Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2020658	11/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Corinthian Reference Lab	6201 Southwest Blvd, Benbrook, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The Laboratory Director and Testing Person were at the entrance conference conducted 11/05/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Laboratory Director and Testing Person on 11/05/2019. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of patient test requisitions, patient final reports, and confirmed in interview the laboratory failed to document the time specimens were received in the

	laboratory for 10 of 10 patients in 2018 (random sampling July) and 9 of 9 in 2019 (random sampling August) for processing and testing. Findings: 1. Review of patient records from 2018 and 2019 revealed the laboratory failed to document the time patient specimens were received into the laboratory for histopathology processing and testing. The following is a random sampling of patients from the test requisition and corresponding final report: Specimen #: S18.1501 Date of biopsy: 07/03/2018 Test requisition date received: 07/05/2018 Final report date received: 07/05/2018 Specimen #: S18.1502 Date of biopsy: 07/03/2018 Test requisition date received: 07 /05/2018 Final report date received: 07/05/2018 Specimen #: S18.1503 Date of biopsy: 07/03/2018 Test requisition date received: 07/05/2018 Final report date received: 07/05/2018 Specimen #: S18.1504 Date of biopsy: 07/03/2018 Test requisition date received: 07/05/2018 Final report date received: 07/05/2018 Specimen #: S18.1505 Date of biopsy: 07/03/2018 Test requisition date received: 07 /05/2018 Final report date received: 07/05/2018 Specimen #: S18.1506 Date of biopsy: 07/05/2018 Test requisition date received: 07/06/2018 Final report date received: 07/06/2018 Specimen #: S18.1507 Date of biopsy: 07/05/2018 Test requisition date received: 07/06/2018 Final report date received: 07/06/2018 Specimen #: S18.1508 Date of biopsy: 07/05/2018 Test requisition date received: 07 /06/2018 Final report date received: 07/06/2018 Specimen #: S18.1509 Date of biopsy: 07/05/2018 Test requisition date received: 07/06/2018 Final report date received: 07/06/2018 Specimen #: S18.1510 Date of biopsy: 07/05/2018 Test requisition date received: 07/06/2018 Final report date received: 07/06/2018 Specimen #: S19.1668 Date of biopsy: 07/31/2019 Test requisition date received: 08 /01/2019 Final report date received: 08/01/2019 Specimen #: S19.1669 Date of biopsy: 07/31/2019 Test requisition date received: 08/01/2019 Final report date received: 08/01/2019 Specimen #: S19.1670 Date of biopsy: 07/30/2019 Test requisition date received: 08/01/2019 Final report date received: 08/01/2019 Specimen #: S19.1671 Date of biopsy: 07/31/2019 Test requisition date received: 08 /01/2019 Final report date received: 08/01/2019 Specimen #: S19.1672 Date of biopsy: 08/01/2019 Test requisition date received: 08/02/2019 Final report date received: 08/02/2019 Specimen #: S19.1673 Date of biopsy: 08/01/2019 Test requisition date received: 08/02/2019 Final report date received: 08/02/2019 Specimen #: S19.1674 Date of biopsy: 08/01/2019 Test requisition date received: 08 /02/2019 Final report date received: 08/02/2019 Specimen #: S19.1675 Date of biopsy: 08/01/2019 Test requisition date received: 08/02/2019 Final report date received: 08/02/2019 Specimen #: S19.1676 Date of biopsy: 08/01/2019 Test requisition date received: 08/02/2019 Final report date received: 08/02/2019 2. The laboratory had an annual volume of 24,000 histopathology tests. 3. During an interview on 11/05/2019 at 12:24 pm, the laboratory director confirmed the laboratory failed to document the time patient specimens were received into the laboratory for histopathology processing and testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, temperature logs, and confirmed in interview, the laboratory failed to ensure the proper storage conditions were maintained for sodium hydroxide pellets and sodium phosphate, monobasic anhydrous reagents for 12 of 12 months in 2018 and 11 of 11 months in 2019. Findings: 1. During a tour of the laboratory on 11/05/2019 at 1:20 pm, the following were found to be stored in the storage room in the laboratory: 1 bottle of sodium hydroxide pellets, lot# 1103507, storage 15-30C 3 bottles of sodium phosphate, monobasic anhydrous, lot #s 1106304, 1820116, 1820115, storage 15-30C The laboratory did not have a thermometer in the storage room. The laboratory failed to define a temperature range to ensure temperatures did not exceed manufacturer's instructions for sodium hydroxide and sodium phosphate. 