tech guide

Calibrators, Controls, and Reference Standards

	Audit MicroControls, Inc. Eatonton, Ga. 866-252-8348 customerservice@auditmicro.com www.auditmicro.com	Audit MicroControls, Inc. Eatonton, Ga. 866-252-8348 customerservice@auditmicro.com www.auditmicro.com	Bio-Rad Laboratories Hercules, Calif. 800-224-6723 www.qcnet.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	Linearity FLQ Special Diabetes for Abbott Systems	InteliQ Diabetes Control
2. What year was the product first released to market?	2021	2021	2021
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA Class 1 510(k) exempt	FDA Class 1 510(k) exempt	FDA Class II, 510(k) exempt; CE mark
4. What is the intended use or primary function of the product?	Linearity	Linearity	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.
5. With what companies, brands, or models of instruments are your products intended to be used?	Intended for use with Ortho Vitros analyzers	Intended for use with Abbott analyzers	Any high-throughput, automated immunoassay instrument such as Siemens Atellica, Roche Cobas, and Abbott Alinity.
6. Where is the product used?	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere
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.	Varies by analyzer; customers may access Auditor QC, a free online data-reduction program.	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.
9. Briefly describe any automated or connectivity features or options that pertain to the product.	N/A	N/A	This control is supported by the Unity interlaboratory quality control data management program.
10. What is the typical training time for the product?	No training is required.	No training is required.	No training is 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, email, or by chat on the company website.	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.	Consists of five levels of human-based serum. These five levels demonstrate a linear relationship to each other when assayed for C-peptide, and insulin. This product has an open vial stability of 7 days when stored at 2-8°C.	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.

Intelligent QC starts with InteliQ.

Transform your QC workflow with load-and-go efficiency

Time is critical when working with patient samples. That's why top performing labs are relying on the load-and-go efficiency of InteliQ for their quality control.

InteliQ set up is fast. Simply load the pre-barcoded controls on your instrument and go. With fewer manual steps, turnaround time is reduced and human error is minimized, getting you from patient samples to reliable patient results more efficiently.

Isn't it time to bring smarter, more efficient QC to your lab?
Find out how: qcnet.com/inteliq

BIO-RAD

InteliQ is compatible with chemistry and immunoassay diagnostic platforms as listed in the product insert.
Bio-Rad is a trademark of Bio-Rad Laboratories, Inc. in certain jurisdictions.

Bio-Rad Laboratories Hercules, Calif. 800-224-6723 www.qcnet.com	**Bio-Rad Laboratories** Hercules, Calif. 800-224-6723 www.qcnet.com	**Bio-Rad Laboratories** Hercules, Calif. 800-224-6723 www.qcnet.com	**Fujirebio Diagnostics, Inc.** Malvern, Pa. 1-800-531-7963 kits@fdi.com www.fujirebio.com
Exact Diagnostics SARS-CoV-2, Flu, RSV Positive Run Control	Exact Diagnostics SARS-CoV-2, Flu, RSV Negative Run Control	InteliQ Immunoassay Plus Control	Fujirebio Diagnostics, Inc.
2021	2021	2020	2010
CE-IVD	CE-IVD	FDA Class I, 510(k) exempt; CE marked as List B product	FDI 510(k), 2010; CE Mark, 2010
External quality control intended to be used with molecular assays to monitor their performance. Routine use allows laboratories to evaluate day-to-day and lot-to-lot variation of molecular assays and test for operator proficiency.	External quality control intended to be used with molecular assays to monitor their performance. Routine use allows laboratories to evaluate day-to-day and lot-to-lot variation of molecular assays and test for operator proficiency.	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.	Quality control product
To be used with single or multiplexed respiratory assays.	To be used with single or multiplexed respiratory assays.	Any high-throughput, automated immunoassay instrument such as Siemens Atellica, Roche Cobas, and Abbott Alinity.	Multiple instruments
❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere
N/A	N/A	N/A	N/A
N/A	N/A	Load-and-go tubes are designed to significantly reduce hands-on time. The time to first result is dependent on the instrument being used.	N/A
This control is supported by the Unity interlaboratory quality control data management program.	This control is supported by the Unity interlaboratory quality control data management program.	This control is supported by the Unity interlaboratory quality control data management program.	N/A
No training required.	No training required.	No training is required; material is run as a patient sample.	N/A
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 by phone or email. Individualized customer support is provided as needed.	Technical support is available as required during std. business hours.
Whole organism SARS-CoV-2, influenza A, influenza B, respiratory syncytial virus (A) run control, with a human genomic DNA background.	Negative for SARS-CoV-2, influenza A, influenza B and RSV (A) and is formulated in a synthetic matrix and contains human genomic DNA.	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.	The only multi-constituent control to contain the novel biomarker HE4, is an assayed, bi-level tumor marker panel containing clinically revelant proportions of fPSA and PSA-ACT as well as excellent reconsitution stability. It is manufactured to the highest quality standards and ensures accurate precision of in-vitro diagnostic laboratory testing procedures and techniques.

