

2024 INQ09 Equine Analytical Chemistry Lab

October 21, 2024

Internal Audit

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GLOSSARY

EACL – Equine Analytical Chemistry Lab
EPO Erythropoietin
HIWU – Horseracing Integrity & Welfare Unit
MARTIN-GATTON CAFE– Martin-Gatton College of Agriculture, Food and Environment
TInformation Technology
LIMS – SampleManager, the EACL's laboratory nformation management system
MOU – Memorandum of Understanding
RBAC – Role-based Access Control
SOPs – Standard Operating Procedures
ГАТ – Turn-Around-Times
JK – University of Kentucky
JKIA – University of Kentucky Internal Audit
JKITS – University of Kentucky Information Fechnology Services
JSEF – United States Equestrian Federation
Jniversity – University of Kentucky

EXECUTIVE SUMMARY

The Equine Analytical Chemistry Lab (EACL) was established in 2019 through a contract with the United States Equestrian Federation (USEF) to provide drug testing services to the equine industry. Dr. Scott Stanley was recruited to UK to establish this laboratory and serve as its director. Though officially under the Martin-Gatton College of Agriculture, Food and Environment (Martin-Gatton CAFE) Equine Program umbrella, it is self-funded and has been operating with near autonomy since its inception.

In February 2024 UK Internal Audit (UKIA) was notified of an allegation by the Horseracing Integrity & Welfare Unit (HIWU) that an EACL test, the supposed results of which had been personally communicated to HIWU by the EACL director, Dr. Scott Stanley, had actually never been performed. UKIA's engagement objective was to evaluate the allegation's validity and examine the Equine Analytical Chemistry Lab's (EACL) internal controls.

UKIA confirmed this allegation. Additionally, four of the 240 samples UKIA selected for administrative testing, all of which were evidence in investigations, lacked results documentation in LIMS. While results for two of the four, which had adverse results, were found to have been communicated to HIWU by Dr. Stanley, UKIA was unable to locate any documentation for the remaining two samples.

UKIA's examination of the EACL's operations indicated inadequate oversight of the unit as well as weak internal controls that gave all EACL staff unrestricted access to data at every stage in its testing workflow and, for investigations, gave Dr. Stanley the ability to control the communication of results.

Additionally, UKIA documented two relationships Dr. Stanley had that each may constitute a conflict of interest. The first was a consulting agreement Dr. Stanley entered into with Thermo Finnigan LLC (a subsidiary of Thermo Fisher Scientific) which he disclosed only once during the scope period. The second conflict of interest resulted from a personal relationship with a woman for whom he created a STEPS position at the EACL and orchestrated her hiring.

Accordingly, UKIA's recommendations – and subsequently, the Martin-Gatton CAFE's Management Action Plan (MAP) – focus on facilitating better oversight of the EACL, enhancing information security and data integrity, and improving the EACL's operational controls.

OBJECTIVE & SCOPE

UK Internal Audit (UKIA) engaged in an investigation of the EACL in February 2024 upon learning that a test the EACL had purportedly performed on a sample provided by HIWU had never been done. The sample was to have been tested for the banned substance, Erythropoietin (EPO), but was found to have never been analyzed, as 100 percent of the sample remained untouched in the lab. Subsequent to this investigation, an evaluation of the EACL's governance and internal controls was also undertaken to determine how they may have contributed to – and even enabled – the activity under investigation. Thus, UKIA's objectives were two-fold:

Investigation

- Verify that all billed services* had been rendered and recorded and that all results were communicated.
- Evaluate any conflicts of interest between vendors and EACL staff.

*Verifications were not performed for any clients other than HIWU. No scientific testing was performed.

Governance/Internal Controls

Identify vulnerabilities associated with these EACL activities:

- IT operations
- Governance
- Business operations

Scope Period

The scope period was determined from the director's tenure. Accordingly, the scope period for this review was FY 2018-19 – FY 2023-24.

UKIA has conducted this review in accordance with the Institute of Internal Auditors' *International Professional Practices Framework* and *Global Internal Audit Standards*.

BACKGROUND

The equine industry generates \$6.5 billion in annual direct, indirect and inducted economic activity in the Commonwealth of Kentucky, with \$2.7 billion being generated by the thoroughbred sector alone. The University of Kentucky – and specifically the MARTIN-GATTON CAFE – plays a major role in supporting this critical industry through its Ag Equine Programs. MARTIN-GATTON CAFE further demonstrated this commitment to the Commonwealth's critical equine industry when the college took over the EACL in 2019 from the United States Equestrian Federation (USEF) to provide drug testing services "to help promote the integrity of the equine industry as well as the health and welfare of the horse."

Dr. Scott Stanley joined UK in 2018 to establish the EACL and serve as its director.

Allegation:

In a February 2024 letter to MARTIN-GATTON CAFE leadership, HIWU alleged that it had received falsified results from the EACL. The letter stated that Dr. Stanley had agreed to perform EPO testing on a sample the EACL received from HIWU on November 9, 2023. The letter then noted that on December 21, 2023, Dr. Stanley had reported to HIWU that the presence of EPO could not be confirmed and that there was just .5mL remaining of the blood sample HIWU had provided. The letter went on to state that on January 3, 2024, Stanley again reported to HIWU that the presence of EPO could not be confirmed. The letter then conveyed that HIWU learned from the associate EACL director in February 2024 that no testing had ever actually been performed as 100 percent of the sample remained.

¹ Economic Impact of the Equine Industry, accessed July 31, 2024, Kentucky Thoroughbred Association, https://www.kentuckybred.org/kentucky-equine-industry-impact/

² Equine Analytical Chemistry Lab 2024, Equine Analytical Chemistry Lab website, Martin-Gatton College of Agriculture, Food and Environment, accessed July 31, 2024, https://eacl.ca.uky.edu/.

AUDIT RESULTS

UKIA's investigation substantiated the instance of falsified results first reported by HIWU. However, its administrative evaluations of the services the EACL provided for HIWU, which did not include any validations of scientific testing, could not substantiate any additional falsification during the scope period. This was due to internal control weaknesses detailed in Observation 2. UKIA also observed conflicts of interest that were direct results of actions taken by Dr. Stanley, yet none were ever disclosed.

Through its evaluation of the EACL's internal controls, UKIA noted inadequate oversight and pronounced process weaknesses related to both business and IT operations that could enable improper activity to occur without detection.

These concerns are detailed in the following observations. Though UKIA made attempts to meet with Dr. Stanley to discuss these concerns, he stopped responding to our requests for an interview.

