

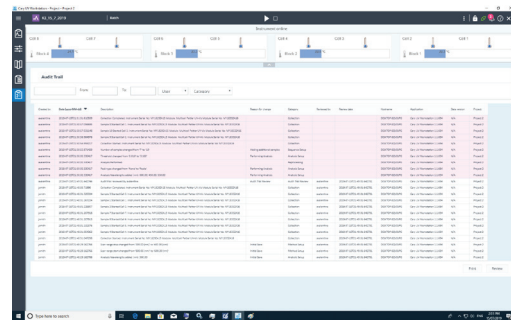
Better Data Integrity With the Cary 3500 Simultaneous Multicell UV-Vis and a System Approach to ALCOA+



Do you want better data integrity for your laboratory? The Cary 3500 Multicell UV-Vis enables truly simultaneous measurements and can help defend your laboratory and its processes from sources of variability, error, and uncertainty. Cary UV Workstation, when coupled with the Agilent OpenLab software, provides maximum support of ALCOA+ principles in data integrity. The ability of the UV-Vis spectrophotometer to collect simultaneous results provides further confidence in your data integrity. With more technical controls designed in, daily operational efficiency and confidence in data quality and integrity can be enhanced.

ALCOA abbreviation		Explanation	Cary 3500 System Features
A	Attributable	Actions and events must be attributable to specific system users. Who did the action?	User actions that relate to creation or modification of a Cary UV Workstation record are recorded and attributed to the logged in user via audit trail and e-signatures. Audit entries can be electronically reviewed, and the review is permanently associated with the record.
L	Legible	Data must be recorded permanently and be human readable. Is the data ready for review?	Cary UV Workstation saves records permanently to a secured database. The reports and audit trails have been designed to be human readable for easy internal reference and audit or regulatory inspection, including via electronic documentation of the review action.
C	Contemporaneous	The data should be recorded at the time the work is performed, with date/time stamps in chronological order. When did the action happen?	The system generates accurate date/time stamps for all events and actions that create or modify an electronic record. The ability to measure standards, samples, and controls simultaneously removes the possibility of unintended variables being introduced during the measurement sequence.

O	Original	The information should be the original record. Is the record a true copy?	Cary UV Workstation creates reports that are traceable to the original electronic record. Any changes or modifications to a record will be captured in the audit trail. No modifications or edits are possible during the measurement sequence, as standards, samples and controls are measured simultaneously. It is not possible to change a sample weight or concentration after it has been measured.
A	Accurate	The record should be accurate with no errors or undocumented edits. Does the record have all changes documented?	The system is designed to record data accurately and prevent and detect tampering. Raw data and analytical results are presented correctly.
	Complete	All data including repeat or reanalysis is included. Is anything missing?	The measurement sequence is defined for the method and the samples are measured simultaneously ensuring no data is missed. Cary UV Workstation reports include all components of the record including repeat measurements and reanalysis information.
	Consistent	System enforces use of approved methods, reporting templates and workflows. Are date/time stamps consistent through the sequence?	Cary UV Workstation method and sequences can be customized and the workflows enforced by roles and privileges. The software ensures that that all workflow steps are followed. Method editing is restricted to users with designated privileges. The audit trail and all date/time stamps are in UTC format and consistently recorded.
	Enduring	Recorded securely. Is media used that ensures records are protected?	Cary UV Workstation uses a secure database that can be backed up. Access to the database is protected by security settings within the OpenLab Control Panel.
	Available	Available and accessible for internal review, audit, or regulatory inspection for the lifetime of the record.	The system uses a content management system. All audit trail reports and record reports can be securely stored and if the right provisions are made, readily accessed by users.



The audit trail, captured by Cary UV Workstation, when coupled with the Agilent OpenLab Software Suite.

1. S.W. Woollen, "Data Quality and the Origin of ALCOA," in Newsletter of the Southern Regional Chapter Society of Quality Assurance, Summer 2010, www.southernsqa.org/newsletters/Summer10.DataQuality.pdf, accessed Apr. 9, 2014.

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