tech guide

Calibrators, Controls, Reference Standards, and Interlaboratory Peer-Reporting Programs

	Audit MicroControls Eatonton, Ga (866) 252-8348 www.auditmicro.com	Audit MicroControls Eatonton, Ga (866) 252-8348 www.auditmicro.com	Bio-Rad Laboratories Hercules, Calif (800) 224-6723 www.qcnet.com/molecular
1. What is the brand name of your company's calibrator or quality control product or product line?	Linearity FLQ Thyroids for Roche Systems (order no. K926M-5)	Linearity FLQ Fertility for Roche Systems (order no. K927M-5)	Amplichek
2. What year was the product first released to market (US, OUS)?	2019	2019	2016
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	510(k) exempt	510(k) exempt	Amplichek I: CE mark, 2016; FDA 510(k), 2016; Amplichek II: CE mark, 2016; FDA de novo 510(k), 2016; Amplichek STI: CE mark, 2016; FDA Class 1 exempt, 2016.
4. What is the intended use or primary function of the product?	Simulates human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for T3, T4, TSH, Free T3, and Free T4.	Simulates human patient samples for use in determining linearity, calibration verification, and the verification of reportable range for AFP, DHEA-S, estradiol, FSH, HCG, HGH, LH, progesterone, prolactin, and testosterone.	Quality control.
5. With what companies, brands, or models of instruments are your products intended to be used?	Roche Systems	Roche Systems	Molecular diagnostic platforms performing real-time polymerase chain reaction (PCR)
6. Where is the product used (check all that apply)?	❑ 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 a patient's home or other self-testing	❑ 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 a patient's home or other self-testing	❑ 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 a patient's home or other self-testing
7. Under ideal conditions, what is the time to first result; how are the test results made available?	Time to first result varies by analyzer; customers may access Auditor QC, a free online data-reduction program, at www.auditmicro.com.	Time to first result varies by analyzer; customers may access Auditor QC, a free online data-reduction program, at www.auditmicro.com.	N/A
8. Briefly describe any automated or connectivity features or options that pertain to the product.	N/A	N/A	The controls are supported by the Unity interlaboratory quality control data management program.
9. 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.	N/A
10. What types of technical support are available?	Technical support is available by phone at (866) 252-8348; via e-mail at technicalsupport@auditmicro.com; or via chat on the company website. Individualized customer support is provided as needed.	Technical support is available by phone at (866) 252-8348; via e-mail at technicalsupport@auditmicro.com; or via chat on the company website. Individualized customer support is provided as needed.	Training, expert support, and service.
11. What capabilities, features, or accessories distinguish this product from others on the market?	The product is an IVD device consisting of 10 levels of liquid material and additives in human-based serum. It has open-vial stability of 7 days when stored at 2° C to 8° C.	The product is an IVD device consisting of 10 levels of liquid material and additives in human-based serum. It has open-vial stability of 7 days when stored at 2° C to 8° C.	Liquid, ready-to-use multianalyte quality control products for molecular infectious disease testing; enables monitoring of the performance of nucleic acid testing procedures for healthcare-associated infections, viral load assays, and more.