Observation 1: Investigation

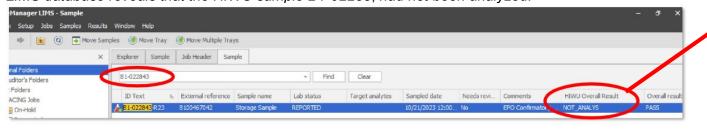
UKIA 's investigation involved comparative evaluations of data found in the EACL's laboratory information management system, SampleManager (LIMS) to ensure all samples received had indeed been recorded as tested and then invoiced appropriately. It also included interviews with select EACL staff, documentation reviews and workflow analysis to gauge internal controls and assess for other inappropriate activity. The results of this analysis are outlined below.

Finding 1.1: HIWU Test Results

UKIA's administrative evaluation confirmed that the sample about which HIWU notified MARTIN-GATTON CAFE, *B1-02283*, was indeed in LIMS and that it had not been analyzed, corroborating the initial allegation of falsified results (See Exhibit 1).

Exhibit 1: HIWU Testing Sample LIMS

LIMS database reveals that the HIWU sample B1-02283, had not been analyzed.



HIWU Overall Result:

Options – 1)
negative, 2) adverse
finding, 3) atypical or
4) not confirmed or
5) not analys,
which is short for
not analyzed.

Additionally, UKIA noted that the type of EPO test HIWU had requested for this sample was *confirmation* testing – highly precise and accurate testing using complex instrumentation and kits to yield definite and specific results. The EACL is not capable of performing

such tests for EPO as it had neither the equipment in its lab nor the standard operating procedures (SOPs) in place to perform EPO confirmation testing. Instead, the EACL's existing capabilities were limited to *screening* for EPO, which is a preliminary test that yields only a preliminary positive or negative result.

To verify whether other tests for which HIWU had been billed had indeed been performed, UKIA administratively evaluated the same 240 HIWU samples for which HIWU had requested substantive documentation to perform their own analysis. This evaluation a) compared samples received to samples tested, and b) compared samples tested to samples invoiced (see diagram below). From this evaluation, UKIA confirmed that all 240 samples were identified in LIMS and all had been invoiced. However, four samples, all of which were evidence in investigations, lacked results documentation in LIMS. UKIA confirmed that results for two of the four, both of which had adverse results, had been communicated to HIWU via email by Dr. Stanley. The remaining two were outsourced to the UK Veterinary Diagnostic Laboratory for toxicology testing and UKIA was not able to obtain documentation.



While UKIA's evaluation did not note any additional instances of falsified results, there were numerous opportunities in the EACL's standard workflow that could potentially allow for sample tampering or records to be changed. These process weaknesses include Dr. Stanley having unfettered access to samples and/or data/analysis from intake to results reporting, including extensive administrative privileges within the LIMS system (as detailed in Observation 2). Moreover, the process for samples related to investigations (such as the HIWU sample that is the center of the allegation and the four samples noted above) occurs largely outside the standard workflow, with sample intake, processing and results communication being very different from the EACL's standard workflow depicted in Appendix B.

Finding 1.2: Conflicts of Interest

Dr. Stanley also made a number of business decisions that constitute conflicts of interest for the university. These decisions are detailed below:

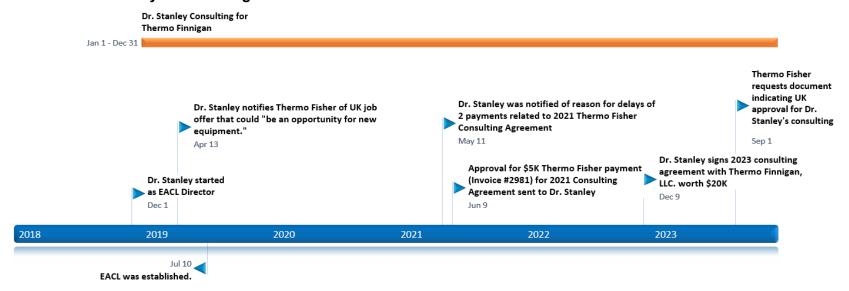
Thermo Finnigan

Within five months of joining the EACL, Dr. Stanley was offered the position of director of *campus core facilities*,¹ after which he informed a sales representative with Thermo Fisher that the new position presents an opportunity to purchase more new equipment from Thermo Fisher Scientific.

UKIA also noted that, while serving as the EACL director, Dr. Stanley was also working as a consultant for Thermo Finnigan, LLC since at least 2019, for which he was to receive payments totaling \$20,000 each year. Though he had completed a Form F Overload form at least once each year since 2019 to disclose external research and some other consulting relationships, Dr. Stanley only disclosed his consulting for Thermo Scientific (parent company) one time, in 2023. Furthermore, he avoided obtaining a letter that Thermo Finnigan had requested which indicated UK General Counsel's approval was requested and instead sought a way to have it only approved by the dean. As part of these agreements, Dr. Stanley directed the EACL to purchase lab instruments and equipment from Thermo Finnigan LLC, while also sharing data with the company and expensing travel for the company to visit UK, among other actions.

¹This position oversees the shared-use core facilities under the Office of the Vice President for Research, which include the Animal Behavior Core, the Division of Laboratory Animal Resources, the Energy Balance & Body Composition Core and the Flow Cytometry, Immune Monitoring Core, Light Microscopy Core, Mass Spectrometry and Proteomics Core, Magnetic Resonance Imaging and Spectroscopy Center and Pathology Research Core.

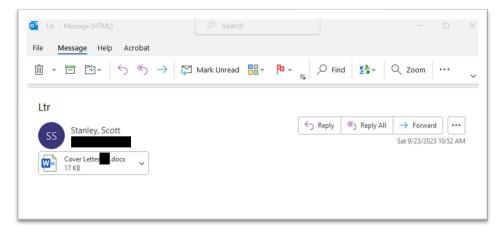
Exhibit 2: Dr. Stanley's Consulting Timeline



Hiring Practices

In October 2023, Dr. Stanley created a new STEPS¹ Technical/Scientific position within the EACL lab. From human resource records and other documentation, UKIA determined that this new position was tailored specifically for a certain person with whom he had a relationship that went beyond professional (see Appendices A1-A4), and for whom he drafted the cover letter (see Exhibit 2). This new employee was a former thoroughbred horse trainer with numerous family connections in the horseracing industry. While the applicant disclosed the industry connections on her job application, their relationship was never disclosed.