2. Review of room temperature logs for 2018 and 2019 revealed the laboratory did document the temperature for the storage closet. 3. During the exit interview on 11/05/2019 at 1:55 pm, testing person-2 and the laboratory director confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on direct observation and staff interview, the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates. Findings: 1. During a tour of the laboratory on 11/05/2019 at 1:20 pm, the surveyor observed the following: 1 bottle labeled "TBS, date 10/26/19" The laboratory failed to label the secondary container with the lot numbers, concentration, and expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 1 bottle labeled "Storage Solution" The laboratory failed to label the secondary container with the lot numbers, concentration, and poured /expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. In a cabinet 1 bottle of "4.0 Buffer Calibration Solution" and 1 bottle of "7.0 Buffer Calibration Solution" The laboratory failed to label the secondary container with lot numbers, concentration, and poured/expiration dates. Without proper labeling, the reagent could not be linked to an original container and therefore the expiration dates could not be determined. 2. During the exit interview on 11/05/2019 at 1:55 pm, testing person-2 and the laboratory director confirmed the laboratory failed to ensure reagents stored in secondary containers were labeled with proper identification, concentration, and poured/expiration dates. II. Based on direct observation, manufacturer's instructions, and confirmed in interview, the laboratory failed to label in-use histopathology reagents with expiration dates. Findings: 1. Review of Vector SG Peroxidase Substrate package insert revealed: "Notes ...Unused working solution is stable for up to 48 hours when stored at 2-8C." 2. During a tour of the laboratory on 11/05/2019 at 1:20 pm, the following in-use reagents were observed to be stored in the reagent refrigerator: 1 bottle of Peroxidase/AP Block, lot #J682-K (expiration date

	10/2021) The in-use peroxidase reagent was not labeled with its new expiration date according to manufacturer's instructions. 3. During the exit interview on 11/05/2019 at 1:55 pm, testing person-2 and the laboratory director confirmed the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, Quality Control (QC) logs and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 2 of 2 days in 2018 (random review 07/2018) and 2 of 2 days in 2019 (random review 08/2019). Findings: 1. Review of laboratory policy "Hematoxylin and Eosin Staining" revealed: "POLICY: Specimens that are processed for H&E staining will be completed fully, and of such quality to facilitate optimal evaluation of dermatological abnormalities ... RESULTS AND INTERPRETATION Each slide will be deemed appropriate for interpretation by the reviewing pathologist. If not appropriate for interpretation, repeat stains will be prepared at the pathologist's request. Pathologist will document deficiency or inadequacy in slide preparation on the H & E Assessment Log. The interpreting pathologist's documentation of the adequacy of the H&E stains will also be reflected on this log. This log will be completed by the interpreting pathologist per batch. These logs will be retained for a minimum of 2 years." The procedure failed to define the staining characteristics for intended reactivity for the H&E stain. 2. A random review in 2018 and 2019 of the "H&E Assessment Log" revealed the following: The log had a column for "Stain Quality," each day stain quality was documented as "S" in the column and initialed by the laboratory director. A key for stain documentation revealed: "S= Satisfactory-H&E stain adequate". The log did not specify if the "S" was indicated for H&E intended reactivity to ensure predictable staining characteristics. The following dates were observed to be documented with "S": 07/06 /2018 Random sampling of patient case numbers: S18.1501, S18.1502, S18.1503, S18. 