnostics.	Directly through Roche Diagnostics.	24/7.
Up to 90% less hands-on time compared to other test options; provides two results in one test (MRSA surveillance screening and presurgical SA screening).	Fast detection of *Streptococcus pyogenes* in throat swab specimens, with a 15-minute turnaround time.	Fast detection and differentiation of influenza A and B, with a 20-minute turnaround time.	Large selection of standard MIC plates or tailor-made solutions specific to formulary requirements, prescription protocols, and local resistance; earlier access to antimicrobial susceptibility testing of new, potent antimicrobials and one of the largest, most up-to-date selections of FDA-cleared antimicrobials; scalable instrumentation to support manual testing to full automation.

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1. What is the brand name of your company's microbiology system?	Thermo Scientific automated workflow solution: Copan WASP Walkaway Specimen Processor + Thermo Scientific Remel media	Thermo Scientific full lab automation: Copan WASPLab + Thermo Scientific Remel media	Thermo Scientific VersaTrek automated microbial detection system
2. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	n/a	n/a	FDA 510(k), year n/a.
3. What is the intended use or primary function of the product?	Automated specimen processing.	Laboratory automation.	Automated microbial detection, including blood culture and mycobacteria testing.
4. What types of specimen/sample does the product employ?	All specimen types.	All specimen types.	Blood and other normally sterile body fluids for cultivating and recovering microorganisms; sterile body specimens and digested-decontaminated clinical specimens for the recovery of mycobacteria.
5. What types of diseases, conditions, or analytes does the system detect?	n/a	n/a	Detection of all organism types, including common and fastidious organisms and mycobacteria, as well as *Mycobacterium tuberculosis (Mtb)* susceptibility testing.
6. Which methodology or clinical standard of care does the product use?	Enrichment cultures.	Enrichment cultures.	Blood cultures.
7. What are the product's maximum specimen capacity and throughput under ideal conditions?	378-plate capacity with nine silo carousel; throughput capacity that matches two to three full-time equivalents.	WASP DT: 378-plate capacity with nine silo carousel; throughput capacity that matches two to three full-time equivalents; Smart Incubator capacity for single: 854 plates; double: 1708 plates.	Maximum annual bottle volume for a 5-day blood culture: 38,500; 7-day blood culture: 27,500; maximum annual bottle volume for myco: 4,700.
8. Briefly describe any automation or connectivity features or options that pertain to the product.	From planting and streaking to Gram slide prep and enrichment broth inoculation, provides full automation of preanalytical processing.	Uses flexible customized conveyors that are designed to fit any lab; robotic plate management system; smart incubators and image acquisition technology.	VersaTrek provides automated microbial detection with laboratory information system connectivity and intuitive software for one-touch access to patient samples and results; search and reporting functionality.
9. What is the typical training time for the product?	1 week.	1–1.5 weeks.	3 days for all user types/shifts.
10. What types of technical support are available?	24/7.	24/7.	24/7.
11. What capabilities, features, or accessories distinguish this product from others on the market?	Brings together the experts in prepared media and automated specimen processing; automates all aspects of specimen processing using Remel media products, optimized for automation; fully automated specimen processing; valuable resources can be redeployed to ensure optimal lab productivity.	Prepared media experts for over 40 years in the microbiology industry; provides trusted solutions for the entire microbiology lab, from planting and streaking to automated specimen processing and diagnosis.	Includes four FDA-cleared tests on one platform (blood culture, *Mtb* susceptibilities, mycobacteria detection, and sterile body fluids); can detect any gas produced or consumed by organisms, to detect a wider range of organisms; two-bottle media system for all patients is FDA-cleared for draws as low as 0.1 ml.