tech guide

Calibrators, Controls, and Reference Standards

	Bio-Rad Labratories Hercules, CA 800-224-6723 www.qcnet.com	**Bio-Rad Labratories** Hercules, CA 800-224-6723 www.qcnet.com	**Diagnostica Stago** Parsippany, NJ 800-222-COAG www.stago-us.com
1. What is the brand name of your company's calibrator or quality control product or product line?	Cardiac Advance Quality Controls	InteliQ Diabetes Control	ExpertCor Routine (PT w/INR, aPTT & Fib), ExpertCor D-Dimer, ExpertCor UFH, ExpertCor LMWH"
2. What year was the product first released to market?	2023	2021	2019
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA Class II, 510(k) exempt;CE Mark	FDA Class II, 510(k) exempt; CE mark	FDA Class I 510(k) exempt
4. What is the intended use or primary function of the product?	Intended to use as an assayed quality control serum to promitor the precision of cardiac assesment assays	Intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Designed to supplement lot conversion, method verification, instrument comparison, and troubleshooting studies.
5. With what companies, brands, or models of instruments are your products intended to be used?	Currently compatible with Siemens and Roche instruments. Compatibility with Beckman-Coulter coming fall 2023.	Any high-throughput, automated immunoassay instrument such as Siemens Atellica, Roche Cobas, and Abbott Alinity.	All hemostasis analyzers
6. Where is the product used?	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting
7. If you answered "elsewhere," explain briefly.	N/A	N/A	N/A
8. Under ideal conditions, what is the time to first result; how are the test results made available?	This is dependent upon instrument being used	The InteliQ load-and-go tubes are designed to significantly reduce hands-on time. The time to first result is dependent on the instrument being used.	Varies by assay and/or analyzer
9. Briefly describe any automated or connectivity features or options that pertain to the product.	This control is supported by the Unity interlaboratory quality control data management system	This control is supported by the Unity interlaboratory quality control data management program.	N/A
10. What is the typical training time for the product?	No training is required; material is run as a patient sample	No training is required; material is run as a patient sample.	No training is required
11. What types of technical support are available?	Technical support is available by phone or email. Individualized customer support is provided as needed.	Technical support is available by phone or email. Individualized customer support is provided as needed.	Technical support is available via phone or email
12. What capabilities, features, or accessories distinguish this product from others on the market?	Cardiac Advance quality control is a comprehensive, multi-analyte control optimized for high sensitivity troponin testing near the limit of instrument detection. Containing the most tested cardiac analytes, this product offers a consolidated formula to monitor the precision of cardiac laboratory testing in one comprehensive control.	These barcoded, load-and-go quality controls help to reduce hands-on time and manual errors, and streamline the QC workflow. Together with Unity's interlaboratory advanced data management tools, InteliQ controls help to improve laboratory efficiency.	ExpertCor is a range of frozen plasma sets designed to simplify method verification, lot conversion and instrument correlation. Can be used on any coag analyzer to supplement local patient samples to ensure assay comparability. Meets regulatory requirements, enhances operational efficiency and enables system standardization.

Diagnostica Stago Parsippany, NJ 800-222-COAG www.stago-us.com	**Eurotrol** Ede, The Netherlands 502-501-1180 SupportUS@eurotrol.com www.eurotrol.com	**LGC Clinical Diagnostics** Milford, MA 800-676-1881 CDx-Sales@lgcgroup.com seracare.com	**LGC Clinical Diagnostics** Milford, MA 800-377-9684 CDx-Sales@lgcgroup.com mainestandards.com
Qualiris	CueSee CO-OX VM & QC	ACCURUN	VALIDATE
2010	2022	1994	2001
ISO 17043	FDA, 510(k) exempt, 2022	FDA 510(k), 1994; GMED CE mark, 2003	FDA 510(k), FDA Listed and CE
Designed to assist with hemostasis proficiency testing accreditation and competency assessment requirements.	Precision, accuracy, AMR validation, routine quality control	Method validation, regulatory compliance, daily third-party quality control	Linearity and calibration verification
All hemostasis analyzers	All common co-oximeters	Universal; assay agnostic for major molecular and serology platforms	Universal; assay agnostic for major biochemistry platforms
■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting
N/A	N/A	N/A	N/A
Varies by assay and/or analyzer	N/A	Varies by analyzer	Varies by analyzer
N/A	N/A	N/A	N/A
No training is required	No training required. Follow IFU	No training required; material is run as a patient sample.	No training required; material is run as a patient sample.
Technical support is available via phone or email	Technical support is available by phone and/or email. This control is supported by CueSee Compare peer data management online program.	Technical support is available by phone or email. Individualized customer support is provided as needed.	Technical support is available by phone or email. Individualized customer support is provided as needed."
Qualiris is a hemostasis web-based EQA program. It provides peer group, monthly, biannual, and annual reports with quantitative and qualitative data. Programs include routine hemostasis tests and a wide variety of specialty tests including D-Dimer, unfractionated heparin, low molecular weight heparin, Factor Assays, and Thrombophilia.	Offers clinically significant ranges for all analytes. Contains all hemoglobin fractions with sample matrix closest to real whole blood. AcuDrop II container offers safe and easy sampling.	ACCURUN controls are specially formulated to exhibit weak reactivity in true patient-like matrices to pressure-test assay performance near critical clinical decision points. ACCURUN independent controls offer sensitive detection of subtle shifts in testing trends and mitigate the risk of reporting false results.	VALIDATE products allow clinical laboratories to complete their required linearity and calibration verification, maximizing the reportable range while minimizing manual dilutions. Use of this product, while augmenting daily QC, assists with fulfilling various quality regulatory requirements.

