tech guide

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

	Audit MicroControls Eatonton, Ga 866-252-8348 customerservice@auditmicro.com www.auditmicro.com	Audit MicroControls Eatonton, Ga 866-252-8348 customerservice@auditmicro.com www.auditmicro.com	Audit MicroControls Eatonton, Ga 866-252-8348 customerservice@auditmicro.com www.auditmicro.com
1. What is the brand name of your company's calibrator or quality control product or product line?	Control LQ Covid-19 Antibodies	CalVer FLQ Drugs of Abuse for Beckman AU	CalVer FLQ Drugs of Abuse for Roche Systems
2. What year was the product first released to market?	2020	2020	2020
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	FDA Class 1 exempt, 2020	FDA Class 1 exempt, 2020	FDA Class 1 exempt, 2020
4. What is the intended use or primary function of the product?	Daily quality control	Calibration verification	Calibration verification
5. With what companies, brands, or models of instruments are your products intended to be used?		Beckman AU systems	Roche systems
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 ❑ 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 a 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 a 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, at www.auditmicro.com.	Varies by analyzer; customers may access Auditor QC, a free online data-reduction program, at www.auditmicro.com.	Varies by analyzer; customers may access Auditor QC, a free online data-reduction program, at www.auditmicro.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?	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; material is run as a patient sample.
11. What types of technical support are available?	Technical support is available by phone at 866-252-8348; email at technicalsupport@auditmicro.com; or chat on the company website. Individualized customer support is provided as needed.	Technical support is available by phone at 866-252-8348; email at technicalsupport@auditmicro.com; or chat on the company website. Individualized customer support is provided as needed.	Technical support is available by phone at 866-252-8348; email at technicalsupport@auditmicro.com; or chat on the company website. Individualized customer support is provided as needed.
12. What capabilities, features, or accessories distinguish this product from others on the market?	The product is a stable, ready-to-use liquid, bilevel control for use with assays designed to produce qualitative results for Covid-19 Total Antibodies and Covid-19 IgG Antibodies. It is intended to simulate negative and positive human patient samples.	The product is intended to simulate human patient samples for use in calibration verification and the verification of reportable range for the following analytes: 6-AM, AMPH, BARB, BENZ, Benzoylecgonine, BUP, METH, OPIA, OXY, PCP, THC.	The product is intended to simulate human patient samples for use in calibration verification and the verification of reportable range for the following analytes: 6-AM, AMPH, BARB, BENZ, BUP, COCA, METH, OPIA, OXY, PCP, THC.

Bio-Rad Laboratories	Bio-Rad Laboratories	Bio-Rad Laboratories	Bio-Rad Laboratories
Hercules, Calif 800-224-6723 www.qcnet.com	Hercules, Calif 800-224-6723 www.qcnet.com	Hercules, Calif 800-224-6723 www.qcnet.com	Hercules, Calif 800-224-6723 www.qcnet.com
InteliQ Immunology Control	InteliQ Cardiac Markers Plus Control LT	VIROTROL SARS-CoV-2	VIROCLEAR SARS-CoV-2
2020	2020	2020	2020
FDA Class I, 510(k) exempt; Europe, nonlist A/B	FDA 510(k) exempt; CE mark 2020	FDA Class 1 Exempt, 2020; CE mark, 2020	FDA Class 1 Exempt, 2020; CE mark, 2020
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.	Intended for use as an assayed quality control serum to monitor the precision of cardiac testing procedures for the analytes listed in the package insert.	Intended for use as an unassayed reactive quality control with in vitro assay procedures for determination of SARS-CoV-2 total IgG/IgM and SARS-CoV-2 IgG in human serum or plasma.	Intended for use as an unassayed nonreactive quality control with in vitro assay procedures for determination of SARS-CoV-2 total IgG/IgM and SARS-CoV-2 IgG in human serum or plasma.
Any high-throughput, automated chemistry instrument such as Siemens Atellica and Abbott Alinity.	Any high-throughput, automated immunoassay instrument such as Siemens Atellica, Abbott Alinity, and Roche Cobas series.	Roche Elecsys Anti-SARS-CoV-2 (Total - IgG/IgM); Abbott SARS-CoV-2 (IgG); Ortho Anti-SARS-CoV-2 (Total IgG/IgM/IgA & IgG); Siemens SARS-CoV-2 (Total IgG/IgM); DiaSorin Liaison (XL) SARS-CoV-2 S1/S2 (IgG); bioMerieux VIDAS anti-SARS-CoV-2 (IgG); Beckman SARS-CoV-2 (IgG); Bio-Rad Platelia SARS-CoV-2 (Total IgG/IgM/IgA); EuroImmun SARS-CoV-2 (IgG); Cellex qSARS-CoV-2 IgG/IgM Rapid Test	Roche Elecsys Anti-SARS-CoV-2 (Total - IgG/IgM); Abbott SARS-CoV-2 (IgG); Ortho Anti-SARS-CoV-2 (Total IgG/IgM/IgA & IgG); Siemens SARS-CoV-2 (Total IgG/IgM); DiaSorin Liaison (XL) SARS-CoV-2 S1/S2 (IgG); bioMerieux VIDAS anti-SARS-CoV-2 (IgG); Beckman SARS-CoV-2 (IgG); Bio-Rad Platelia SARS-CoV-2 (Total IgG/IgM/IgA); EuroImmun SARS-CoV-2 (IgG); Cellex qSARS-CoV-2 IgG/IgM Rapid Test
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N/A	N/A	N/A	N/A
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.	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 analyzer	Varies by analyzer
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.	This control is supported by the Unity interlaboratory quality control data management program.
No training is required; material is run as a patient sample.	No training is required; material is run as a patient sample.	No training required	No training required
Training, expert support, and postmarket service.	Training, expert support, and postmarket service.	Technical support is available by phone at 800-854 6737 and via email at qsd.techservice@bio-rad.com. Individualized customer support is provided as needed.	Technical support is available by phone at 800-854 6737 and via email at qsd.techservice@bio-rad.com. Individualized customer support is provided as needed.
These barcoded, load-and-go quality controls reduce hands-on time and manual errors, streamlining the QC workflow. Together with Unity's interlaboratory advanced data management tools, InteliQ controls improve laboratory efficiency.	These barcoded, load-and-go quality controls reduce hands-on time and manual errors, streamlining the QC workflow. Together with Unity's interlaboratory advanced data management tools, InteliQ controls improve laboratory efficiency.	VIROTROL SARS-CoV-2 provides a long shelf life and open vial stability. It has the ability to challenge the assay cutoff of a broad range of methodologies.	VIROCLEAR SARS-CoV-2 provides a long shelf life and open vial stability. It has the ability to challenge the assay cutoff of a broad range of methodologies.