Exhibit 2: Dr. Stanley's Email Containing the Draft Cover Letter



¹ UK's temporary staffing agency

Observation 2: Governance and Internal Controls

As noted in Observation 1, Dr. Stanley had the ability to perform every role, from intake to results communication. Indeed, such inadequate separation of duties, coupled with insufficient oversight, gave Dr. Stanley near unilateral control over the entire program. Moreover, UKIA noted that the weaknesses permeating the EACL's processes and practices could allow <u>any</u> EACL employee to alter results while eluding identification – a fact which has precluded UKIA from determining whether any additional samples may have been altered, amended or otherwise falsified and by whom. These weaknesses are detailed below.

Finding 2.1: Governance

UKIA noted that EACL Advisory Boards, which were contractually obligated, have not been meeting. This lack of monitoring, combined with a lack of documented guidance for several key functions, contributed to the weak processes that have left the lab and the university vulnerable to inappropriate activity. Moreover, the EACL failed to execute a contract with the LIMS vendor. As this vendor was not properly maintaining the EACL's LIMS and the EACL has also not developed a disaster recovery plan, the risk of a breach is not only greater, the recovery time following such an event may be longer.

2.1a: Advisory Boards

The July 2019 contract UK entered into with USEF to establish the EACL required a seven-person Equine Analytics Laboratory Advisory Board to be created and maintained at all times. The contract specified that this board, which was to be comprised of three members appointed by USEF, three by UK and one joint appointee, was to meet quarterly "for the purpose of prioritizing research projects, reviewing and providing input into the budget, reviewing the operations of the (EACL), including ensuring appropriate accreditations of the (EACL); and reviewing recommendations from the Scientific Advisory Board." However, UKIA noted that only one meeting had been held since January 2022, as Dr. Stanley stopped calling such meetings once he became responsible for scheduling them.

Additionally, a Scientific Advisory Board was to have been established to advise the Lab Advisory Board on scientific and technical matters important to the efficient and productive operation of the UK Lab, but no such board was ever formed.

As a result, the EACL's contractual obligations to USEF are not being met.

2.1b: Policies and Procedures

Per a 2021 EACL press release posted on its website, the EACL "is responsible for testing all US Equestrian drug and medication samples." The press release goes on to state that "the report it provides is 'not pass or fail,' but provides detail on any substances found" and that "the results are provided on a three- to five-day turnaround." Such varied responsibilities under such strict time constraints necessitates numerous SOPs. However, UKIA noted that the EACL has not developed policies or SOPs to provide guidance for both its EPO testing and IT operations, other than those related to using LIMS functions. This lack of guidance has resulted in inconsistent and unreliable operations.

Additionally, given the sensitivity of the testing EACL performs for its clients, ensuring the security of its data is paramount. However, the EACL lacks a comprehensive cybersecurity policy and does not conduct regular cybersecurity posture assessments, exposing the EACL to the potential for data breaches and operational disruptions that could damage the EACL's reputation and lead to long term losses in revenue. Furthermore, the LIMS SOPs that are in place have not been updated to reflect changes to the computing environment and associated backup methodologies.

2.1c: Contract Management for IT Service

The vendor that has been responsible for all activities in LIMS since 2019 has been providing these services without a contract. Instead, it has been providing services under "scopes of work" and "memoranda of understanding." Without clearly delineated responsibilities and a formalized contract to limit liability, UK's risk exposure is heightened. The EACL was also not regularly assessing this vendor's performance, exacerbating concerns related to a lack of a contract, especially considering the regulatory compliance requirements of the equine industry and the nature of the lab's activities.

2.1d: IT Service Continuity/Disaster Recovery

UKIA noted that the EACL lacks documented IT service continuity and disaster recovery plans to minimize any down time in the event of a disaster. As a horse's health – as well as its race eligibility – often hinges on the results of EACL's testing, timely results are critical.

Finding 2.2: IT Operations

UKIA noted that the EACL has insufficient access controls and inadequate safeguards in place to ensure the integrity of its data.

2.2a: Access Controls

UKIA noted that the EACL's access controls were inadequate, leaving its critical data at risk of loss, theft or manipulation. These weaknesses are detailed below:

- EACL staff use shared credentials to access servers, applications and documents, including sensitive information, which is stored on their file shares.
- LIMS access is managed by the external vendor, which does not conduct routine deprovisioning practices. Consequently, several former employees have retained active user accounts within the LIMS system.
- The LIMS vendor maintains *administrative access* to EACL servers and databases, provided through a third-party remote access method (ZeroTier) rather than a more controlled *sponsored account* and use of enterprise Virtual Private Network infrastructure, which is the standard protocol.
- All EACL systems are not integrated with the active directory. Instead, EACL systems use a mix of local, active
 directory, and shared accounts to access lab resources and as a result, activity is not always attributable to individual
 users. Moreover, the shared credentials and inadequate deprovisioning protocols noted above increase the risk of
 unauthorized and unattributable access to these sensitive systems and data.

2.2b: Data Integrity

UKIA noted that the EACL's primary File Share is not properly protected. Due to the fact that instrument data, LIMS tracking data, chain of custody information, relevant SOPs, and the HIWU Excel file with sample batch results from LIMS are all manually uploaded to this file share (See Appendix B #4 and 5), which can be accessed by all EACL staff, critical EACL data may be compromised. Moreover, due to the shared credentials noted above, this data could be altered while obfuscating detection of the bad actor.

UKIA also observed that a second EACL server had been created and maintained by an EACL IT employee solely to facilitate reporting of results to HIWU. This server provides yet another opportunity for lab results to be altered, as this server is also accessible using a shared account that precludes the identification of the user.

2.2c: Asset Management

The EACL has no formal system in place to track or manage its non-capital IT assets, such as desktop computers, and laptops and tablets. When such assets are not properly managed, the risk of loss, theft or cybersecurity breach increases.

Finding 2.3: Business Operations

UKIA noted a lack of duty separation that, together with its established practice of providing detailed results only for adverse findings, presented numerous opportunities to tamper with samples or manipulate test results. Given the weak access controls discussed in previous findings, UKIA also confirmed that such activity could be undertaken with minimum risk of detection.

2.3a: Separation of Duties

The weak access controls noted above, together with the ability for the EACL director to perform key steps in the process completely outside the LIMS such that it would not be documented in the system, resulted in inadequate segregation of duties related to the quality control and communication of test results. For example, UKIA noted that the EACL director has access to the entire process from beginning to end, including:

- Access to both the samples in the coolers and the seals for the coolers prior to the intake process (Appendix B #1)
- Full control of the samples and data that are uploaded into LIMS
- Sole responsibility for the results that are reported to clients (Appendix B #2)

Such unhindered access from intake through reporting could potentially allow for samples to be tampered with and resealed in the coolers, changes to test results and/or misreporting of results to the client – all while avoiding detection.

