Pace Analytical®
Life Sciences

February 23, 2018

Art Czabaniuk
Program Division Director
US Food and Drug Administration

Dear Mr. Czabaniuk,

This letter acknowledges the receipt of the FDA 483 as related to the January 9 – February 7, 2018 inspection at Pace Analytical Life Sciences, LLC in Oakdale, MN. Each observation has been addressed and the response is attached. The response identifies Corrections and/or Corrective Actions, as appropriate, along with Responsible Individual and Target Date.

Respectfully,

Cynthia Hansen
Senior Director of Quality
Pace Analytical Life Sciences, LLC
1311 Helmo Avenue North
Oakdale, MN 55128

Greg Kupp
VP/COO
Pace Analytical Life Sciences, LLC
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Oakdale, MN 55128

Encl.: Inspection Response
Copy CATs 2122 - 2134

OBSERVATION 1: The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

CORRECTIVE ACTION: A high level change control SOP will be written identifying all existing change control processes including identifying quality control unit responsibilities; see CAT 2122.

RESPONSIBLE INDIVIDUAL: Cynthia Hansen

TARGET DATE: 31 Aug 2018

1. Specifically, your firm's Standard Operating Procedure (SOP) L12, *Work Order Generation, Work Completion, and Reporting of Results,* ver. 17, effective 03 Jan 2018 is inadequate to manage and document change to client Analysis Reports / Certificate of Analysis (CoA) consistent with regulatory requirements and current good manufacturing practices (cGMPs). The procedure is omit of comprehensive investigative methodologies/procedures, including corrective and preventative actions (CAPA). Further, the practical application of the current procedure may result in circumvention of established Laboratory Investigation (LIR, SOP L8) and Corrective Action (CA, SOP 42) procedures. A specific example where a conventional LIR, including CA would have been warranted include, but may not be limited to:
   - Work Order 1747812, Revised Report Record of Change (SOP L12 A4, Date 07 Apr 2016).

RESPONSE: As discussed during the inspection, the scope of SOP L8, Laboratory Investigations, is related to suspect results that are generated by Pace. The need to revise a report does not imply that the results presented on the original report, or on a revised report, are suspect and therefore in scope of SOP L8. SOP L8 is very closely aligned with FDA guidance document "Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production (October 2006)" and requires investigation of all suspect results generated by Pace.

CORRECTIVE ACTION: SOP L12 will be updated to include additional considerations to be recorded as part of the change management process currently described by SOP L12. As an example, SOP L12 A4 will be updated to require that additional investigative questions be answered including but not limited to 1) whether or not other samples/tests were tested during the analysis in question, 2) whether or not the lot has previously been tested and 3) if there is any impact to the results based on 1 and 2. Sections will also be added to SOP L12 A4 to allow for recording if the revision has led to results now meeting definition of suspect results found in SOP L8 and any corrective actions that are initiated as an outcome of the impact assessment. SOP L12 A4 forms will also be assigned a tracking number. See CAT 2123.

RESPONSIBLE INDIVIDUAL: Greg Kupp

TARGET DATE: 30 Jun 2018

2. Specifically, your firms internally developed "PacePort" and "Validation Package" Oracle Database 10g applications (SQL) / tools, including associated servers critical to Pace Analytical Life Sciences, LLC. (PLS) GMP Quality System workflows are not managed and tracked under a centralized Change Management System (CMS) consistent with regulatory requirements, cGMPs and internal operating procedures, including Incoming Inventory

Assessment (SOP 19 A3) outlined in SOP 19 *Laboratory Inventory and Change Control Procedures,* ver. 7, effective 28 Jun 2016.

RESPONSE: Neither the "PacePort" drop box tool nor the "Validation Package" data package assembly tool are interfaced to any laboratory instruments/software and do not contain any records that have not been reviewed and approved by Quality Assurance staff prior to use of PacePort or Validation Package. PacePort is used to deliver a static pdf file to clients, with all components reviewed prior to delivery of the data package to the client and similar to mailing/faxing/emailing a paper copy of all described records. Pace considers delivery of data packages to clients via PacePort to be a like for like mechanism replacing previous processes of mailing/faxing/emailing and allowing timely delivery of a large amount of information useful for clients in making any decisions based on testing results provided by Pace. Likewise, Validation Package is a tool that assembles all relevant records into a single data package. Validation Package replaced the manual process of a human retrieving thousands of pages of records allowing for fewer errors and more timely delivery of a large amount of information useful for clients in making any decisions based on testing results provided by Pace. At the time Pace made the decision to implement these tools and replace previous processes (including mail/fax/email of data and manual assembly of such data), Pace did so knowing that the tools were located on servers located at Pace's parent company facility in Minneapolis, MN. As the tools were located in Minneapolis and not in Pace's control, they did not fall under the scope of SOP 19 for incoming inventory or change management.