Bio-Rad Laboratories	Biochemical Diagnostics	EuroTrol	Maine Molecular Quality Controls
Hercules, Calif (800) 224-6723 www.qcnet.com/inteliq	Edgewood, NY (631) 595-9200 www.biochemicaldiagnostics.com	Ede, The Netherlands (502) 501-1180 www.eurotrol.com	Saco, Maine (207) 885-1072 www.mmqci.com
InteliQ quality controls	Stat-Skreen liquid urine control	HemoTrol WB	Introl
2018	2005	2019	2005
FDA 510(k), 2018.	FDA 510(k), CE mark	FDA 510(k), 2019	FDA 510(k), 2006
Quality control to monitor clinical chemistry and immunoassay testing procedures.	Drugs of abuse lateral-flow rapid test controls.	An assayed hemoglobin control intended for use in verifying the precision and accuracy of the HemoCue Hb301 and Hb801 systems.	Multiplex quality controls to assess molecular testing, including the extraction, amplification, and detection steps. Immediate detection of errors, shifts, or trends caused by changes in the environment and test system components.
Compatible with automated clinical chemistry and immunoassay platforms as listed in the instructions for use.	Independent third-party external control; works with all lateral-flow screening devices.	HemoCue Hb301 and Hb 801 systems	Introl controls for laboratory-developed tests. Controls for platforms by BioFire, Cepheid, Curetis, GenMark, Illumina (NGS), Luminex, and Qiagen. Custom products for assay manufacturers.
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Test results are made available through the Unity interlaboratory quality control data management program.	Results can be manually read or can be accessed via a device reader, if available.	The quality controls are used on compatible instruments; results are read directly from the instrument.	Assay dependent.
InteliQ provides a universal file (XML format) that permits secure access, downloading, and uploading of value assignment data into instruments.	If automated device reader is used, results can be sent to laboratory information system.	Eurotrol provides all customers with CueSee, a free online program for comparing quality control data with peers. Users enter results anonymously and generate statistical reports to compare data. Users share data to improve patient care.	N/A
1 week	Less than 30 minutes	Minimal	Minimal
Full-service global technical support.	Technical service staff available.	Staff are always available to assist in placing an order, evaluating a sample, or responding to questions or feedback.	Phone support and troubleshooting materials.
Available in a barcoded load-and-go tube configuration designed to optimize workflow efficiency and support the lab's risk management program. Features include access to the Unity data management program, large peer-group comparisons, technical support, and easy XML data upload.	Human urine matrix mimics patients samples; 17 drug formulations; 5 mL, 10 mL, and 20 mL sizes available; positive and negative levels.	Formulated with real blood cells to closely mimic whole blood and provide superior quality control for HemoCue Hb801 systems. It features 30-day open-vial stability. Developed with HemoCue and recommended as the company's preferred quality control.	The synthetic controls are 100% safe, nonhazardous, robust, and stable.

More Diagnostics	Quantimetrix	Quantimetrix	Randox Laboratories
Los Osos, Calif (800) 758-0978 www.morediagnostics.com	Redondo Beach, Calif (310) 536-0006 www.quantimetrix.com	Redondo Beach, Calif (310) 536-0006 www.quantimetrix.com	Kearneysville, W Va (310) 536-0006 www.randox.com
Immunosuppressant Rap/Tac/Csa Control (order no. #290)	Dipper POCT Liquid Urinalysis Quality Control	Chromascopics Urinalysis Control with Microscopics	Acusera linearity verifier for Roche Cobas
2005	2018	2018	2019
CE mark; 510(k), 2005.	CE mark, 2018; FDA 510(k) exempt.	CE mark, 2018; FDA 510(k) exempt.	
A whole-blood precision control product to check calibration in chemistry analyzers that measure cyclosporine, rapamycin (sirolimus), and tacrolimus.	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.	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.	Designed to challenge the entire analytical measuring range of Roche Cobas analyzers, while helping to meet CLIA requirements.
Abbott Architect, Siemens Atellica solution, Siemens Dimension, Siemens Syva EMIT 2000, Siemens Vista; also appropriate for LC-MS/MS and automated immunoassay systems that correlate with chromatographic methods.			Roche Cobas
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N/A	Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program.	Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program.	Analyzer dependent
Customer may participate in a free peer-to-peer quality control data program.	N/A	N/A	Complimentary data reduction software is provided, delivering an immediate indication of performance.
No training required; material is run as patient sample.	N/A	N/A	N/A
Technical support may be reached at (800) 758-0978, or via support@morediagnostics.com.	Technical support is available at (310) 536-0006, ext. 213; via techsupport@quantimetrix.com; or via live chat at www.quantimetrix.com.	Technical support is available at (310) 536-0006, ext. 213; via techsupport@quantimetrix.com; or via live chat at www.quantimetrix.com.	Aftercare support is supplied via a technical services division and can be contacted via e-mail at technical.services@randox.com.
An easy-to-use liquid whole-blood product with 5 mL fill volume. The product has a 4-year frozen shelf life and 45 days open-vial stability when stored at 2° C to 8° C.	The control is stable for 3 months when stored at room temperature and up to 3 years when stored at 2° C to 8° C; full dipstick immersion; zero wasted QC product.	Microscopics sediment elements 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.	Sets are designed to challenge a larger area of an instrument's reportable range and test whether a system's calibration is still valid. Materials cover a wide range of testing, including CRP, RF, lipids, therapeutic drugs, esoterics, and more. Testing five levels offers a more in-depth understanding than CLIA's advised three levels.