Fujirebio Diagnostics, Inc.	**Fujirebio Diagnostics, Inc.**	**LGC Clinical Diagnostics**	**LGC Clinical Diagnostics**
Malvern, Pa. 1-800-531-7963 kits@fdi.com www.fujirebio.com	Malvern, Pa. 1-800-531-7963 kits@fdi.com www.fujirebio.com	Milford, Mass 800-676-1881 CDx-CustomerService@lgcgroup.com seracare.com	Milford, Mass 800-676-1881 CDx-CustomerService@lgcgroup.com seracare.com
Fujirebio Diagnostics, Inc.	Fujirebio Diagnostics, Inc.	ACCURUN	Seraseq
2011	2017	1994	2016
FDI 510k, 2011; CE Mark, 2011	Device Listing	FDA 510(k), 1994; GMED CE mark, 2003	N/A
Quality control product	Quality Control Product	Method validation, regulatory compliance, daily third party quality control	Method validation, reference material for daily quality control
Multiple instruments	Multiple instruments	Universal; assay agnostic for major molecular and serology platforms	Universal; assay agnostic for major NGS platforms
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N/A	N/A	N/A	N/A
N/A	N/A	Varies by analyzer	Varies by analyzer
N/A	N/A	N/A	N/A
N/A	N/A	No training required; material is run as a patient sample.	No training required; material is run as a patient sample.
Technical support is available as required during std. business hours.	Technical support is available as required during std. Business hours.	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.
It is an assayed,tri-level control containing both 25(OH) vitamin D2 and 25(OH) vitamin D3. It contains clinically relevant concentrations of 25(OH) vitamin D as well as excellent reconstitution stability. It is manufactured to the highest quality standards and ensures accurate precision monitoring of in-vitro diagnostics laboratory testing procedures and techniques.	It is an unassayed precision control reagents for the qualitative determination of total antibodies to treponema pallidum. It contains two (2) levels of controls. The vials of each control level are color-coded for easy recognition, and all vials are supplied ready to use. It is manufactured to the highest quality standards and can assist laboratories in analyzing and identifying problems in a test run as well as verifying test results.	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.	Seraseq reference materials help scientists and clinicians build, validate, and implement clinical genomics assays for patient disease testing. These highly multiplexed, patient-like reference materials are available in a variety of matrices (FFPE, plasma, purified NA) to support NGS assays used in oncology and reproductive health.

LGC Clinical Diagnostics	Technopath Clinical Diagnostics	Maine Molecular Quality Controls	Microbiologics
Milford, Mass 800-377-9684 CDx-CustomerService@lgcgroup.com mainestandards.com	Ballina, Co., Ireland 888-235-3597 info@technopathusa.com technopathclinicaldiagnostics.com	Saco, Maine 207-885-1072 www.mmqci.com	Saint Cloud, Minn 320-253-7400 info@microbiologics.com www.microbiologics.co
VALIDATE	Multichem	Introl	Microbiologics Helix Elite
2001	2013	2005	1971
FDA 510(k), FDA Listed and CE	FDA510(k) and CE mark, 2013	FDA 510(k), 2006	FDA 510(k), FDA 510(k) exempt, CE Mark
Linearity and calibration verification	Independent, third-party quality control	Multiplex quality controls to assess molecular testing extraction, amplification, and detection. Immediate detection of errors, shifts, or trends.	Third-party IVD quality controls that monitor the extraction, amplification, and detection process of molecular testing assays.
Universal; assay agnostic for major biochemistry platforms	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
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N/A	N/A	N/A	N/A
Varies by analyzer	Varies by analyzer	Assay dependent	Varies by assay and/or instrument
N/A	Barcoded products are ready to load and store on the analyzer and target values are automatically downloaded. QC results are automatically uploaded to the IAMQC software.	N/A	N/A
No training required; material is run as a patient sample.	No training required; material can be run as a patient sample and/or following the analyzer manufacturer instructions for quality control.	Minimal training required.	Minimal training required
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.	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
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.	Technopath Clinical Diagnostics is one of the largest manufacturers of liquid-ready quality controls globally in compliance with the highest quality standards. Multichem is our class leading third-party test-consolidated QC product range with an extensive list of analytes. IAMQC software supports QC data management for laboratory accreditation.	The synthetic controls are 100% safe, nonhazardous, robust, and stable.	Microbiologics quality controls are designed to mimic patient samples that can be used to monitor the extraction, amplification, and detection process of molecular testing assays. To meet the needs of laboratories, we offer 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, and more.

LGC maine standards

Validate®

Linearity and Calibration Verification Test Kits for Clinical Analyzers

Easy

VALIDATE® test kits use human-sourced raw materials, where available, and require no reconstitution.

Liquid, ready-to-use solutions are supplied in multi-use dropper bottles for easy dispensing.

Order once per year with extended open-vial stability and additional material for troubleshooting.

Fast

VALIDATE® test kits increase productivity, reducing the need for sample preparation and manual dilutions.

Levels 1 - 5 are prepared according to CLSI's EP06-A guideline.

Fulfill CLIA '88, CAP, ISO 15189, COLA, JCAHO, JCI and other accreditation and regulatory requirements.