CORRECTIVE ACTION: Pace will relocate "PacePort" and "Validation Package" tools to Oakdale from Minneapolis, assign asset numbers to the tools as described in SOP 19 and require change management as described in SOP 19; see CAT 2124.

RESONSIBLE INDIVIDUAL: Greg Kupp

TARGET DATE: 31 Dec 2020

3. Specifically, your firm did not conduct a formalized risk assessment consistent with regulatory requirements, cGMPs and internal operating procedures outlined in SOP 18 *Risk Assessment,* ver.7 effective 02 Mar 2017 when implementing and updating database applications critical to PLS core GMP Quality System (QS) workflows, including the internally developed "PacePort" and "Validation Package" applications (SQL) / tools and the Facilities and Equipment tracking application developed in the Laboratory Information Management System (LIMS, Horizon/EPIC Pro).

RESPONSE: As presented during the inspection, Pace authored Risk Assessment RA 296 to retrospectively describe the decision making process at the time PacePort was implemented in 2010. RA 296 concluded that there was no perceived risk associated with replacement of the mail/fax/email delivery processes by PacePort and Validation Package. SOP 18 does not require a Risk Assessment be written for any specific situation, but rather describes a process to be used when a decision is made to document a perceived risk. Pace did not write a risk assessment at the time Validation Package was implemented, replacing a manual data package assembly process, as there was no perceived risk. All records utilized by Validation Package to assemble a data package that is delivered to a client via PacePort are reviewed and approved by QA prior to use of Validation Package and PacePort. The output of Validation Package is a static pdf file which is made available to clients for download through PacePort. Pace did author

a change control, CRF 1422, presented during the inspection, capturing the decision to move from historical Facilities/Equipment tracking tools (i.e. bound logbook, Excel spreadsheet, Access database, internally built database) to use of a validated tool, LIMS. The risk decision associated with this CRF was documented as part of CRF 1422 and an additional Risk Assessment report was not determined to be necessary at the time of the CRF.

CORRECTIVE ACTION: Pace will author a retrospective Risk Assessment describing the decision making process at the time Validation Package was implemented; see CAT 2125. Pace will author a retrospective Risk Assessment describing the decision making process at the time LIMS was identified as a replacement to historical tools; see CAT 2126.

RESPONSIBLE INDIVIDUAL: Cynthia Hansen

TARGET DATE: 31 Mar 2018

4. Specifically, a comprehensive/centralized operating procedure specific to the use, administration, control, tracking, versioning and validation, including elements specific to data integrity do not exist for custom fields/calculations constructed in the Empower Chromatographic Data System (CDS). These calculations are used to support the analysis of regulated drug products, including in-process, finished product and stability testing.

CORRECTIVE ACTION: A new SOP will be written describing use and validation of Empower custom calculations; see CAT 2127.

RESPONSIBLE INDIVIDUAL: Cynthia Hansen

TARGET DATE: 31 Dec 2018

5. Specifically, your firm did not conform to SOP 30, *Complaint Handling,* ver.6, effective 07 Mar 2017 including the initiation of a Complaint Resolution Form when addressing client complaints. The scope of the procedure includes, but is not limited to complaint resolution for "poor service, reporting errors, billing errors, or performance of incorrect analysis." Specific examples where your firm failed to initiate the complaint resolution procedure include, but may not be limited to:
   - Work Order 1747812, Revised Report and Record of Change, Form SOP L12 A4 (Date 07 Apr 2016): The content of this document supported by discussions conducted during the inspection reflect a revision request by the client based on a chromatographic error. This constitutes a "reporting error".
   - Stability Protocol 60064593; Deviation 1812, *Rationale for Accepting the Deviation:* "While reviewing an investigation related to project 1745354 the client informed [name redacted] that Pace Analytical Life Sciences (PLS) had deviated from the protocol 60064593 by analyzing 3 MCRD test units and not 9." This constitutes an "incorrect analysis".