1504, S18.1505 07/09/2018 Random sampling of patient case numbers: S18.1506, S18.1507, S18.1508, S18.1509, S18.1510 08/02/2019 Random sampling of patient case numbers: S19.1668, S19.1669, S19.1670, S19.1671 08/05/2019 Random sampling of patient case numbers: S19.1672, S19.1673, S19.1674, S19.1675, S19. 1676 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics for the above dates. 3. During an interview on 11/05/2019 at 10: 51 am, testing person-2 and the laboratory director confirmed the above findings. II. Based on review of laboratory policy, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document amyloid (Congo red) intended reactivity (positive or negative) to ensure predictable staining characteristics each day of use for 2 of 2 days in 2019 (random review August). Findings: 1. Review of laboratory policy Amyloid (Congo Red) Staining Protocol (Modified Highmans) revealed: "QUALITY CONTROL Purchased control from Histology Control Systems- CS001-25 that contains Amyloid or any control from an in house [sic] specimen that tested positive for amyloid. A known negative control will be processed

	in the same manner. The quality control slides are intended to be used to verify histological techniques and reagent activity. They are to be used for qualitative purpose of determining positive or negative results ... RESULT INTERPRETATION AND EVALUATION ... Reporting results: Results are reported by the pathologist after review of the control slides and the patient slide. Pathologist will document adequacy of control stains on the Amyloid Stain Control Log which is submitted with each batch of slides." 2. Review of Amyloid (Congo Red) Stain QA Log revealed the laboratory failed to document positive or negative reactivity on the following dates patients were tested in 2019: 08/02/2019 Random sampling of patient case numbers: S19.1668, S19.1669, S19.1670, S19.1671 08/05/2019 Random sampling of patient case numbers: S19.1672, S19.1673, S19.1674, S19.1675, S19.1676 Note: Amyloid stain and slide quality were also not documented. The laboratory failed to document amyloid (Congo red) intended reactivity (positive or negative) to ensure predictable staining characteristics. 3. During an interview on 11/05/2019 at 12:21 pm, testing person-2 and the laboratory director confirmed the above findings.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document CD3 fluorescent stain for positive or negative reactivity to ensure stain quality each day of use for 1 of 1 day in 2019 (random review August). Findings: 1. Review of laboratory policy CD3 Staining Protocol revealed: "QUALITY CONTROL Purchased control from Newcomer Supply that contains CD3 T-Cells or any control from an in house [sic] specimen that tested positive for inflammation. A known negative control will be processed in the same manner. The quality control slides are intended to be used to verify histological techniques and reagent reactivity. They are to be used for qualitative purpose of determining positive or negative results. Positive control slide will be Heat Induced Epitope Retrieved (HIER) using 40 mL of EDTA Buffer solution in a lightly capped coplin jar for 3 minutes at high pressure in a pressure cooker. Remove from pressure cooker and cool to room temperature ... RESULT INTERPRETATION AND EVALUATION ... Reporting results: Results are reported by the pathologist after review of the control slides and the patient slide. Pathologist will document adequacy of control stains on the CD3 Control Log which is submitted with each batch of slides." 2. Review of CD3 IHC Stain Assessment QA Log revealed the laboratory failed to document positive or negative reactivity on the following dates patients were tested in 2019: 08/02/2019 Random sampling of patient case numbers: S19.1668, S19.1669, S19.1670, S19.1671 The laboratory failed to document CD3 fluorescent stain for positive or negative reactivity to ensure stain quality. 3. During an interview on 11/05/2019 at 12:21 pm, testing person-2 and the laboratory director confirmed the above findings. II. Based on review of laboratory policy, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document PGP 9.5 fluorescent stain for positive or negative reactivity to ensure stain