Streck La Vista, Neb (800) 843-0912 www.streck.com	**Streck** La Vista, Neb (800) 843-0912 www.streck.com	**Utak Laboratories** Valencia, Calif (888) 882-5522 www.utak.com	**Verichem Laboratories** Providence, RI (800) 552-5859 www.verichemlabs.com
Sperm-Chex and Sperm-Chex Post VC	A1c-Cellular and A1c-Cellular Linearity	Custom controls	No brand name used.
2015	2004 and 2012	1973	1988
CE mark, 2015; 510(k), 2004.	CE mark, 2004 and 2012; 510(k), 2004 and 2012.	ISO 13485; Medical Device Single Audit Program certified.	All products are FDA 510(k) cleared.
Manual sperm count controls to help validate the quantification of sperm counting by manual methods.	HbA1c control and linearity materials containing intact red blood cells to challenge the entire HbA1c procedure, including the lysing of red blood cells. A1c-Cellular contains two levels; A1c-Cellular Linearity is available in a five-level set.	Quality control materials for therapeutic drug monitoring, drugs of abuse testing, and more, for clinical, research, and toxicology labs.	Standards and reference materials used for the calibration, or calibration verification, of wet chemistry assays on automated test systems.
Hemocytometer, Makler counting chamber.	Assayed on the top HbA1c analyzers.	Products can be used with any instrument or testing methodology.	Compatible with wet chemistry analyzers from Abbott, Advanced Instruments, Alfa Wassermann, Beckman Coulter, EKF Diagnostics, Horiba Medical, Instrumentation Laboratory, Medica, Randox, Roche, and Siemens.
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Dependent on the analysis method in use.	Dependent on the analysis method in use.	Dependent on instrument and method; materials are run alongside patient samples.	Time to first result is dependent on the test analyzer being used.
N/A	N/A	Controls can be aliquoted into vials suitable for any automated method.	The Cal-Ver quality assurance program is offered free to all customers and offers CLIA-compliant test reports verifying the analyzer's accuracy, linearity, calibration verification, and reportable range.
Requires minimal training	Requires minimal training	No additional training required.	None required.
Medical technologists are readily available during business hours to assist with technical questions, via technicalservices@streck.com.	Medical technologists are readily available during business hours to assist with technical questions, via technicalservices@streck.com.	Technical and troubleshooting support is available by phone at (888) 882-5522; via e-mail at welovecontrol@utak.com; or via chat on www.utak.com.	Phone, e-mail, website, and on site.
The only manual sperm count controls that contain real sperm cells. Available in two clinically significant levels. Same chamber-loading or optical characteristics as a patient sample. Compatible with hemocytometers and other counting chambers. Offers 42-day open-vial stability; 12-month closed-vial stability.	Ready-to-use liquid control and linearity material for immunoassay and ion exchange HPLC methodologies. Available in plastic cap-pierceable vials for analyzer autosampling.	Hand-crafted quality controls made with 100% real human matrix and the purest drugs available. Personalized controls are customized for specified analytes and concentrations and matrix-matched to patient samples to eliminate matrix effects.	Products are compatible with all major wet chemistry systems; are CLIA compliant; have certified accuracy using available USP, ACS, and NIST materials. Most come with an individual certificate of analysis, are liquid stable and ready to use, and offer long shelf-life and lot-to-lot consistency.