RESPONSE: Pace has processes for handling "reporting errors" (SOP L12) and "performance of incorrect analysis" (SOPs L12, 17, L8). As processes already exist for evaluating and recording these incidents including impact assessment, root cause analysis and corrective action determination, "reporting errors" and "performance of incorrect analysis" will be removed from the scope of the SOP.

CORRECTIVE ACTION: Update SOP 30 to remove "reporting errors" and "performance of incorrect analysis" from scope; see CAT 2128.

RESPONSIBLE INDIVIDUAL: Cynthia Hansen

TARGET DATE: 31 Mar 2018

OBSERVATION 2: Routine checking of electronic equipment is not performed according to a written program designed to assure proper performance. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

RESPONSE: Pace maintains the appropriate procedures to ensure routine checking of electronic equipment in accordance with a written program (SOPs 10 and SOP 46). . Some of the specific examples below are situations where Pace made a conscious decision not to apply the principals outlined in SOP 10 and SOP 46 based on the intended use of the systems (e.g. Validation Package is equivalent to a manual assembly of a data package by a person). As some of these situations were not considered within the scope of SOP 10 and SOP 46 at the time they were implemented, it was determined that a broader corrective action was not required and that each example below requires a different response and corrective action specific to the situation.

1. Specifically, “Validation Package”, an internally developed Oracle Database 10g application (SQL), critical to the dissemination of client GMP data, including in process, finished product and stability testing for regulated drug products, has not been qualified for its intended purpose according to an established protocol and acceptance criteria, including all appropriate operational and Quality Unit (QU) reviews and approvals.

RESPONSE: Activity records generated during sample testing, including but not limited to worksheets, notebooks, and instrument files, are reviewed by Quality Assurance data review staff. Activity records are signed, either with pen on paper or electronically, and a pdf representation is created from the approved activity records. All pdf files reside on Pace Analytical Life Sciences, LLC qualified network (see Quality Documents Q37 “Network Infrastructure Qualification Plan”, Q38 “Network Infrastructure Requirements Specification”, Q38 “Network Infrastructure Test Protocol”, Q42 “IT Network Diagram” and Q45 “Network Infrastructure Traceability Matrix”, all provided during the inspection). “Validation Package” is an internally developed tool that uses Pace’s LIMS system to identify which files are relevant to a client project, retrieves identified static pdf files stored on the qualified network, and assembles them into one consolidated pdf file. The consolidated file, existing of independently reviewed activity records, represents the data package deliverable for the client project and is saved as one pdf file. This file is delivered to the client via the “PacePort” web portal. Prior to use of “Validation Package”, the data package assembly process was performed by a human. Implementation of the automated data package assembly process, “Validation Package”, allowed for a more robust and accurate assembly process and much quicker delivery to the client allowing for ease in evaluating testing results. Storage of documents in pdf format on the Pace network is described by SOP 38 “Document and Record Retention and Disaster Recovery”.
Pace did not validate the manual data package assembly process and at the time the decision was made to implement the automated tool, the decision was also made to not validate the automated process.

CORRECTIVE ACTION: While Pace respectfully disagrees that "Validation Package" requires qualification based on the risk associated with the tool, Pace will write a validation protocol to confirm the assembly process performs as intended; see CAT 2129.
RESPONSIBLE INDIVIDUAL: Cynthia Hansen
TARGET DATE: 30 Sep 2018

2. Specifically, "PacePort" (Web-based portal) an internally developed Oracle Database 10g application (SQL), or tool, critical to the dissemination of client GMP data, including in-process, finished product and stability testing for regulated drug products, has not been qualified for its intended purpose according to an established protocol and acceptance criteria, including all operational and QU reviews and approvals.

RESPONSE: As presented during the inspection, the original intended purpose of "PacePort" was to allow quick and secure delivery of client project deliverables (e.g. Analysis Request Form, Analysis Report, Data Package) to clients. Implementation of "PacePort" replaced historical practices including but not limited to delivery via United States Postal Service, FedEx, UPS, fax and email none of which had been validated. The original intended purpose is described in URS 76 "User Requirements Specifications for PacePort" issued on 07 Apr 2010 and fully approved by Pace QU prior to use of "PacePort"

As presented during the inspection, Pace initially validated "PacePort" prior to implementation. Pace wrote and issued the following documents: URS 76 "User Requirement Specifications for PacePort", VMP 10 "Validation Master Plan for PacePort" and VP 149 "Validation of PacePort" as required by SOP 10 "Validation/Qualification Program for Laboratory Systems". A protocol and master plan was established, including acceptance criteria, and fully approved by Pace QU prior to execution. Execution of validation activities commenced in April 2010. A Validation Summary report was written and fully approved by Pace QU upon completion of execution and prior to release to production in May 2010. Validation execution demonstrated that identified user requirements were met. All documents and reports identified here were presented during the inspection.