2.3b: Results Reporting

UKIA noted that the client only receives the full data packet from the EACL when the results are adverse. These packets contain an affidavit of positive finding(s), an image of the sample tags, a letter to the Organization Official regarding the positive finding(s), any associated air bills or packing lists and the liquid chromatography/tandem mass spectrometry confirmation data. Clients with no adverse results are only provided the outcome in the form of a certificate of analysis. Consequently, results could be falsely reported as not being adverse as no further documentation is required (see Appendix B #7).

2.3c: Invoice Timeliness

UKIA noted that the EACL business officer is only in the office twice per month. As a result, invoice timing is inconsistent. Furthermore, these invoices are generated based on how the samples are received.

RECOMMENDATIONS

Though it is under the Martin-Gatton CAFE Equine Program umbrella, UKIA noted that the EACL is self-funded and operates with near autonomy. Accordingly, the recommended remediation strategies, categorized and outlined below, are designed to ensure an adequate internal controls environment while facilitating greater trust, transparency and accountability for the EACL. Thus, these recommendations are associated with governance and internal operational controls and focus solely on remediating the findings noted within this report. Please note that they are specific to EACL, as UKIA has not performed sufficient work to date to understand the Martin-Gatton CAFE governance structure for each self-funded unit within its purview.

UK Internal Audit is continuing its work to evaluate all accounts to which Dr. Stanley had access over his tenure as EACL director for fraudulent activity. The results of this analysis will be provided separately. Relevant results have/will be relayed as appropriate.

Governance

- 1. Advisory Boards: The compositions and objectives of the advisory boards in the USEF contract will help to ensure appropriate governance. Accordingly, it is imperative that the Equine Analytics Laboratory Advisory Board resume its quarterly meetings and the Scientific Advisory Board is established in accordance with the contract.
- 2. Martin-Gatton CAFE Oversight: A reporting structure for the financial administration and quality control functions should be established that facilitates stronger oversight from within the Martin-Gatton CAFE. These positions must be accountable to both the EACL director and the University as transparency for this particular self-funded entity is paramount. Appropriate steps include:
 - i. Assess the financial acumen of the current financial administrator to determine requisite training needs
 - ii. Ensure completion of this training by the financial administrator, to include UK Fraud Training through the FAST program.
 - iii. Establish a reporting process for Martin-Gatton CAFE leadership to regularly review EACL payables, receivables, and all billable activities.
 - iv. Verify that the quality control officer completes relevant training for research ethics and scientific integrity.
 - v. Require all EACL staff members to annually disclose their business interests and overloads to Martin-Gatton CAFE leadership to be assessed for conflicts of interest and/or conflicts of commitment.

- 3. Information Security: UKIA identified several critical deficiencies in the EACL's current approach to information security that expose the lab to significant risks, including unauthorized access to sensitive data, potential data manipulation, and a lack of preparedness for cybersecurity incidents. To address these issues and enhance the security of the lab's operations, UKIA recommends the following steps be taken:
 - i. **Develop and Implement a Formal Information Security Policy** The EACL must develop a comprehensive cybersecurity policy that outlines clear procedures for safeguarding sensitive data. This policy should align with Information Technology Services' (UK ITS) policies and cover access control, data handling, incident response, ongoing monitoring and vulnerability management, ensuring that all staff adhere to best practices in information security.
 - ii. Implement Comprehensive Role-based Access Control (RBAC) and Eliminate Shared Credentials —
 The current practice of using shared credentials for access to EACL systems must be discontinued immediately. The
 EACL should replace existing use/instances of shared (or local-only system) credentials with individual user accounts
 based on role and integrate lab systems into the university's existing enterprise Active Directory infrastructure for
 authentication and authorization. This integration will allow for centralized control over access rights and facilitate the
 use of RBAC across critical lab systems, ensuring adherence to the principle of least privilege.
 - iii. **Manage Vendor Access** Vendor access provided to both EACL's systems *and* University networks should be granted only through secure, University-approved external access methods, to include the creation of sponsored external LinkBlue accounts with defined expiry and review periods for vendor staff, and the transition to use of enterprise Virtual Private Network (VPN) infrastructure for network access. Additionally, vendor activity must be closely monitored, and access should be routinely reviewed to ensure compliance with enterprise security policies and protocols.

EACL Operations

1. Contract Management: An RFP should be issued for a vendor to provide and maintain a laboratory information management system. This contract should require the vendor to properly maintain and update the system in conjunction with Martin-Gatton CAFE IT personnel. Once a new contract is finalized, the contract should be appropriately managed to ensure vendor compliance.

Going forward, all personal service contracts, memorandums of understanding and requests for proposals should undergo the following:

- i. The creation of a proforma, including cost forecasting, which should be submitted to the business officer for vetting and to the chair for authorization to ensure transparency.
- ii. Submittal through Procurement Services to ensure all contracts are appropriately executed and all requisite associated agreements are obtained.

2. Standard Operating Procedures (SOPs): The EACL should revise its SoPs to conform with the industry framework, as follows:

Operations

- i. Ensure alignment with industry standards such that all duties are documented and appropriately separated from intake through results communication.
- ii. Provide detailed step-by-step guidance and criteria for each type of test the EACL is capable of performing. As capabilities and/or testing guidelines change, these SoPs should be updated accordingly. Procedures should specifically note that requests for tests for which there are no documented SoPs will not be accepted.
- iii. Prohibit the director or any staff member from being able to bypass SampleManager or otherwise go outside the process, regardless of the type of sample or the test results.
- iv. Require that test results are consistently communicated, in compliance with industry and accreditation standards and in a manner that instills confidence in the test results.
- v. Establish an expected timeline from intake through results communication, such that any variances from this timeline can be detected and addressed appropriately.
- vi. Tie invoicing to results communication rather than how the samples were received or their source.