Biochemical Diagnostics	**Biochemical Diagnostics**	**EuroTrol**	**EuroTrol**
Edgewood, NY 631-595-9200; support@biochemicaldiagnostics.com www.biochemicaldiagnostics.com	Edgewood, NY 631-595-9200; support@biochemicaldiagnostics.com www.biochemicaldiagnostics.co	Ede, The Netherlands 502-501-1180 officeusa@eurotrol.com www.eurotrol.com	Ede, The Netherlands 502-501-1180 officeusa@eurotrol.com www.eurotrol.com
Detectabuse Liquid Urine Controls, Stat-Skreen	Pregnancy-Skreen Liquid HCG Controls	CueSee Hypoxic	HemoTrol Duo
1992	2005	2016	2020
FDA 510(k), CE mark	FDA 510(k), CE mark	FDA 510(k), 2016	FDA 510(k), 2019
Drugs of abuse human urine matrix liquid quality controls for screening and confirmation testing	HCG human urine liquid quality controls	Hypoxic is a pretonometered bovine oxyhemoglobin (O2Hb) quality control material for professional use in the performance assessment of blood gas analyzers, especially in the critically low pO2 value range.	A hemoglobin solution matrix intended for use in the verification of the precision and accuracy of the HemoCue Hb301 and Hb 801 systems.
Independent third-party external control; works with all devices	Independent third-party external control; works with all devices	All common blood gas instruments	HemoCue Hb 301 and Hb 801 systems
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N/A	N/A	N/A	N/A
Analyzer dependent	Analyzer dependent	Quality controls are used on compatible instruments; results read directly from instrument.	Quality controls are used on compatible instruments; results read directly from instrument.
N/A	N/A	All common blood gas instruments+K14	Eurotrol provides all customers with CueSee, a free online service 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.
Minimal	Minimal	Minimal	Minimal
Technical support is available at 631-595-9200 and via email at support@biochemicaldiagnostics.com.	Technical support is available at 631-595-9200 and via email at support@biochemicaldiagnostics.com.	Staff are always available to assist in placing an order, evaluating a sample, or responding to questions or feedback.	Staff are always available to assist in placing an order, evaluating a sample, or responding to questions or feedback.
Human urine matrix mimics patient samples with a broad range of stock and custom DOA formulations; 30-day open stability, up to 3 years unopened.	Human urine matrix mimics patient samples. Positive, negative levels available.	The only low pO2 control that behaves like real blood, CueSee Hypoxic has true hemoglobin buffering with 10 min open ampule stability. CueSee Hypoxic offers comparable result to whole blood tonometry and is compatible with all common blood gas instruments.	The hemoglobin solution matrix is based on a purified hemolysate and provides superior quality control for the HemoCue Hb 301 and HemoCue Hb 801 System. It features 30-day open vial stability. Developed in cooperation with HemoCue and recommended as the company's preferred quality control.

