tech guide

Calibrators, Controls, and Reference Standards

	Audit MicroControls, Inc. Eatonton, GA 866-252-8348 customerservice@auditmicro.com www.auditmicro.com	**Bio-Rad Labratories** Hercules, CA 800-224-6723 www.qcnet.com	**LGC Clinical Diagnostics** Milford, MA 800-676-1881 CDx-Sales@lgcgroup.com seracare.com
1. What is the brand name of your company's calibrator or quality control product or product line?	Linearity FLQ TDM for Ortho Vitros	Cardiac Advance Quality Controls	ACCURUN
2. What year was the product first released to market?	2021	2023	1994
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA Class 1 510(k) exempt	FDA Class II, 510(k) exempt;CE Mark	FDA 510(k), 1994; GMED CE mark, 2003
4. What is the intended use or primary function of the product?	Linearity	Intended to use as an assayed quality control serum to promitor the precision of cardiac assesment assays	Method validation, regulatory compliance, daily third-party quality control
5. With what companies, brands, or models of instruments are your products intended to be used?	Intended for use with Ortho Vitros analyzers	Currently compatable with Siemens and Roche instruments. Compatability with Beckman-Coulter coming fall 2023.	Universal; assay agnostic for major molecular and serology platforms
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 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
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; customers may access Auditor QC, a free online data-reduction program.	This is dependent upon instrument being used	Varies by analyzer
9. Briefly describe any automated or connectivity features or options that pertain to the product.	N/A	This control is supported by the Unity interlaboratory quality control data managment system	N/A
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 required; material is run as 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. Individualized customer support is provided as needed.
12. What capabilities, features, or accessories distinguish this product from others on the market?	Consists of five levels of human-based serum. These five levels demonstrate a linear relationship to each other when assayed for acetaminophen, carbamazepine, digoxin, gentamicin, lithium, phenytoin, salicylate, theophylline, tobramycin, valproic acid, and vancomycin. This product has an open vial stability of 7 days when stored at 2-8°C.	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.	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.

LGC Clinical Diagnostics Milford, MA 800-377-9684 CDx-Sales@lgcgroup.com mainestandards.com	**Maine Molecular Quality Controls, Inc. (MMQCI)** Saco, ME 207-885-1072 Info@mmqci.com www.mmqci.com	**Microbiologics** Saint Cloud, MN 320-253-7400 info@microbiologics.com www.microbiologics.com	**Quantimetrix** Redondo Beach, CA 310-536-0006
VALIDATE	Introl	Microbiologics Helix Elite	Dipper POCT Liquid Urinalysis Quality Control
2001	2005	1971	2018
FDA 510(k), FDA Listed and CE	FDA 510(k), 2006; Qarad CE mark: 2022	FDA 510(k), FDA 510(k) exempt, CE Mark	CE mark, 2018; FDA 510(k) exempt.
Linearity and calibration verification	Multiplex quality controls for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. .	Third-party IVD quality controls that monitor the extraction, amplification, and detection process of molecular testing assays.	Monitor the performance of visual and instrument readings of urinalysis dipsticks by immersing the dipstick into the control, in the same way that patient samples are tested.
Universal; assay agnostic for major biochemistry platforms	Controls for laboratory developed tests. Controls for platforms by BioFire, Cepheid, Curetis, GenMark, Illumina (NGS), Luminex, and Qiagen. Custom products for assay manufacturers.	Multiple platform compatibility	Dipper POCT is designed for use in every testing environment, including: central labs, reference labs, nursing stations, and doctors' offices.
■ 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	■ 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 analyzer	N/A	Varies by assay and/or instrument	Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program, via quantimetrx.com.
N/A	Assay dependent	N/A	N/A
No training required; material is run as a patient sample.	Minimal training required.	Minimal training required	N/A
Technical support is available by phone or email. Individualized customer support is provided as needed."	Email and phone support available, as well as troubleshooting materials.	Technical support is avaliable by phone at 320-229-7045 and via email at techsupport@microbiologics.com	Technical support is available at (310) 536-0006, Ext: 213; via techsupport@quantimetrix.com.; or via our live chat at quantimetrix.com
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.	These multiplex synthetic controls are 100% safe, nonhazardous, robust, and stable."	Designed to be processed like patient samples. Offers a wide range of formats—from synthetic nucleic acid RNA and DNA sequences to inactivated, fully intact whole organisms. Targets covered include respiratory, women's health and STIs, gastrointestinal, COVID, blood culture ID, healthcare associated infections.	The control is stable for 3 months when stored at room temperature, and up to 3 years when stored at 2–8°C; full dipstick immersion; zero wasted QC product. Patented single use format.

