tech guide

Calibrators, Controls, and Reference Standards

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1. What is the brand name of your company's calibrator or quality control product or product line?	Audit MicroControls Linearity and Daily Controls	Specialty Immunoassay Plus Control	Multichem
2. What year was the product first released to market?	2002	2024	2008 (OUS) and 2012 (US)
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA Class 1 510(k) exempt	FDA Class I, 510(k) exempt; CE mark	CE Mark IVDR 2024; FDA Furls; HCA (Health Canada)
4. What is the intended use or primary function of the product?	Linearity and calibration verification, daily third-party controls	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	Multichem is a portfolio of third-party quality controls, covering serum chemistry and immunoassays, as well as other whole blood assays.
5. With what companies, brands, or models of instruments are your products intended to be used?	Universal; system-specific available for major platforms	Compatible with most major immunoassay platforms, such as Siemens, Roche, and Beckman-Coulter instruments.	Abbott Architect & Alinity, Roche cobas systems, and any other major platforms on the market including Siemens, Beckman, Ortho
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 patient's home or other self-testing
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?	Varies by analyzer	This is dependent upon instrument being used	Dependent on instrument or assay being utilized
9. Briefly describe any automated or connectivity features or options that pertain to the product.	Auditor QC is our free web-based software for data reduction of your linearity and daily quality control results providing instant reports including charts, graphs, statistics and peer group data.	This control is supported by the Unity interlaboratory quality control data management system	Multichem is supported by IAMQC Infinity for daily QC needs and IAMQC Peer for peer reporting.
10. What is the typical training time for the product?	No training is required.	No training is required; material is run as a patient sample	No training is required. The QC is run like a patient sample.
11. What types of technical support are available?	Technical support is available by phone, email, or by chat on the company website.	Technical support is available by phone or email. Individualized customer support is provided as needed.	Technical support is available by phone or email. Focused customer support or on-site support is provided as needed.
12. What capabilities, features, or accessories distinguish this product from others on the market?	At AUDIT our mission is to supply daily quality control and calibration verification/linearity materials to clinical laboratories worldwide while providing value to our customers through accessible and responsive support, real-time data-reduction tools, same-day shipping, and superior-quality products at a fair price.	Comprehensive quality controls that monitor the precision of laboratory specialty IA testing procedures. Includes clinically relevant analytes Procalcitonin, IL-6, Active Vitamin B12, and more. Offered in automation-compatible InteliQ tubes and standard Liquichek vials to help streamline your lab's workflows.	Multichem is available in barcoded load and go formats for Abbott and Roche instruments, where QC targets and ranges are automatically loaded into the system. Overall Multichem provides increased consolidation across chemistry and IA in its leading products Multichem S+ and IA+.

Maine Molecular Quality Controls, Inc. (MMQCI) Saco, ME 207-885-1072 Info@mmqci.com www.mmqci.com	**Randox Laboratories Ltd.** Kearneysville, WV 304-728-2890 www.randox.com	**Verichem Labs** Providence, RI 800-552-5859; customerservice@verichemlabs.com www.verichemlabs.com	**ZeptoMetrix** Buffalo, NY 800-274-5487 diagnostic.cs@zeptometrix.com www.zeptometrix.com
INTROL, Birlinn	Serology Negative Control	Matrix Plus Chemistry Reference Materials; Matrix Plus Cholesterol Reference Materials; Enzyme ER Verifiers; TruZero Bilirubin Standard	ZeptoMetrix PROtrol Antigen Controls
2005	2020	1988	2023
FDA 510(k): 2006; Qarad (EU Authorised Representative) CE mark: 2022; Intertek ISO13485:2016: 2022, BSI ISO 13485:2016 recertification: 2024; MDSAP: 2025	CE Mark; FDA 510(k) clearance	All products are FDA 510(k) cleared.	ISO13485:2016; FDA 21 CFR Part 820
Multiplex quality controls for routine monitoring of molecular diagnostic test systems, validation, verification, proficiency assessment, and training procedures.	Intended for use as an unassayed non-reactive quality assurance reagent with in vitro assays detecting antibody to a wide range of pathogens.	Gravimetric standards, linearity verifiers, and reference materials for calibration or calibration verification of wet chemistry assays on automated clinical testing systems.	Intended for use in analytical and quality control testing of antigen-based assays. The suitability and performance characteristics should be determined by laboratories for each intended usage.
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.	True third-party control, suitable for use on most immunoassay analyzers	Compatible with wet chemistry analyzers from Abbott, Roche, Siemens, Advanced Instruments, Alfa Wassermann, Beckman Coulter, EKF Diagnostics, Horiba, and others.	PROtrol products have demonstrated performance on a number of antigen testing 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	■ 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	■ 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 patient's home or other self-testing
N/A	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.	N/A
All controls are processed like patient sample; time to first result depends on the analyzer.	Same as patient sample	All products are treated like patient specimens; time to first result depends on the analyzer.	This is dependent upon the platform being used
N/A	Connects to Acusera 24.7 with interlaboratory data management software. With the unique ability to generate real-time peer group data while also automatically calculating measurement uncertainty.	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.	N/A
No additional training required, controls are processed like patient samples.	This control is liquid ready to use. Therefore minimal preperation and training time required.	None required.	No training is required
Technical support is available via phone and email. MMQCI's Tech Support team offers prompt individualized service to get your lab up and running ASAP!	Technical support is available by phone or email. Individualized customer support is provided as needed. Online educational material and references, onsite support (available in certain circumstances)	Support available via phone, email, website, and on-site.	Technical support is available by phone or email.
These multiplex synthetic controls are designed to be processed like patient samples, 100% safe, nonhazardous, robust, and stable.	Range comprises both positive and negative controls for a wide range of pathogens including HIV & hepatitis and syphilis. These 100% human serum controls ensure a matrix similar to that of a patient. With an open vial stability of 60 days for these multi-analyte controls, waste and preparation time is kept to a minimum.	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.	QC solutions for antigen testing and provides comprehensive testing data. It offers an inactivated whole organism that mimics a true clinical specimen, with reported protein concentration and pre-inactivation viral titer to minimize qualification testing, reducing repeat testing to save time and costs.