	quality each day of use for 2 of 2 days in 2018 (random review July) and 2 of 2 days in 2019 (random review August). Findings: 1. Review of laboratory policy Immunocytochemistry, Day 1 and Day 2 (PGP 9.5) revealed: "QUALITY CONTROL POLICY A known positive patient control for nerve tissue is used along with a known negative control. The quality control slides are intended to be used to verify histological techniques and reagent activity. They are to be used for qualitative purpose of determining positive or negative results. Results are documented by the interpreting pathologist on the PGP Stain Control Log. QC is performed with each batch in the same manner as patient specimens, with the exception of the negative control specimens which are not exposed to the antibody solutions." 2. Review of PGP 9.5 (ENFD) Stain QA Log revealed the laboratory failed to document positive or negative reactivity on the following dates patients were tested in 2018 and 2019: 07/06 /2018 Random sampling of patient case numbers: S18.1501, S18.1502, S18.1503, S18. 1504, S18.1505 07/09/2018 Random sampling of patient case numbers: S18.1506, S18.1507, S18.1508, S18.1509, S18.1510 08/02/2019 Random sampling of patient case numbers: S19.1668, S19.1669, S19.1670, S19.1671 08/05/2019 Random sampling of patient case numbers: S19.1672, S19.1673, S19.1674, S19.1675, S19. 1676 The laboratory failed to document PGP 9.5 fluorescent stain for positive or negative reactivity to ensure stain quality. 3. During an interview on 11/05/2019 at 12: 21 pm, testing person-2 stated he could not find the PGP 9.5 QC logs for the above-mentioned dates, confirming the findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and interview, the laboratory director failed to specify, in writing, the responsibilities and duties for testing persons (TP-2, TP-4, TP-5, TP-6) performing high complexity testing. Findings: 1. Review of the CMS 209 form listed TP-3, TP-4, TP-5, TP-6 as testing persons performing high complexity testing, histopathology. 2. Review of TP-2, TP-4, TP-5, TP-6 personnel records revealed the laboratory director did not specify in writing the responsibilities and duties for the testing persons performing high complexity testing. 3. During an interview on 11/05/2019 at 10:00 am TP-2 and the laboratory director confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

	This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to perform the annual competency evaluations for 1 of 1 testing persons (TP-2) for the high complexity testing in the specialty of histopathology for 2018 and 2019. Findings: 1. Review of the CMS 209 form revealed TP-2 listed to perform high complexity testing. 2. Review of laboratory personnel records revealed TP-2 had annual competency performed on 02/12/2018 and 02/29/2019 [sic]. The annual competency was performed by a histology technician and not the TS. The TS failed to perform annual competency assessments for TP-2. 3. During an interview on 11/05 /2019 at 10:00 am, TP-2 and the TS confirmed the above findings.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or

cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of CMS 209 form, patient test requisitions, patient final test reports and confirmed in interview, the general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 10 of 10 patient specimens in 2018 (random review July) and 9 of 9 patient specimens in 2019 (random review August). 1. Review of the CMS 209 form listed the laboratory director as the clinical consultant, general supervisor (GS), technical supervisor (TS) and testing person. The form included 4 testing persons (TP-3, TP-4, TP-5, TP-6) who perform reading and interpretation of the slides and also included one additional testing person (TP-2), who performed the gross examinations of specimens received from outside clients. The laboratory director/general supervisor /technical supervisor was not onsite. TP-3, TP-4, TP-5, TP-6 were also not onsite. TP-2 did not qualify as general supervisor or technical supervisor, requiring review within 24 hours. Gross examination included all documented physical examination /descriptions including measurement of the specimen. 2. During an interview on 11/05 /2019 at 9:15 am, the laboratory director (TS/GS) stated that slides are mailed to him and he reads them at another facility where he is primarily located. During an interview on 11/05/2019 at 11:43 am, the laboratory director (TS/GS) stated that he reviews the grossing during his slide review. 