Efficient

Together with our MSDRx® software, VALIDATE® provides a comprehensive calibration verification assessment.

Instrument-specific configurations maximize range coverage and minimize dilutions.

Use for installation, preventative maintenance and troubleshooting of reagents, QC and calibrations.

We are so certain you will find value in VALIDATE®, all products come with a 100% satisfaction guarantee.

1.207.892.1300 or 1.800.377.9684
MSC.Sales@LGCGroup.com

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Calibrators, Controls, and Reference Standards

	Qnostics	Quantimetrix	Quantimetrix
	Glasgow, Scotland www.qnostics.com +44 (0) 28 9442 2413	Redondo Beach, Calif. (310) 536-0006	Redondo Beach, CA (310) 536-0006
1. What is the brand name of your company's calibrator or quality control product or product line?	Qnostics	Dipper POCT Liquid Urinalysis Quality Control	Dip & Spin Urinalysis Dipstick & Microscopics Control
2. What year was the product first released to market?	2017	2018	1996
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE Marked, FDA 510 (k)	CE mark, 2018; FDA 510(k) exempt.	CE mark, 1996; FDA 510(k) exempt. Urinalysis Microscopics Control 1993 #K874890
4. What is the intended use or primary function of the product?	QC solutions for molecular infectious disease testing.	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.	Combined urinalysis dipstick and microscopy control to monitor the performance of both urinalysis dipsticks and manual/automated urine sediment microscopy methods.
5. With what companies, brands, or models of instruments are your products intended to be used?	Range comprises hundreds of characterized viral, bacterial, and fungal targets, which cover a wide range of diseases and therefore we have something available for a wide range of platforms.	Dipper POCT is designed for use in every testing environment including: central labs, reference labs, nursing stations, and doctors' offices.	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.
6. Where is the product used?	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere	❑ 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 ❑ In patient's home or other self-testing ❑ Elsewhere
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?	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.	Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program, via quantimetrx.com.
9. Briefly describe any automated or connectivity features or options that pertain to the product.	N/A	N/A	N/A
10. What is the typical training time for the product?	Qnostics controls require professional use, however, some of our products are perfect for staff training.	N/A	N/A
11. What types of technical support are available?	A technical support department is available to deal with all queries via telephone, email and ocassionally visits	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 at (310) 536-0006, Ext: 213; via techsupport@quantimetrix.com.; or via our live chat at quantimetrix.com
12. What capabilities, features, or accessories distinguish this product from others on the market?	Whole pathogen controls designed to mimic the performance of patient samples; monitoring entire testing process including extraction, amplification and detection; samples supplied in convenient liquid formats meaning there is little to no preparation required.	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.	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.

Randox Laboratories	Thermo Fisher Scientific	Thermo Fisher Scientific	Verichem Labs
Crumlin, County Antrim www.randox.com +44 (0) 28 9442 2413	Fremont, Calif. www.thermofisher.com 1-800-232-3342 sales.diagnostics.fmt @thermofisher.com	Fremont, Calif. www.thermofisher.com 1-800-232-3342 sales.diagnostics.fmt @thermofisher.com	Providence, R.I. 800-552-5859; customerservice@verichemlabs.com www.verichemlabs.com
Acusera	Thermo Scientific	Thermo Scientific	Matrix Plus Chemisty Reference Materials; Matrix Plus Cholesterol Reference Materials; Enzyme ER Verifiers; TruZero Bilirubin Standard
2010	2015	2014	1988
CE marked, FDA 510 (k)	FDA 510(k) exempt; CE marked	FDA 510(k) exempt; CE marked	All products are FDA 510(k) cleared.
True third-party controls designed to deliver a cost-effective yet high-quality solution for any lab regardless of their size or budget	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 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.
Control portfolio is wide and includes a vast array of instruments, methods and companies that can use our products.	Any immunoassay analyzers.	Next-generation sequencing platforms	Compatible with wet chemistry analyzers from Abbott, Roche, Siemens, Advanced Instruments, Alfa Wassermann, Beckman Coulter, EKF Diagnostics, Horiba, and others.
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N/A	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	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.
Designed to complement our range of third-party controls, Acusera 247 is a live, cloud based interlaboratory data management and peer group reporting software, intended to assist in the management of daily QC activities.	Thermo Scientific MAS Lablink xL software is a 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.
Some controls are perfect for POCT and therefore require little training. There are also some others that require laboratory experience to use.	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.
Randox Technical Support is available via email and telephone to help with queries. There is also an online help chat.	Transition, 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.
Range of multi-analyte controls help to reduce number of individual controls required to cover your test menu, ultimately reducing time and costs. Flexible options are guaranteed with a choice of assayed, or unassayed.	Highly consolidated third-party control enabling reduction of number of QC references. The 3 years lot stability of the product allow laboratories to stay longer on the same lot and significantly reduce the number of lot crossover. All MAS QC are liquid, ready-to-use.	The Thermo Scientific AcroMetrix Oncology Hotspot Control is a unique IVD highly multiplexed quality.	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.