Systems (Laboratory Information Management Application)

Collaborate with the vendor selected for its laboratory information management applications and systems, along with designated EACL IT support personnel, to thoroughly review and update all existing SoPs related to information technology. Ensure that these SoPs comprehensively and accurately reflect the state of the computing and information systems environment, including but not limited to:

- Access controls, reviews, and account lifecycle management
- Third-party/vendor access to lab systems and networks
- Secure data handling and integrity controls
- Vulnerability management and monitoring
- Change management
- IT asset management
- Backup and recovery procedures
- Physical security controls
- Confidentiality and data privacy

- 3. Training: All EACL employees who are directly involved in research should be trained on these revised SoPs and associated research standards to ensure compliance. Additionally, all those tangentially involved, such as the financial administrator should also be trained on how their role(s) are also tied to the integrity of the data, such that results communication is verified at the time of invoicing.
- **4. Business Continuity:** Due to the fact that there is no disaster recovery in place, and their backups are stored all on site, the EACL is at significant risk of a major disruption to their operations. A business continuity plan should be developed that includes the following:
 - i. **Risk Assessment** Identifies the various kinds of disruptions and associated risks the EACL is more likely to face and their causes, such as a natural disaster, fire, cyberattack, pandemic or terrorism.
 - ii. **Business Impact Analysis** identifies the consequences of the risks noted in the Risk Assessment to the EACL's operations, then inventories and prioritizes the critical functions of the EACL that must be restored and lists the equipment, systems, processes and the key personnel necessary/responsible for their restoration.
 - iii. **Recovery Strategies** Details the steps, roles and responsibilities that are necessary to restore the EACL to full operations. These steps may vary somewhat depending on the type of incident. These details should include a recovery time objective (RTO) and a recovery point objective (RPO) which establishes the time duration goal between point of failure and the ability to resume operations and the maximum amount of data loss the EACL can endure and retain the ability to operate, respectively.

MANAGEMENT ACTION PLAN

Martin-Gatton CAFE leadership is currently working with University administration to partner with an external entity to create the next generation of the EACL. To that end, we are in the process of preparing and issuing a Request for Proposal (RFP) related to management of the EACL. This RFP will seek industry entities looking to partner with the college to provide both best-in-class and state-of-the-art analytical chemistry drug testing services for the equine industry, as well as cutting-edge research to support the testing operations.

To the extent that this process is successful and the EACL comes under new management, many of the issues identified in the Internal Audit report will become the responsibility of the successful bidder as they assume management responsibilities. To the extent that the process does not result in the EACL coming under new management, Martin-Gatton CAFE will proceed as set forth below.

It should be noted that many of the processes detailed below are already in place and were implemented when the Acting Director took over leadership of the EACL one week after the former director was removed.

GOVERNANCE

1. **Recommendation:** Advisory Boards: The compositions and objectives of the advisory boards in the USEF contract will help to ensure appropriate governance. Accordingly, it is imperative that the Equine Analytics Laboratory Advisory Board resume its quarterly meetings and the Scientific Advisory Board is established in accordance with the contract.

Response: Because the contract with the USEF has been terminated, the advisory board it created no longer exists. However, the college is very much invested in making sure that the industry is adequately represented in the management of the EACL and commits to reconstituting a new Advisory Board with substantially the same objectives as set forth in that contract, those being to:

- review and provide input into the budget of the EACL;
- review the operations of the EACL;
- prioritize research projects for the EACL;
- ensure appropriate accreditations of the EACL; and
- review recommendations from the EACL Scientific Advisory Board.

An early priority for the Advisory Board will be the establishment of the Scientific Advisory Board.

To the extent that the University issues an RFP related to the management of the EACL, it will include a requirement that an advisory board and a scientific advisory board be formed, and that the Martin-Gatton CAFE has a presence on those boards.

- 2. Recommendation: Martin-Gatton CAFE Oversight: A reporting structure for the financial administration and quality control functions should be established that facilitates stronger oversight from within the Martin-Gatton CAFE. These positions must be accountable to both the EACL director and the University as transparency for this particular self-funded entity is paramount. Appropriate steps include:
 - i. Assess the financial acumen of the current financial administrator to determine requisite training needs
 - ii. Ensure completion of this training by the financial administrator, to include UK Fraud Training through the FAST program.
 - iii. Establish a reporting process for Martin-Gatton CAFE leadership to regularly review EACL payables, receivables, and all billable activities.
 - iv. Verify that the quality control officer completes relevant training for research ethics and scientific integrity.
 - v. Require all EACL staff members to annually disclose their business interests and overloads to Martin-Gatton CAFE leadership to be assessed for conflicts of interest and/or conflicts of commitment.

Response: The EACL has filled its vacant Quality Control Manager position and has changed the reporting line so that it reports to the college's Associate Dean for Research. Having this position report outside of the leadership structure of the EACL will facilitate stronger oversight from Martin-Gatton CAFE administration and provide greater independence for the Quality Control Manager to address problems as they are discovered.

- i. The Martin-Gatton CAFE Business Center, under the leadership of the Associate Dean for Finance, has taken over responsibility for supporting the EACL and providing business and human resources support through its business analyst team. To the extent that the analysts identify deficiencies, they will be addressed through training, corrective action and follow-up during the annual evaluation period.
- ii. The college Business Center, under the leadership of the Associate Dean for Finance, will ensure that all laboratory personnel performing business functions receive all necessary training, including the fraud training given through the FAST program. The fraud training will be completed within three months.
- iii. The Martin-Gatton CAFE Business Center, under the leadership of the Associate Dean for Finance, has taken over responsibility for supporting the EACL and providing business and human resources support through its business analyst team. They are tasked with, among other things, reviewing all billable activities, including all payables and receivables.
- iv. The college's Associate Dean for Research is now the supervisor of the laboratory's Quality Control Officer and has confirmed that she has completed all necessary training, including research ethics and scientific integrity.
- v. College leadership expects all employees to comply with the university's rules and regulations, including those that pertain to conflicts of interest and conflicts of commitment. The college Associate Dean for Research will address

these topics with laboratory staff and require them to make at least annual disclosures of their business interests. Overload appointments shall be approved in advance of the work being done, consistent with university policy.

- 3. **Recommendation:** Information Security: UKIA identified several critical deficiencies in the EACL's current approach to information security that expose the lab to significant risks, including unauthorized access to sensitive data, potential data manipulation, and a lack of preparedness for cybersecurity incidents. To address these issues and enhance the security of the lab's operations, UKIA recommends the following steps be taken:
 - i. Develop and Implement a Formal Information Security Policy The EACL must develop a comprehensive cybersecurity policy that outlines clear procedures for safeguarding sensitive data. This policy should align with Information Technology Services' (UK ITS) policies and cover access control, data handling, incident response, ongoing monitoring and vulnerability management, ensuring that all staff adhere to best practices in information security.
 - ii. Implement Comprehensive Role-based Access Control (RBAC) and Eliminate Shared Credentials —
 The current practice of using shared credentials for access to EACL systems must be discontinued immediately. The
 EACL should replace existing use/instances of shared (or local-only system) credentials with individual user accounts
 based on role and integrate lab systems into the university's existing enterprise Active Directory infrastructure for
 authentication and authorization. This integration will allow for centralized control over access rights and facilitate the
 use of RBAC across critical lab systems, ensuring adherence to the principle of least privilege.
 - iii. **Manage Vendor Access** Vendor access provided to both EACL's systems and University networks should be granted only through secure, University-approved external access methods, to include the creation of sponsored external LinkBlue accounts with defined expiry and review periods for vendor staff, and the transition to use of enterprise Virtual Private Network (VPN) infrastructure for network access. Additionally, vendor activity must be closely monitored, and access should be routinely reviewed to ensure compliance with enterprise security policies and protocols.