Quantimetrix Redondo Beach, CA 310-536-0006	**Randox Laboratories Ltd.** Crumlin, Northern Ireland (+)44 28 94422413 marketing@randox.com www.randox.com	**Randox Laboratories Ltd.** Crumlin, Northern Ireland (+)44 28 94422413 marketing@randox.com www.randox.com	**StatLab Medical Products** McKinney, TX 1-800-442-3573 orders@statlab.com truqcontrols.com
Dip & Spin Urinalysis Dipstick & Microscopics Control	Serum Indices Control	Anti-Müllerian Hormone Control	TruQ Bioengineered Tissue Microarray (TMA) Controls
1996	2022	2023	US - 2016
CE mark, 1996; FDA 510(k) exempt. Urinalysis Microscopics Control 1993 #K874890	FDA (501K) Exempt, UK CA	FDA (501K) Exempt, UK CA	US - Research Use Only
Combined urinalysis dipstick and microscopy control to monitor the performance of both urinalysis dipsticks and manual/automated urine sediment microscopy methods.	Designed to monitor an IVD instrument's response in the detection of haemolytic, icteric and lipemic interference to aid in improving error detection of the pre-analytical errors which affect clinical chemistry testing.	Designed for use as a third-party control for the quantitative determination of Anti-Müllerian Hormone (AMH).	TruQ bioengineered tissue microarray control blocks and slides are to be used to monitor the performance of the IHC staining assay during initial validation and for troubleshooting activities.
Compatible with most urine strip brands, manual microscopy methods, confirmatory tests, and automated analyzers such as: iQ200, UriSed, COBIO-XS, sediMAX, iRICELL, LabUMat2/UriSed2. Now with values for Roche Cobas 6500.	As a true, third-party control, this control can be used with any automated analyser which has onboard HIL detection capabilities.	As a true, third-party control, this control can be used with any automated analyser	Ventana Benchmark, Leica BOND, Dako Omnis, Quantum HDx
■ 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	
N/A	N/A	N/A	
Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program, via quantimetrx.com.	The Serum Indices control is designed to improve laboratory turnaround times, the time to first result will depend on the instrument in question	Varies depending on IVD instumentation	TruQ is designed to be used as an on-slide control for immunotaining; time to first result is dependant on the immunostainer and stain being performed.
N/A	The Serum indices control can be supported by Acusera 24.7 - The Interlaboratory Data Management Software	The AMH control can be supported by Acusera 24.7 - The Interlaboratory Data Management Software	Can be used with digital pathology
N/A	No training is required as this control is run as a patient sample.	No training is required as this control is run as a patient sample.	Product is designed to be used as a substitute for tissue controls; validation of new control methodology is independently verified by each lab.
Technical support is available at (310) 536-0006, Ext: 213; via techsupport@quantimetrix.com.; or via our live chat at quantimetrix.com	Technical support is available by phone or email.	Technical support is available by phone or email.	The product is support by StatLab's Technical Support team, available by phone or email at 1-800-442-3573, option 5 or tech@statlab.com
Microscopics sediment element include calcium oxalate dihydrate crystals, E. coli bacteria, red blood cells, and white blood cells. Can also be used for βhCG screening methods and for confirmatory tests such as K-Check and Ictotest.	Supplied as 4 separate levels (-, +, ++, +++), this third-party control is manufactured using human serum, ensuring a commutable matrix and unbiased testing. This lyophilised product has a 2-year shelf-life and a reconstituted stability of 14 days at 2-8°C.	Supplied in 4 clinically significant levels, this third-party control is manufactured using human serum for a truly commutable matrix. This control has an open vial stability of 30 days at 2-8°C and is supplied with assayed targets for most clinical chemistry analyzers.	TruQ Bioengineered TMA Controls are created using a patented histosynthesis process utilizing cell lines. TruQ Bioengineered Tissue Microarray (TMA) Controls deliver the first reference-standard control that meets CAP recommendations for on-slide positive and negative IHC controls—with the look of tissue.