As presented during the inspection, Pace determined a second purpose for "PacePort". As described in URS 123 "User Requirement Specifications for PLS Files in PacePort", "Pace has determined a need for replacing the current directory structure used to organize PLS client files with a document management system for use by Pace internal users on PacePort. Doing this will provide the ability for external customers to have access to their files." URS 123 was issued on 04 Feb 2013. Additionally, VMP 18 "Validation Master Plan for PLS Files in PacePort" and VP 257 "Validation of PLS Files in PacePort" were written and issued, including acceptance criteria, and full approval by Pace QU prior to execution of the validation as required by SOP 10 "Validation/Qualification Program for Laboratory Systems." Execution of validation activities commenced in March 2013. A Validation Summary report was written and fully approved by Pace QU upon completion of execution and prior to release to production in April 2013. Validation execution demonstrated that identified user requirements were met. All documents and reports identified here were presented during inspection.

All documents and records available via "PacePort" have been reviewed and approved,

including by Pace QU, as required by Pace Quality Systems, prior to being made available in PacePort. All files available through PacePort are pdf files fully traceable to all original documents and records. If any modifications or alterations are made to pdfs made available through PacePort, they would no longer be aligned with original documents and records used to generate such pdfs. Pace respectfully disagrees that "PacePort" has not been qualified for its intended purpose according to an established protocol and acceptance criteria, including all operational and QU reviews and approvals and at this time will take no further action. Upon relocation of PacePort to the Oakdale network, appropriate change control, risk assessment and validation protocols will be used as described by Pace Quality Systems.

3. Specifically, Custom Fields/Calculations (user defined calculations) constructed in the Empower 3 Chromatographic Data System (CDS) used to support that analysis of regulated drug products employ complex mathematical calculations/formulas using advance syntax and rules beyond the scope of the internal calculation wizard's base functionality, have not been qualified/validated for their intended use according to an established protocol and acceptance criteria, with all appropriate operational unit approvals and reviews, including the QU. Positive external confirmation of a subset of calculations is insufficient to ensure performance for such complex software applications, including identifying, understanding and controlling all relevant modes of failure, many of which may exist outside of the pure mathematical operations, and may not be reflected in abbreviated equivalency testing (external confirmation of calculation).

RESPONSE: Pace utilized functionality inherently available in Waters Empower 3 Chromatography Data Acquisition System (Empower) including advance syntax and rules that are in the scope of the software's base functionality. As discussed during the inspection, Pace only uses syntax and rules that are available through Empower. Pace has not developed any code or programming beyond what is inherently available in Empower. Due to limitations of Empower, in order to represent calculations appearing in client methods, complex formulae are often needed and employed. All custom calculation programming is available and audited for each Empower analysis completed. Current Quality System processes require that all custom calculations are 100% reviewed by Pace QU after laboratory staff perform the calculations and before any results are released to Pace clients.
During 2017 Management Review, a proposal was made to implement a review process at the front end of the process in order to minimize delays if errors are found during 100% review at the end of the process. CAT 2105 was initiated on 10 Jan 2018 and was offered for review during the inspection.
Pace will continue to maintain 100% review by Pace QU at the end of the process in addition to any new processes that are implemented.
CORRECTIVE ACTION: Pace will implement a validation process for Empower custom calculations. Upon implementation, any new calculations will be validated prior to use; see CAT 2130. All existing calculations will be validated over time; see CAT 2131.
RESPONSIBLE INDIVIDUAL: Greg Kupp (validation protocol issued)
TARGET DATE: 30 Sep 2018
RESPONSIBLE INDIVIDUAL: Angela Rollag (ongoing validation of existing calculations after validation and change control processes are implemented).
TARGET DATE: 31 Dec 2020

4. Specifically, your firm's HORIZON Laboratory Information Management System (EPIC Pro) application for the management, tracking, scheduling and notification (via report) of facilities and equipment qualification, calibrations and preventative maintenance events has not been qualified for its intended purpose (PLS Workflow) according to an established protocol and acceptance criteria with all appropriate operational unit reviews and approvals, including the QU.