Response:

- i. The EACL is currently developing a comprehensive cybersecurity policy that outlines clear procedures for safeguarding sensitive data. This policy will align with Information Technology Services' (UK ITS) policies and cover access control, data handling, incident response, ongoing monitoring and vulnerability management, ensuring that all staff adhere to best practices in information security.
- ii. The EACL has eliminated all shared credentials for the LIMS and each LIMS user has a unique login and password. The lab is in the process of eliminating shared credentials for its laptops and servers as part of its complete overhaul of IT operations. In addition, EACL will integrate the lab systems into the university's existing enterprise

- Active Directory infrastructure for authentication and authorization. The EACL is in the process of revising and improving the role-based access for employees and improving the audit and tracking capability of its system.
- iii. Vendors no longer have access to the LIMS or any other lab systems. To the extent that it becomes necessary to allow access, EACL management will work with UK ITS to ensure that access is given in a manner consistent with industry best practices and university policy.

EACL OPERATIONS

1. **Recommendation: Contract Management:** An RFP should be issued for a vendor to provide and maintain a laboratory information management system. This contract should require the vendor to properly maintain and update the system in conjunction with Martin-Gatton CAFE IT personnel. Once a new contract is finalized, the contract should be appropriately managed to ensure vendor compliance.

Going forward, all personal service contracts, memorandums of understanding and requests for proposals should undergo the following:

- i. The creation of a proforma, including cost forecasting, which should be submitted to the business officer for vetting and to the chair for authorization to ensure transparency.
- ii. Submittal through Procurement Services to ensure all contracts are appropriately executed and all requisite associated agreements are obtained.

Response: The EACL has moved the management of its Laboratory Information Management System (LIMS) in-house and has hired a LIMS manager currently in training. The LIMS Manager will be responsible for properly maintaining the LIMS in conjunction with Martin-Gatton CAFE and UK ITS, and for ensuring compliance with industry best practices and university policies and procedures.

For all contracts, memorandums of understanding (MOUs) purchases and other business transactions, the EACL will ensure that all documents are appropriately reviewed, approved and executed pursuant with university polices. The Martin-Gatton CAFE Business Center will provide support as necessary.

2. **Recommendation: Standard Operating Procedures (SOPs):** The EACL should revise its SOPs to conform with the industry framework, as follows:

Operations

- Ensure alignment with industry standards such that all duties are documented and appropriately separated from intake through results communication.
- ii. Provide detailed step-by-step guidance and criteria for each type of test the EACL is capable of performing. As capabilities and/or testing guidelines change, these SOPs should be updated accordingly. Procedures should specifically note that requests for tests for which there are no documented SOPs will not be accepted.
- iii. Prohibit the director or any staff member from being able to bypass SampleManager software or otherwise go outside the process, regardless of the type of sample or the test results.
- iv. Require that all results, adverse or not, are communicated the same way, with a packet that includes an affidavit of positive finding(s), an image of the sample tags, a letter to the Organization Official regarding the positive finding(s), any associated air bills or packing lists and the liquid chromatography/tandem mass spectrometry confirmation data.
- v. Establish an expected timeline from intake through results communication, such that any variances from this timeline can be detected and addressed appropriately.
- vi. Tie invoicing to results communication rather than how the samples were received or their source.

Response: The EACL has revised or drafted new SOPs to address the need for more transparency and consistency with industry standards, as follows:

- i. The EACL is revising its procedures, so all roles and responsibilities are documented and access is limited, consistent with industry best practices and accreditation standards. Audit and tracking capability and Quality oversight will serve as a check on inappropriate use of discretion on the testing process by senior laboratory leadership.
- ii. EACL is currently implementing a new Quality Management System (<u>Ideagen</u>). This system will be used to manage employee training and training records, document revision control, proficiency testing, and corrective and preventive action procedures, among other things.
- iii. The current SOPs provide detailed guidance and criteria for each type of test the EACL is capable of performing. SOPs will be reviewed on a regular schedule for updates and revisions, and this will be managed using the new QMS (Ideagen). Requests for tests for which there are no documented SOPs will not be accepted unless the client is aware that a new test will need to be developed and validated, and they are apprised and approve of the cost.
- iv. There may be situations where senior laboratory leadership need to deviate from the standard workflow process as defined by SOP and within the LIMS. As such, the LIMS is being revised to require a justification and the approval of the Quality Control Manager prior to any such deviation. Process deviations will be managed using the new QMS (Ideagen).

- v. The EACL will work with its clients to develop robust external and internal proficiency testing programs and results reporting processes that will ensure accountability and compliance with industry and accreditation standards. This, combined with new laboratory management and implementation of a new rigorous Quality Management System, should provide the confidence in the integrity of the testing process. The EACL will provide whatever additional data and supporting documentation requested by the client with the understanding that the additional work may increase the testing costs.
- vi. Expected timeline for sample Turn-Around-Times (TAT) are negotiated with clients prior to accepting samples. The Service Manager and Associate Service Manager are charged with monitoring TAT, informing clients of delays, and discussing with laboratory leadership the cause for delays in TATs and possible remedies.
- vii. The EACL is currently invoicing clients based on results returned rather than samples received.

Systems (Laboratory Information Management Application)

Collaborate with the vendor selected for its laboratory information management applications and systems, along with designated EACL IT support personnel, to thoroughly review and update all existing SoPs related to information technology. Ensure that these SoPs comprehensively and accurately reflect the state of the computing and information systems environment, including but not limited to:

- · Access controls, reviews, and account lifecycle management
- Third-party/vendor access to lab systems and networks
- Secure data handling and integrity controls
- Vulnerability management and monitoring
- Change management
- IT asset management
- Backup and recovery procedures
- Physical security controls
- Confidentiality and data privacy

Response: EACL management and the new LIMS Manager are working with Martin-Gatton CAFE IT to thoroughly review and update all existing SOPs related to information technology. The updated SOPs will be complete by January 30, 2025 and will ensure that they comprehensively and accurately reflect the current state of the computing and information systems environment, including but not limited to:

- · Access controls, reviews, and account lifecycle management
- Third-party/vendor access to lab systems and networks
- Secure data handling and integrity controls
- Vulnerability management and monitoring
- Change management
- IT asset management
- Backup and recovery procedures
- Physical security controls
- Confidentiality and data privacy

These SOPs will be reviewed annually and updated as necessary.

