tech guide

Calibrators, Controls, & Standards

	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?	Control LQ glycohemoglobin A1c; K067M-8	Control LQ blood glucose; K078M-8	Amplichek
2. What year was the product first released to market?	2013	2016	2016
3. Specify the authorizing agency, type, and year of the product's regulatory authorizations.	CE mark, 2010; FDA 510(k), 1995.	CE mark, 2016; FDA 510(k), 2016.	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?	To simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for glycohemoglobin A1c.	To simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for glucose assays.	Quality control.
5. 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 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
6. If you answered "elsewhere," explain briefly.			
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	All Bio-Rad quality controls are supported by the Unity interlaboratory program.
9. What types of technical support are available?	Customers may reach technical support by phone at (866) 252-8348, via e-mail at technicalsupport@auditmicro.com, or via chat on the official website. Individualized customer support is provided as needed.	Customers may reach technical support by phone at (866) 252-8348, via e-mail at technicalsupport@auditmicro.com, or via chat on the official website. Individualized customer support is provided as needed.	Training, expert support, and service.
10. What capabilities, features, or accessories distinguish this product from others on the market ?	Assayed, stable, ready-to-use liquid; human blood based material for use with assays designed to quantitate glycohemoglobin A1c; open-vial stability of 50 days when stored at 2–8°C.	Assayed, stable, ready-to-use liquid; for use with assays designed to quantitate glucose; open-vial stability of 7 days when stored at 2–8°C.	Liquid, ready-to-use multianalyte quality control products for molecular infectious disease testing enable monitoring of the performance of nucleic acid testing procedures for healthcare-associated infections, viral load assays, and more.

Eurotrol Burlington, Mass (978) 598-3779 www.eurotrol.com	**Maine Standards Company LLC** Cumberland Foreside, Maine (800) 377-9684 www.mainestandards.com	**Quantimetrix** Redondo Beach, Calif (310) 536-0006 quantimetrix.com	**Randox Laboratories Ltd** Kearneysville, W Va (866) 472-6369 www.randoxqc.com
CueSee Hypoxic	Validate	Quantimetrix Dipper urinalysis dipstick control	Acusera liquid immunoassay premium control
2015	2001	1988	2011
FDA 510(k), 2016.	CE mark, 2001; FDA 510(k), 2001.	CE mark, 1988; FDA 510(k), 1988.	CE mark, 2011; FDA 510(k), 2011.
Validate extremely low pO2.	Calibration verification and linearity testing.	Intended as a control for creatinine, microalbumin, and urinalysis reagent strips by the listed test methods, and as a control for confirmatory tests such as K-Check and Ictotest reagent tablets, and for human chorionic gonadotropin (hCG) methods.	To ensure analyzers are working to their optimum level.
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Analyzer dependent.	n/a	Same as patient sample.	Analyzer dependent.
It can be used with CueSee Online, a free data submission service that can be used to compare results with peers, generate reports, graphs, and statistical analysis.	n/a	n/a	Suitable for use with the Acusera 24.7 Live Online software, facilitating quality control (QC) data management and providing access to automatically generated QC statistics, real-time peer group data, and a wide range of troubleshooting tools.
Email, online, or phone.	Guaranteed same-day technical support with responses within normal business hours.	Phone support at (310) 536-0006, ext. 213, and online technical support by contacting techsupport@quantimetrix.com.	Aftercare support is supplied via a technical services division and can be contacted via e-mail at technical.services@randox.com.
Has a real buffered hemoglobin matrix; enables an extremely low pO2 concentration; 10-minute open ampule stability; extremely commutable, performing almost the same on any blood gas analyzer.	Liquid samples require no reconstitution; product line is formulated into specialized configurations with different analyte concentrations that challenge analyzers' full reportable range; long open-vial stability; levels 1 through 5 are prepared to create "equal deltas"; enough product volume to complete two calibration verification and linearity testing cycles; 5-day turnaround of data reduction; peer group statistics.	Monitors the performance of visual and instrument readings of urinalysis dipsticks by immersing the dipstick into the control, the same way patient samples are tested; values included for all dipstick analytes plus microalbumin and creatinine, and qualitative results for hCG early pregnancy detection test methods; designed for use with most urinalysis reagent strips; can also be used for confirmatory tests and refractometry.	Designed for use in the routine monitoring and precision of multiple instruments; consolidates up to 44 analytes in a single vial; can reduce the number of controls required to cover complete test menues; true third-party control, with assayed values available for most immunoassay platforms and a wide range of analytes, including hormones, therapeutic drugs, and vitamins.

Randox Laboratories Ltd	**Streck**	**Streck**	**Streck**
Kearneysville, W Va (866) 472-6369 www.randoxqc.com	La Vista, Neb (800) 843-0912 www.streck.com	La Vista, Neb (800) 843-0912 www.streck.com	La Vista, Neb (800) 843-0912 www.streck.com
Acusera liquid tumor marker control	Para 12 Extend	Sperm-Chex	Cell-Chex Auto
2013	2000	2015	2006
CE mark, 2012; FDA 510(k), 2013.	CE mark, 2003.	CE mark, 2015.	CE mark, 2006; FDA 510(k), 2006.
To ensure analyzers used to run tumor marker tests are working at their optimum level.	Assayed hematology control.	Sperm-Chex is a two-level, manual sperm count control that contains stabilized sperm cells.	Tests the instrument's reportable range at lower linearity limits.
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		Fertility, reproductive, and urology clinics.	Transplant and oncology centers.
Analyzer dependent.	Same as a patient sample.	Manual test, used like a patient sample.	Results are available on the assay instrument files.
Suitable for use with the Acusera 24.7 Live Online software, facilitating quality control (QC) data management and providing access to automatically generated QC statistics, real-time peer group data, and a wide range of troubleshooting tools.	n/a	n/a	n/a
Aftercare support is supplied via a technical services division and can be contacted via e-mail at technical.services@randox.com.	Streck Technical Services, a team of medical technologists that are readily available to assist with product technical questions.	Streck Technical Services, a team of medical technologists that are readily available to assist with product technical questions.	Streck Technical Services, a team of medical technologists that are readily available to assist with product technical questions.
The multianalyte control has been designed for use in the daily monitoring of 15 routine and esoteric tumor markers; supplied in a liquid ready-to-use format; true third-party control provided with assayed target values and ranges for all analytes; ensures an unbiased assessment of performance for a wide range of chemistry and immunoassay instruments.	The control features 6-month closed-vial stability and 30-day open-vial stability.	The only sperm count control on the market with stabilized sperm cells; semen analysis provides vital information regarding a man's fertility; noninvasive; two clinically significant levels of control to simulate the sperm cell concentration that technologists encounter in patient samples; has the same chamber loading and optical characteristics as a patient sample; when used like a patient sample, verifies the sperm analysis process and tests the technologist's proficiency in sperm cell quantification.	Provides confidence that instrument counts are accurate on patient body fluid samples; two-part WBC parameter values are listed on the assay for the Sysmex XE-5000 and XT-4000i instruments; the first automated body fluid cell count control for Abbott, Beckman Coulter, Siemens Healthineers, and Sysmex hematology instruments; the Streck Stats interlaboratory quality control program now features real-time reporting through the online report program, Stats-Link.