Fairbanks Analytical Testing Audit Summary
(Presentation for August 18, 2021 MCB Meeting)

2019 Purpose: June - A2LA audit/EHL document review; STEC reporting; Tech. Director Hire **Scope: Regulated parameters against AK Reg. and CLCD**	**2020 Purpose: June - Potency only audit** **Scope: Regulated Parameters against AK Reg. and CLCD**	**2021 Purpose: May - Full Audit** **Scope: Regulated Parameters against AK Reg. and CLCD**
Elapsed time for documented correction – 66 days (35-day full license suspension, 31 days *Aspergillus* and STEC suspension)	*Elapsed time for documented correction* – 101 days (no license suspension)	*Elapsed time for documented correction* – 92+ days (no license suspension)
	Repeat findings of prior audit – 9 deficiencies (items represented in **bold font** below)	*Repeat findings of prior audits* – 17 deficiencies (items represented in **bold font** below)
Traceability – 8 deficiencies (documentation gaps)	*Traceability* – not evaluated as benchsheets and raw data not observed	*Traceability* – 3 deficiencies (**documentation gaps**)
Data Defense – 17 deficiencies (unaddressed outliers, no calibrations and documentation gaps for support materials and equipment, lack of accuracy/precision assessments occurring, micro positive controls not documented – no negative control, potency lacking confirmation aspect)	*Data Defense* – 19 deficiencies (unable to start defense, potency calculation errors, unaddressed outliers, SOP deficiencies (QC and **2^o λ**), reporting outside calibration – re: linearity study, **support equipment calibration**)	*Data Defense* – 20 deficiencies (**documentation gaps**, **unable to start defense**, unavailable client reports, **support equip calibrations**, white-out use, calibration inconsistencies, **calculation errors**, **2^o λ not per SOP**, **reporting outside calibration** – re: gap from low:high calibrations)
Data Reproducibility – 5 deficiencies (documentation gaps)	*Data Reproducibility* – 6 deficiencies (unable to start, potency calculation errors for all matrices)	*Data Reproducibility* – 7 deficiencies (**unable to start, documentation gaps**)
Quality Control/Training/PT – 16 deficiencies (not performing or documentation gaps, internal audits not performed)	*Quality Control/Training/PT* – 9 deficiencies (**PT missing & outliers**, **training gaps**, **QC results management**, **documentation gaps, internal audits not performed**)	*Quality Control/Training/PT* – 4 deficiencies (**PT outliers**, calibration anomalies, **micro control documentation gaps**, **internal audits not performed**, **QC results management**)

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SOP Conformity – 3 deficiencies (QC called for but not applied, text from other labs, state logo applied to a document)	*SOP Conformity* – 1 deficiency (**several document anomalies (inconsistencies between QAM and SOPs**))	*SOP Conformity* – 5 deficiencies (**procedure changes not reflected in SOP, text from other labs, deviation from SOPs**)

Definitions: Data Reproducibility – Sufficient information available to replicate the reported result.
Data Defense – Sufficient documentation, quality control, and quality assurance to support integrity and veracity of reported data.
Traceability – Sufficient documentation present to recreate activities.