3. **Recommendation: Training:** All EACL employees who are directly involved in research should be trained on these revised SoPs and associated research standards to ensure compliance. Additionally, all those tangentially involved, such as the financial administrator should also be trained on how their role(s) are also tied to the integrity of the data, such that results communication is verified at the time of invoicing.

Response: All EACL employees have undergone extensive re-training on new and revised SOPs. The lab does minimal research but, to the extent that it is involved in such activities, employees will receive appropriate training regarding the conduct of research studies and how these may vary from service sample analysis.

- 4. **Recommendation: Business Continuity:** Due to the fact that there is no disaster recovery in place, and their backups are stored all on site, the EACL is at significant risk of a major disruption to their operations. A business continuity plan should be developed that includes the following:
 - i. **Risk Assessment** Identifies the various kinds of disruptions and associated risks the EACL is more likely to face and their causes, such as a natural disaster, fire, cyberattack, pandemic or terrorism.

- i. **Business Impact Analysis** identifies the consequences of the risks noted in the Risk Assessment to the EACL's operations, then inventories and prioritizes the critical functions of the EACL that must be restored and lists the equipment, systems, processes and the key personnel necessary/responsible for their restoration.
- iii. **Recovery Strategies** Details the steps, roles and responsibilities that are necessary to restore the EACL to full operations. These steps may vary somewhat depending on the type of incident. These details should include a recovery time objective (RTO) and a recovery point objective (RPO) which establishes the time duration goal between point of failure and the ability to resume operations and the maximum amount of data loss the EACL can endure and retain the ability to operate, respectively.

Response: A Risk Assessment has already been added to the EACL's Management Review process, which is conducted as part of the ISO 17025 accreditation process. Protocols for Business Impact Analysis and Recovery Strategies will be drafted as key components of the Risk Assessment. These will be completed by January 1, 2025 and implemented by senior EACL leadership no later than January 30, 2025.

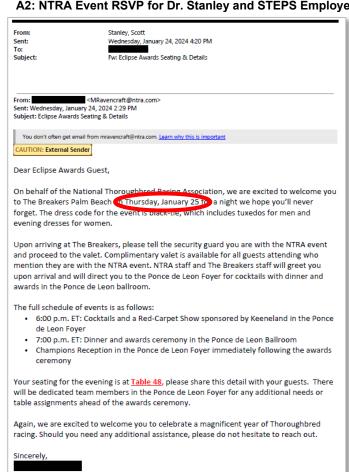
APPENDIX

Appendix A: Supporting Documentation Related to Conflict of Interest/Personal Relationship with STEPS employee

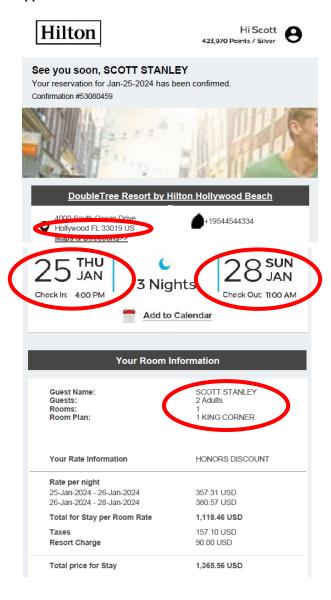
A1: Letter to STAFF Employee's Professor to Request Excuse from Class