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SUPERIOR PERFORMANCE

Our high-performance assays deliver superior methodologies and help to deliver more accurate results compared to traditional methods.

CONFIDENCE IN PATIENT RESULTS

The traceability of material and extremely tight manufacturing tolerances ensure uniformity across our reagent batches.

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Reduce your time spent on running tests through liquid ready-to-use reagents, automated methods and our easy - fit options.

APPLICATIONS AVAILABLE

Instrument specific applications are available for a wide range of clinical chemistry analyzers offering complete convenience and supplier consolidation.

REDUCE COSTS

By providing reagents with exceptional stability, ensuring top-quality products to avoid costly re-runs, and offering a variety of kit sizes, including smaller kits for niche tests, we can assist your laboratory in achieving cost savings.

Aldolase	Creatinine (Enzymatic)	Immunoglobulin E (IgE)
Apolipoprotein C-II	Cystatin C	Lipoprotein (a)
Apolipoprotein C-III	D-3-Hydroxybutyrate (Ranbut)	Microalbumin
Apolipoprotein E	Fructosamine (Enzymatic)	Non-Esterified Fatty Acids (NEFA)
Bile Acids (5th Generation)	Glucose-6-Phosphate Dehydrogenase (G6PDH)	Soluble Transferrin Receptor (sTfR)
Bilirubin (Vanadate Oxidation)	Glutathione Peroxidase (Ransel)	Superoxide Dismutase (Ransod)
Small Dense LDL Cholesterol (sdLDL-C)	Glutathione Reductase	Total Antioxidant Status (TAS)
Copper	Homocysteine	Zinc

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Thermo Scientific MAS OMNI•IMMUNE PRO	Thermo Scientific Acrometrix Oncology Hotspot Control	Matrix Plus Chemisty Reference Materials; Matrix Plus Cholesterol Reference Materials; Enzyme ER Verifiers; TruZero Bilirubin Standard	NATtrol Molecular Controls
2015	2014	1988	2012
FDA 510(k) exempt; CE marked	FDA 510(k) exempt; CE marked	All products are FDA 510(k) cleared.	RUO, IVD, CE Mark, FDA 510(k), FDA 510(k)exempt
Thermo Scientific MAS Omni•IMMUNE PRO is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations	The AcroMetrix Oncology Hotspot Control is intended for use with next generation sequencing (NGS) assays that are designed to identify somatic mutations in DNA from human samples.	Gravimetric standards, linearity verifiers, and reference materials for calibration or calibration verification of wet chemistry assays on automated clinical testing systems.	Third-party quality controls that monitor the extraction, amplification, and detection process of molecular testing assays.
Any immunoassay analyzer.	Next-generation sequencing platforms	Compatible with wet chemistry analyzers from Abbott, Roche, Siemens, Advanced Instruments, Alfa Wassermann, Beckman Coulter, EKF Diagnostics, Horiba, and others.	Multiple platform compatibility
■ 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	■ 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
		IVD manufacturer instrument/assay development, analytical measurement range monitoring, clinical assay troubleshooting, bias to true value. product development applications, and tracking normal range drift.	
The time to first result is dependent on the instrument being used.	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.	Varies by assay and/or instrument
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	N/A	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 training is required as the quality control products are run as patient samples	No training is required as the quality control products are run similar to clinical samples	None required.	Minimal training required
Transition support. Training. Expert customer support. Technical support available at mas.controls@thermofisher.com	Training. Expert customer support. Technical support available at mas.controls@thermofisher.com	Support available via phone, email, website, and on-site.	Technical support is available by phone or email. Individualized customer support is provided as needed.
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.	The Thermo Scientific AcroMetrix Oncology Hotspot Control is a unique IVD highly multiplexed quality control used to assess the performance of next-generation sequencing (NGS) assays that detect somatic mutations. Over 500 SNPs, insertions, and deletions of varying lengths and complexities.	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.	Designed to mimic a true clinical specimen that can monitor the extraction, amplification, and detection process of molecular testing assays. Refrigerated ready-to-use, non-infectious and are whole microorganisms. Targets include respiratory, women's health, STIs, gastrointestinal, SARS-CoV-2, blood culture ID, healthcare associated infections, and more.

Quality Controls

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