Kova International	**Kova International**	**Maine Molecular Quality Controls**	**More Diagnostics**
Garden Grove, Calif 714-902-1732 www.kovaintl.com	Garden Grove, Calif 714-902-1732 www.kovaintl.com	Saco, Maine 207-885-1072 www.mmqci.com	Los Osos, Calif 800-758-0978 www.morediagnostics.com
Kova Liqua-Trol	Kova POC	Introl	Immunosuppressant Rap/Tac/CsA Control (order Cat #290)
1994	2018	2005	2005
FDA 510(k), CE mark	FDA 510(k), CE mark	FDA 510(k), 2006	CE mark; 510(k) 2005
Urinalysis control	Urinalysis control	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.	To be used as a whole blood precision control product to check calibration in chemistry analyzers which measure rapamycin (sirolimus), tacrolimus, and cyclosporine.
Independent third-party control works for use manually or with automated systems (Siemens, Roche, Dirui, Mindray, McKesson)	Independent third-party control works for use manually or with automated systems (Siemens, Roche, Dirui, Mindray, McKesson)	Controls for laboratory developed tests and platforms by BioFire, Cepheid, Curetis, GenMark, Illumina (NGS), Luminex, Qiagen. Custom products for assay manufacturers.	Siemens Atellica Solution, Siemens Dimension and Vista; Siemens Syva EMIT 2000, Abbott Architect and LC-MS/MS; also appropriate for other automated immunoassay systems that correlate with chromatographic methods.
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N/A	N/A	N/A	N/A
Instrument dependent; LCD display or printed	Instrument dependent; LCD display or printed	Assay dependent	N/A
Results can be sent to laboratory information system if automated device reader is used.	Results can be sent to laboratory information system if automated device reader is used.	N/A	Customer may participate in a free peer-to-peer quality control data program.
Less than 30 minutes	Less than 30 minutes	Minimal	No training required; material is run as patient sample.
Technical support is available at 855-217-6399 or techservices@kovaintl.com.	Technical support is available at 855-217-6399 or techservices@kovaintl.com.	Email and phone support. Troubleshooting materials.	Technical support may be reached at 800-758-0978 or support@morediagnostics.com.
Human urine matrix mimics patients samples. Multiple analytes and microscopic cells/artifacts.	Human urine matrix mimics patients samples. Multiple analytes and microscopic cells/artifacts.	The synthetic controls are 100% safe, nonhazardous, robust, and stable.	Immunosuppressant Rap/Tac/CsA Control is an easy-to-use liquid whole blood product with 5 mL fill volume. This product has a 4-year frozen shelf life and 45 days open vial stability when stored at 2°C to 8°C.

More Diagnostics	Quantimetrix	Quantimetrix	Qnostics
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	Glasgow, United Kingdom +44 (0) 28 9442 2413 www.qnostics.com
Ev/Rap/Tac/CsA Control (order Cat #285)	Dipper POCT Liquid Urinalysis Quality Control	Chromascopics Urinalysis Control with Microscopics	Qnostics
2005	2018	2018	2017
510(k) 2005	CE mark, 2018; FDA 510(k) exempt.	CE mark, 2018; FDA 510(k) exempt.	CE mark, FDA 510(k)
A whole blood precision control product to check calibration in chemistry analyzers that measure everolimus, rapamycin (sirolimus), tacrolimus, and cyclosporine.	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.	Quality control solutions for molecular infectious disease testing.
Chromatography methods, assayed for LC-MS/MS.	Dipper POCT is designed for use in every testing environment including: central labs, reference labs, nursing stations, and doctors' offices.	Clinitek Novus, Clinitek Advantus, Clintek Atlas, Clinitek Status, Clinitek Status Plus, Clinitek 50, Clinitek 500, Atellica UAS 800, Atellica 1500 Automated Urinalysis System.	Range comprises hundreds of characterized viral, bacterial, and fungal targets that cover a wide range of diseases and are available for a wide range of platforms.
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N/A	N/A	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.	Time to first result varies by analyzer; customers may access Quantrol, a free online peer-to-peer quality control data program.	N/A
Customer may participate in a free peer-to-peer quality control data program.	N/A	N/A	N/A
No training required; material is run as patient sample.	N/A	N/A	Qnostics controls require professional use; however, some products are perfect for staff training.
Technical support may be reached at 800-758-0978 or support@morediagnostics.com.	Technical support is available at 310-536-0006, Ext: 213; via techsupport@quantimetrix.com; or via live chat at quantimetrix.com.	Technical support is available at 310-536-0006, Ext: 213; via techsupport@quantimetrix.com; or via live chat at quantimetrix.com.	A technical support department is available to deal with all queries via telephone, email, and occasional visits.
An easy-to-use liquid whole blood product with 4 levels and 4 analytes. This 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.	Whole pathogen controls designed to mimic patient samples can be used to monitor entire testing process including extraction, amplification, and detection. Samples are supplied in convenient liquid formats requiring little to no preparation. Targets covered include transplant associated, respiratory, blood borne, gastrointestinal, covid, and more.