A2: NTRA Event RSVP for Dr. Stanley and STEPS Employee





Appendix A3: Hotel Confirmation

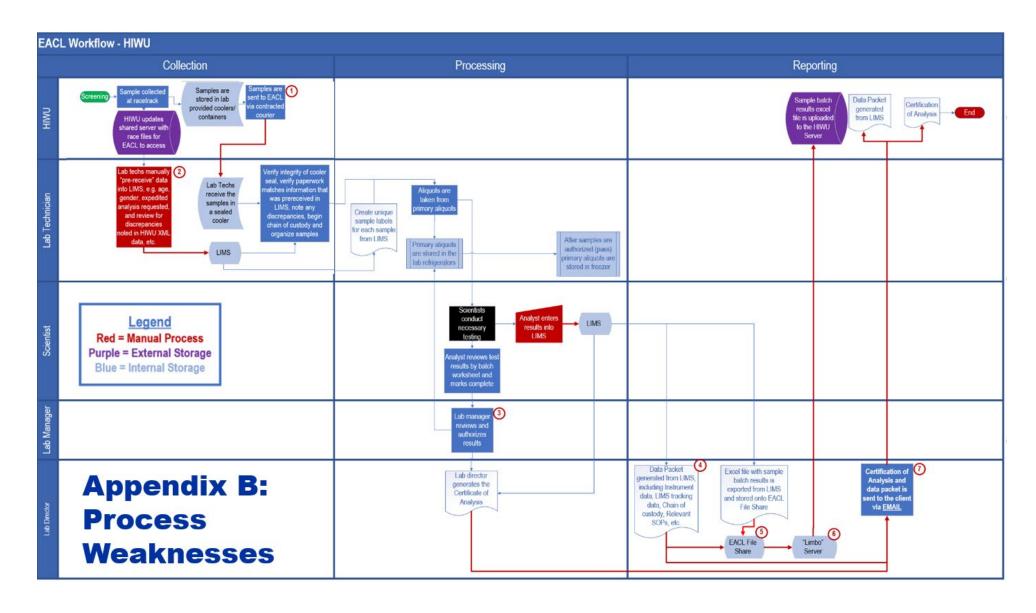


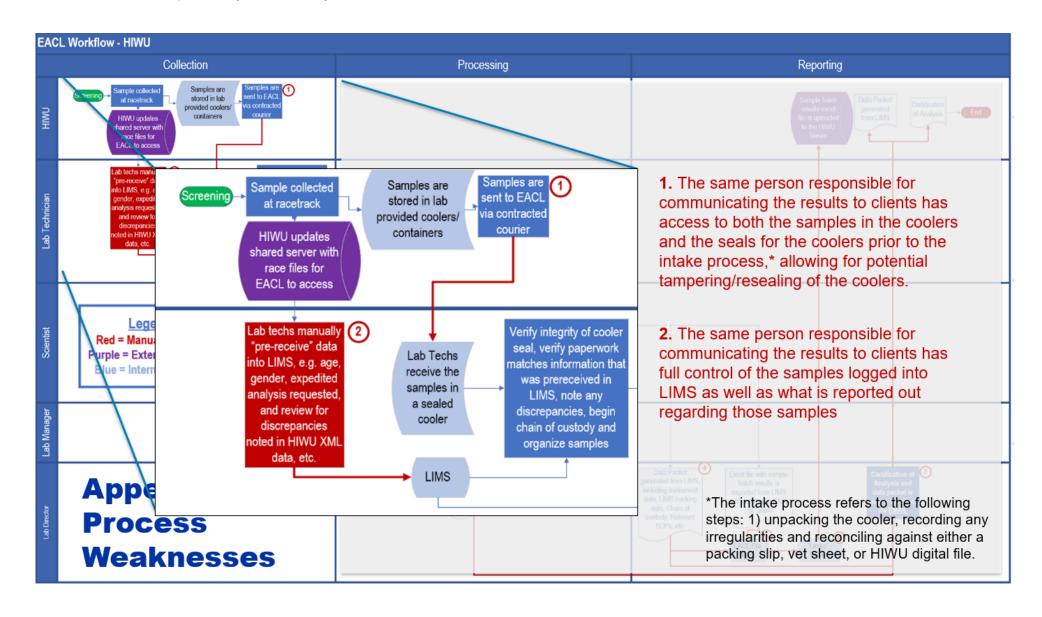
Appendix A4: Airfare Confirmation for STEPS Employee to Same Location

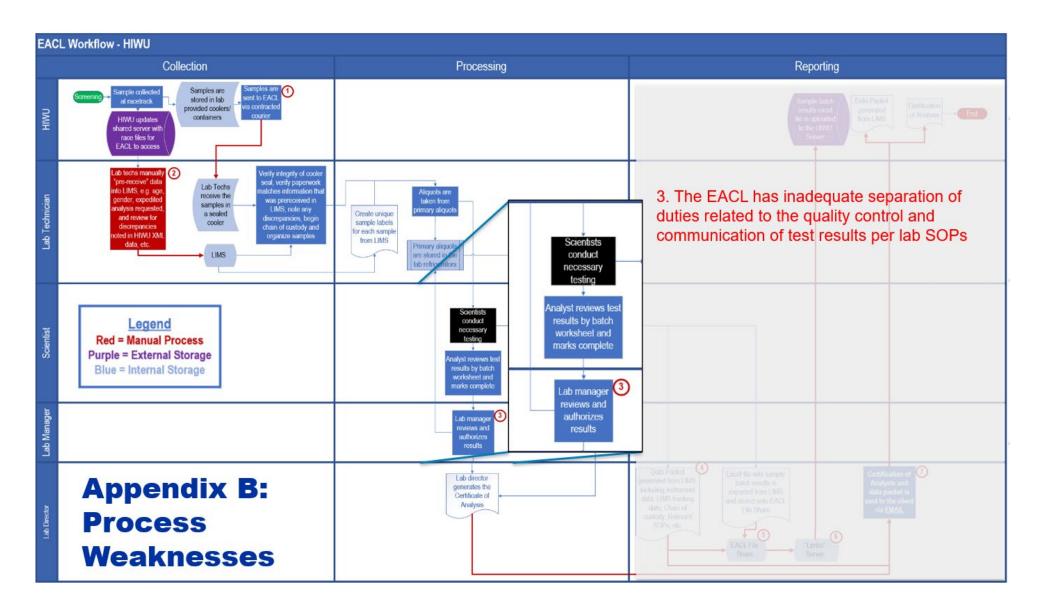
From: Delta Air Lines < DeltaAirLines@t.delta.com>
Sent: Tuesday, January 9, 2024 4:06:53 PM
To: Stanley, Scott < scott.stanley2@uky.edu>
Subject: Your Flight Receipt - 25JAN24

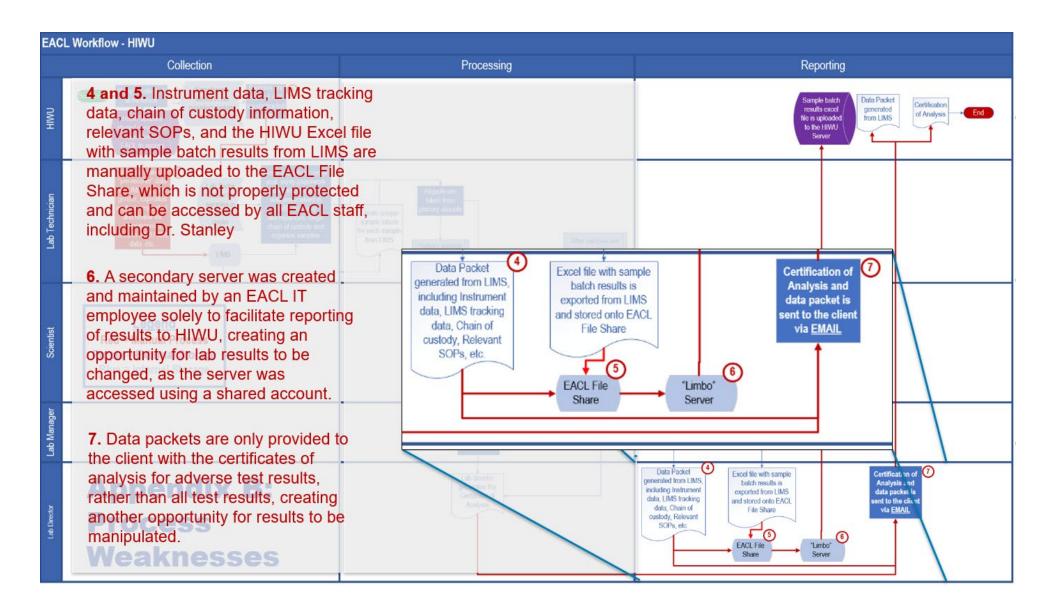
CAUTION: External Sender

FLIGHT		SEAT	
DELTA 1275		18C	
DELTA 1709		19B	
DELTA 1295		19C	
DELTA 2213	13 17E		
Thu, 25JAN	DEPART		ARRIVE
Thu, 25JAN	DEPART		
DELTA 1275 Main Cabin (T)	LEXINGTO 5:52am	IN, KY	ATLANTA 7:34am
DELTA 1275 Main Cabin (T) DELTA 1709	LEXINGTO	N, KY	ATLANTA
Thu, 25JAN DELTA 1275 Main Cabin (T) DELTA 1709 Delta Comfort+® (W) Sun, 28JAN	LEXINGTO 5:52am	N, KY	ATLANTA 7:34am
DELTA 1275 Main Cabin (T) DELTA 1709 Delta Comfort+® (W)	LEXINGTO 5:52am ATLANTA 8:10am		ATLANTA 7:34am FT LAUDERDALE, FL 10:06am











2024 INQ09 Equine Analytical Chemistry Lab

October 21, 2024

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