

The Case of the Failing Pipette – A Case Study of Auditing in an Electronic Bioanalytical Laboratory

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Background

A common problem that every laboratory faces is when a pipette fails to meet the acceptance criteria during a re-calibration activity. Several questions need answered in order to properly assess the impact of the failing pipette on the bioanalytical data.

1. What studies were impacted by using this pipette?
2. Did we find and document every study where this pipette was used?
3. Was this pipette used by multiple analysts?



Calibration Type:		As Found
Site	7840 Innovation Blvd	
	Indianapolis	
073	Indiana	46278
2016	Next Due:	Mar 2017
	Status:	FAILED
: 32910-022		
:		

Searching the ELN

A **query** can be ran to search any data held electronically within the electronic laboratory notebook (ELN). Queries can be as broad or as specific as the end user needs. This search would find in minutes data that would normally take days or may even be impossible to located. Audit trails can also be utilized to review the data and date/time the pipette was used. A thorough audit to determine where this pipette was used can be completed in just a few minutes.

Search Criteria

The last calibration of the pipette was performed four months ago. The 'As Left' calibration 'Passed' at that time'. Therefore our electronic search will be for all completed electronic experiments from the date of last passing calibration to the 'As Found' failure for the specific pipette in question. Each pipette is labeled with a four digit unique code. Each experiment where this pipette was utilized will be documented using this unique four digit number. A search of the Electronic Laboratory Notebook (ELN) for all experiments using the pipette in question returns all of the experiments where this pipette was used.

Search Results Example

Experiment	
	Experiment Path
CS_QC-BAM.0396-058111-20-Oct-2016-CS-QC	/Root/AIT Bioscience/Sponsor Node/0229/Sponsor Specific Template Lifecycle

Assessing the Impact

The search results show that this pipette was utilized in 34 experiments from the time of the last passing calibration until the 'As Found' failure. The experiments where this pipette was utilized are calibration standard and quality control sample preparation experiments (CS/QC). Since these samples are all spiked to known concentrations, the assessment of the impact on these experiments are easy to assess. The final results from the CS/QC sample preparation experiments are reviewed and it is confirmed that all of the CS/QC samples prepared using this pipette met the acceptance criteria. In closing, no data was impacted by the use of this pipette.