RESPONSE: As discussed during the inspection, Pace historically utilized various tools (bound logbooks, SOP forms, Excel, Access, custom databases) dating back to 1996 to capture equipment related metadata (e.g. manufacturer, model, serial number, purchase date) and subsequent assignment of a unique tracking number (PLS number). Additionally, Pace has utilized the same tools to manage and track associated scheduled events (i.e. Calibration, Qualification, Preventive Maintenance). Over time, each iteration of the tools was more robust than the previous tools. Historically none of tools allowed for assignment of work or ability to track status of events (e.g. in progress, assigned, completed, reviewed). Lastly, none of the tools were validated.

As discussed during the inspection, in order to minimize risk of equipment being used when it shouldn't be, SOPs 10 "Validation/Qualification Program for Laboratory Systems", L20 "Equipment, Laboratory Systems and Facilities Maintenance and Repairs" and L17 "Calibration Program" all require that equipment be labeled with current qualification, preventive maintenance and calibration due dates. As described in SOP L23 "Equipment, Laboratory Systems and Facilities Use", It is the responsibility of the end user to evaluate the dates, record the dates in their activity records and ensure that the equipment is current. In the event a label is not updated, or an event is truly past due, the end user would detect this and is responsible for not using the equipment. In the unlikely event that the user does not recognize a lapsed due date, the Pace QU verifies the documented calibration/qualification/preventive maintenance due dates as a part of the activity record review process. The risk of using equipment that is not appropriate for use based on historical and current systems is minimal.

As discussed during the inspection, due to the fact that the Pace LIMS system allows for numbering items sequentially, tracking metadata and assignment of tasks, it was considered for use in managing the equipment program. Use of LIMS Client, Profile, Line Item and Acodes is aligned with numbering and tracking metadata. Use of LIMS Work Orders to assign work is aligned with assignment of tasks. Use of Clients, Profiles, Line Items and Acodes as well as Work Orders was validated as described in VP 96/97 Validation Summary Report for LIMS, approved by Pace QU in June 2010. LIMS was released to production in June 2010.

Pace decided to implement use of validated LIMS processes associated with Clients, Profiles, Line Items and Acodes in 2013. Creation of LIMS Clients (e.g. PLS numbers) and migration of metadata into Profiles and Line Items was initiated in 2013. Routine use of Work Orders was initiated in 2014. While the decisions to migrate from one tool to a different tool had not historically been documented, including the decision to migrate to use of LIMS, in 2015, change control record CRF 1422 was initiated to capture the decision to move to LIMS. The CRF acknowledged that the migration from historical tools to LIMS was still in progress, outlined

tasks necessary to complete the migration and assigned risk with a status of Low. During the entire migration process, the non-validated historical tool was used in parallel with use of LIMS as documented in CRF 1422. CRF 1422 was approved on 02 Oct 2015 for implementation and was closed on 17 Jan 2018. CRF 1422 included steps to confirm that the appropriate metadata was transferred to LIMS and that the scheduled events had also been appropriately migrated to LIMS. Qualification, calibration and preventive maintenance labeling processes and requirements have not changed with implementation of LIMS, and therefore all controls afforded by use of labels keep the risk of using a piece of equipment that is not appropriate extremely low. CRF 1422, demonstrating "an established protocol and acceptance criteria with all appropriate operational unit reviews and approvals, including the QU" and capturing risk associated with the change was presented during the inspection and retained by the inspector.

Use of any tools, whether validated or not, does not prevent an event from not being completed on time. There are many factors related to scheduling of tasks. With respect to meeting client expectations for turn-around time, it is important that appropriate equipment be available for use in testing. There is redundancy with most equipment at Pace and therefore risk of not having appropriate equipment available is extremely low and again, use of LIMS is not intended to mitigate all factors associated with on-time completion. Equipment that is not calibrated or qualified on time, or had preventive maintenance performed on-time is removed from service as described by SOP 23.

Risk associated with use of any past non-validated tools, as well as use of the current validated tool, to track equipment and scheduled events is minimal due to numerous checks and balances established and in use for twenty years.