Randox Laboratories	**Streck**	**Streck**	**Utak Laboratories**
Crumlin, United Kingdom +44 (0) 28 9442 2413 www.randox.com	La Vista, Neb 800-843-0912 www.streck.com	La Vista, Neb 800-843-0912 www.streck.com	Valencia, Calif 888-882-5522 welovecontrol@utak.com
Acusera	UA-Cellular Complete	Sperm-Chex and Sperm-Chex Post VC	Covid TDM QC
2010	2014	2015	2020
CE mark, FDA 510(k)	CE mark, 2014; 510(k), 2014, 2017	CE mark, 2015; 510(k), 2004	CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015
Designed to deliver a cost-effective yet high-quality solution for any lab regardless of size or budget.	Ready-to-use tri-level liquid urine control comprised of true cellular urine sediment components and common urine chemistry analytes plus hCG.	Manual sperm count controls to help validate the quantification of sperm counting by manual methods.	Outsourced, third-party, unbiased quality control
Control portfolio is wide and includes a vast array of instruments, methods, and companies that can use our products.	Siemens Clinitek Atlas/Sysmex UF-1000i, Arkray Aution Hybrid AU-4050, Clinitek Status automated chemistry strip readers, Siemens Multistix 10SG manual reagent strips, Siemens Clinitest hCG Pregnancy test	Hemacytometer, Makler counting chamber	Mass Spectrometry
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N/A	N/A	N/A	N/A
N/A	Dependent on the analysis method in use.	Dependent on the analysis method in use.	N/A
Live, cloud-based interlaboratory data management and peer group reporting software intended to assist in the management of daily QC activities.	N/A	N/A	N/A
Some controls require little training; others require laboratory experience.	No additional training required	Requires minimal training	None required
Technical support is available via email, telephone, and an online help chat.	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 phone or via email.	Support available by phone or email.
True third-party controls; choice of assayed or unassayed, liquid or lyophilized, single or multi-analyte; controls are designed to mimic the patient sample, therefore helping to meet ISO 15189:2012 requirements, while minimizing costly shifts in QC when changing reagent batches.	Combined chemistry and sediment control performs as a patient sample and can replace multiple separate controls for instruments from manual dip-strip through high-throughput automated microscopy platforms. Real cellular components test the entire system.	The only 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 hemacytometers and other counting chambers. Offers 42-day open-vial stability; 12-month closed-vial stability.	100% real human matrix matched quality control.

Utak Laboratories	**Utak Laboratories**	**Utak Laboratories**	**Verichem Laboratories**
Valencia, Calif 888-882-5522 welovecontrol@utak.com utak.com	Valencia, Calif 888-882-5522 welovecontrol@utak.com utak.com	Valencia, Calif 888-882-5522 welovecontrol@utak.com utak.com	Providence, RI 800-552-5859 customerservice@verichemlabs.com www.verichemlabs.com
Hydrolysis QC	Pain Management QC	Drugs of Abuse QC	Matrix Plus Chemisty Reference Materials; Matrix Plus Cholesterol Reference Materials; Enzyme ER Verifiers; TruZero Bilirubin Standard
2020	2007	2003	1988
CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015	CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015	CE mark, ISO 13485:2016 (MDSAP), ISO 9001:2015	All products are FDA 510(k) cleared.
Outsourced, third-party, unbiased quality control	Outsourced, third-party, unbiased quality control	Outsourced, third-party, unbiased quality control	Gravimetric standards, linearity verifiers, and reference materials used for calibration or calibration verification of wet chemistry assays on automated clinical testing systems.
Mass Spectrometry	Mass Spectrometry	Mass Spectrometry	Compatible with wet chemistry analyzers available from Abbott, Roche, Siemens, Advanced Instruments, Alfa Wassermann, Beckman Coulter, EKF Diagnostics, Horiba, Instrumentation Laboratory, Medica, Randox, 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	N/A	N/A	All products are treated like patient specimens; time to first result depends on the analyzer.
N/A	N/A	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.
None required	None required	None required	None required
Support available by phone or email.	Support available by phone or email.	Support available by phone or email.	Support available via phone, email, website, and on-site.
100% real human matrix matched quality control.	100% real human matrix matched quality control.	100% real human matrix matched quality control.	Products are compatible with all major wet chemistry systems; are CLIA compliant; have certified accuracy using available USP, ACS, NIST materials. Most include a lot-specific certificate of analysis, are liquid stable and ready-to-use, and offer long shelf-life claims and lot-to-lot consistency.