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	Maine Molecular Quality Controls, Inc. (MMQCI) Saco, ME 207-885-1072; Info@mmqci.com www.mmqci.com	**Thermo Fisher Scientific** Fremont, CA 1-800-232-3342 sales.diagnostics.fmt@thermofisher.com www.thermofisher.com	**Verichem Labs** Providence, RI 800-552-5859; customerservice@verichemlabs.com www.verichemlabs.com
1. What is the brand name of your company's calibrator or quality control product or product line?	INTROL	Thermo Scientific MAS OMNI•IMMUNE PRO	Matrix Plus Chemistry Reference Materials; Matrix Plus Cholesterol Reference Materials; Enzyme ER Verifiers; TruZero Bilirubin Standard
2. What year was the product first released to market?	2005	2015	1988
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA 510(k), 2006; Qarad CE mark: 2022	FDA 510(k) exempt; CE marked	All products are FDA 510(k) cleared.
4. What is the intended use or primary function of the product?	Multiplex quality controls for routine monitoring of molecular diagnostic test systems, validation, verification, proficiency assessment, and training procedures.	Thermo Scientific MAS Omni•IMMUNE PRO is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations	Gravimetric standards, linearity verifiers, and reference materials for calibration or calibration verification of wet chemistry assays on automated clinical testing systems.
5. With what companies, brands, or models of instruments are your products intended to be used?	Controls for LDTs and for platforms by bioMérieux (BioFire), Cepheid, OpGen (Curetis), Roche (GenMark), Illumina (NGS), DiaSorin (Luminex), Qiagen and others. Custom IVD products for assay manufacturers.	Any immunoassay analyzer.	Compatible with wet chemistry analyzers from Abbott, Roche, Siemens, Advanced Instruments, Alfa Wassermann, Beckman Coulter, EKF Diagnostics, Horiba, and others.
6. Where is the product used?	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting	■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting	■ At a community screening event ■ In a reference lab or other independent lab setting ■ In a hospital or inpatient setting ■ In a physician's office or outpatient setting ■ Elsewhere
7. If you answered "elsewhere," explain briefly.	N/A		IVD manufacturer instrument/assay development, analytical measurement range monitoring, clinical assay troubleshooting, bias to true value. product development applications, and tracking normal range drift.
8. Under ideal conditions, what is the time to first result; how are the test results made available?	N/A	The time to first result is dependent on the instrument being used.	All products are treated like patient specimens; time to first result depends on the analyzer.
9. Briefly describe any automated or connectivity features or options that pertain to the product.	N/A	Thermo Scientific MAS Lablink xL software is a truly real-time, cloud-based software that allows laboratories to manage their QC on a daily basis and also offers international peer comparison	Calibration verification and quality assurance program is offered free to all customers and offers CLIA-compliant test report verifying accuracy, linearity, calibration verification, and reportable range.
10. What is the typical training time for the product?	No training required, controls are processed like patient samples.	No training is required as the quality control products are run as patient samples	None required.
11. What types of technical support are available?	Technical support is available via phone & e-mail. MMQCI's Tech Support team offers prompt individualized service.	Transition support. Training. Expert customer support. Technical support available at mas.controls@thermofisher.com	Support available via phone, email, website, and on-site.
12. What capabilities, features, or accessories distinguish this product from others on the market?	These multiplex synthetic controls are designed to be processed like patient samples, 100% safe, non-hazardous, robust, and stable.	Highly consolidated third-party control enabling the laboratories to reduce their number of QC references. The 4 years lot stability of the product allows laboratories to stay longer on the same lot and significantly reduce the number of lot-to-lot validation. All MAS QC are liquid, ready-to-use, straight-from the fridge.	Products are compatible with all major wet chemistry systems; CLIA compliant; certified accuracy using available USP, ACS, NIST materials. Most include a lot-specific certificate of analysis, are liquid stable and ready-to-use, offer long shelf-life claims, and lot-to-lot consistency.