CORRECTIVE ACTION: A validation protocol will be written to demonstrate that LIMS functions as intended with respect to the equipment program, see CAT 2132.
RESPONSIBLE INDIVIDUAL: Cynthia Hansen
TARGET DATE: 31 Mar 2019

5. Specifically, the Steris Reliance 500XLS Laboratory Glassware Washer (PLS # 4613) has not undergone an adequate performance qualification (PQ) according to cGMPs and regulatory requirements. The PQ (QP 208, Sep 2016) does not include procedures or testing results that demonstrate the successfully removal of residue(s) or analyte(s) specific to PLS regulated drug testing operations, including acceptance levels/criteria.

RESPONSE: As discussed during the inspection, Pace (formerly Part Three Corporation) performed glassware cleaning validation, starting in 1998, according to P3.VP1 "Laboratory Glassware Cleaning Initial Validation". Pace performed glassware cleaning validation annually for approximately five years, after which time the practice was discontinued. Due to continuing validation evidence that no APIs were present on glassware that had been cleaned, the risk associated with not continuing was low. At the time of these decisions, in approximately 2003, Risk Assessments were not yet in place and the decision was not captured. At the time a Quality System exception, including but not limited to deviations, investigations and modifications, is recorded, there is the opportunity to evaluate root cause. Additionally Quality System exceptions are trended annually, allowing additional opportunities to evaluate root

causes and trends. During annual Quality System Exception trending, glassware cleanliness has never been identified as a trend, supporting the decision to discontinue glassware cleaning validation fifteen years ago.

As discussed during the inspection, the glassware washers are qualified annually according to a Qualification Protocol, including acceptance criteria, that has been fully reviewed and approved by Pace's QU. The qualification protocol includes testing used to assess if detergent residue is being removed during the washing process. Additionally, glassware is visually examined upon removal from the glassware washers to ensure there is no visual reside as described in SOP C6 "Analytical Labware Cleaning". SOP L6 "General Laboratory Procedures" requires that any glassware removed from storage for use must be visually inspected for cleanliness before use. SOP L6 also specifies the process to use when glassware removed from storage is intended for use in impurities level analysis (rinse with solvent identified in method).

As discussed during the inspection, Pace has taken all of these factors into consideration and has not implemented glassware cleaning validation since it was discontinued in 2003.

CORRECTIVE ACTION: Evaluate options for performing glassware cleaning verification, see CAT 2133.
RESPONSIBLE INDIVIDUAL: Angela Strantz
TARGET DATE: 30 Sep 2018

OBSERVATION 3: Laboratory records do not include complete data derived from all tests, examination and assay necessary to assure compliance with established specifications and standards.

1. Specifically, your firm excluded failing testing results on the final Certificate of Analysis (CoA) when conducting individual impurities assessment for Mesalamine (USP 38/NF 33; Work Order 1754363; Samples 1754363003, 1754363004; LIR 1634) without a valid, documented, scientific justification for its exclusion. The QU reported only the passing results on the final CoA, thus disregarding the original failing results. The initial results were not invalidated by a valid laboratory investigation (LIR 1634). Further, re-test procedures stipulate the reporting of only passing results even if the investigation is inconclusive. Specific examples of these instructions/procedures include:

    - LIR 1634, Re-test Plan: "The original suspect results will be compared to the four individual retest results for each sample. For each sample, if the four retest results agree with each other, meet client specifications and disagree with the result from the original preparation, the four sample retest results will be reported."
    - LIR 1929, Re-test Plan: "The original suspect result will be compared to the four retest results. If the four retest results agree with each other and pass the client provided specification for SD3A Alcohol and disagree with the result from the original preparation, the sample retest will be reported."

RESPONSE: As discussed during the course of the inspection, all laboratory records (e.g. notebooks, worksheets) include all data, including suspect, confirmed and retest results associated with laboratory investigations. All laboratory records are provided to clients as part

of a data package along with the laboratory investigation at the time results are reported to a client. Every analysis report (CoA) includes all retest results along with a reference to all applicable laboratory investigations where all suspect results are indicated. Clients are presented with all results, suspect as well as confirmed and re-test results, in association with every laboratory investigation initiated. Clients are responsible for making decisions based on all results that are provided to them and ensuring that any laboratory investigation references are considered before making decisions related to testing results generated by Pace.

CORRECTIVE ACTION: SOP L8 will be updated to describe inclusion of all suspect results on analysis reports; see CAT 2134. Analysis reports will continue to include a reference to any laboratory investigations, however suspect results will be provided on analysis reports.

RESPONSIBLE INDIVIDUAL: Greg Kupp

TARGET DATE: 31 Jul 2018