3. Review of patient test requisitions revealed gross examinations were documented on the requisitions and included initials of TP-2. Review of patient test reports revealed gross examinations were documented and electronically signed by the TS/GS and/or TP-4. There was no documentation of the TS/GS review of the tissue and blocks within 24 hours of the gross examinations for TP-2. The following are a random sampling of patients in 2018 and 2019: Specimen #: S18.1501 Test requisition date received: 07/05/2018, test requisition included grossing examination, TP-2 initials and date (07/05/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1502 Test requisition date received: 07/05/2018, test requisition included grossing examination, TP-2 initials and date (07/05/2018) Final report was electronically signed by TP-4 on 07/13 /2018 Specimen #: S18.1503 Test requisition date received: 07/05/2018, test requisition included grossing examination, TP-2 initials and date (07/05/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1504 Test requisition date received: 07/05/2018, test requisition included grossing examination, TP-2 initials and date (07/05/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1505 Test requisition date received: 07/05/2018, test requisition included grossing examination, TP-2 initials and date (07/05/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1506 Test requisition date received: 07/06/2018, test requisition included grossing examination,

	TP-2 initials and date (07/06/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1507 Test requisition date received: 07/06/2018, test requisition included grossing examination, TP-2 initials and date (07/06/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1508 Test requisition date received: 07/06/2018, test requisition included grossing examination, TP-2 initials and date (07/06/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1509 Test requisition date received: 07/06/2018, test requisition included grossing examination, TP-2 initials and date (07/06/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S18.1510 Test requisition date received: 07/06/2018, test requisition included grossing examination, TP-2 initials and date (07/06/2018) Final report was electronically signed by TP-4 on 07/13/2018 Specimen #: S19.1668 Test requisition date received: 08/01/2019, test requisition included grossing examination, TP-2 initials and date (08/01/2019) Final report was electronically signed by TS/GS and TP-4 on 08/12/2019 Specimen #: S19. 1669 Test requisition date received: 08/01/2019, test requisition included grossing examination, TP-2 initials and date (08/01/2019) Final report was electronically signed by TS/GS and TP-4 on 08/12/2019 Specimen #: S19.1670 Test requisition date received: 08/01/2019, test requisition included grossing examination, TP-2 initials and date (08/01/2019) Final report was electronically signed by TS/GS and TP-4 on 08/12 /2019 Specimen #: S19.1671 Test requisition date received: 08/01/2019, test requisition included grossing examination, TP-2 initials and date (08/01/2019) Final report was electronically signed by TS/GS and TP-4 on 08/12/2019 Specimen #: S19. 1672 Test requisition date received: 08/02/2019, test requisition included grossing examination, TP-2 initials and date (08/02/2019) Final report was electronically signed by TS/GS and TP-4 on 08/14/2019 Specimen #: S19.1673 Test requisition date received: 08/02/2019, test requisition included grossing examination, TP-2 initials and date (08/02/2019) Final report was electronically signed by TS/GS and TP-4 on 08/14 /2019 Specimen #: S19.1674 Test requisition date received: 08/02/2019, test requisition included grossing examination, TP-2 initials and date (08/02/2019) Final report was electronically signed by TS/GS and TP-4 on 08/14/2019 Specimen #: S19. 1675 Test requisition date received: 08/02/2019, test requisition included grossing examination, TP-2 initials and date (08/02/2019) Final report was electronically signed by TS/GS and TP-4 on 08/14/2019 Specimen #: S19.1676 Test requisition date received: 08/02/2019, test requisition included grossing examination, TP-2 initials and date (08/02/2019) Final report was electronically signed by TS/GS and TP-4 on 08/14 /2019 The laboratory did not ensure tissue and blocks were reviewed and documented within 24 hours by the TS/GS, as required. 4. During an interview on11/05/2019 at 12: 10 pm, the laboratory director and TP-2 confirmed the above findings.