Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2105916	01/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Pro Health Diagnostic, Llc	2695 Villa Creek Dr Suite B109, Farmers Branch, 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	Based on the onsite survey conducted 01/09/2018 and review of additional documents provided by drop-off and electronic mail on 01/11/2018, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1219 Histopathology 493.1240 Preanalytic systems 493.1441 Laboratory Director High Complexity 493.1497 Testing Personnel The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. The Chief Operating Officer was informed at the exit conference on 01/09/2018 that the survey results were being sent to CMS Regional Office for evaluation and review, and that the CMS 2567 survey report would be sent by the CMS Regional Office.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, H&E (hematoxylin & eosin) stain worksheets, quality control logs, manufacturer's instructions, temperature charts, test requisitions, receipt logs, special stains quality control sheets, and histology daily quality control logs, the laboratory failed to meet the requirements for the specialty of histopathology, as evidenced by: 1. The laboratory failed to implement a written procedure for the GMS (Grocott's Methenamine Silver) special stain. Refer to D5403, I. 2. The laboratory failed to implement a written procedure that defined the intended reactivity of the H&E stain to ensure predictable characteristics. Refer to D5403, II. 3. The laboratory failed to implement written procedures for the specimen type accepted and processed. Refer to D5403, III. 4. The laboratory failed to define the room

	temperature range in accordance with manufacturer's storage requirements; and failed to ensure reagents were stored in accordance with manufacturer's storage requirements for days documented. Refer to D5413, I. 5. The laboratory failed to ensure reagents and solutions were stored in accordance with manufacturer's requirements. Refer to D5413, II. 6. The laboratory failed to have a mechanism in place to monitor the storage conditions of reagents stored in the refrigerator. Refer to D5413, III. 7. The laboratory failed to document room and refrigerator temperatures in which reagents were stored with condition requirements. Refer to D5413, IV. 8. The laboratory failed to document the storage room temperature in which patient samples were stored. Refer to D5413, V. 9. The laboratory failed to ensure the defined temperature range on precision oven charts reflected the range in their own written policy; and failed to ensure the precision oven temperatures were within the range in their policy. Refer to D5413, VI. 10. The laboratory failed to ensure reagents did not exceed their expiration date. Refer D5417. 11. The laboratory failed to perform and document maintenance for the Tissue Processor at the frequency defined in the logs. Refer to D5429, I. 12. The laboratory failed to perform and document microscope maintenance in 2017. Refer to D5429, II. 13. The laboratory failed to document H&E intended reactivity to ensure predictable staining characteristics each day of use. Refer to D5473. 14. The laboratory failed to document the reactions of control slides with PAS (Periodic Acid Schiff) and GMS (Grocott's Methenamine Silver) stains. Refer to D5601.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, patient requisitions, final test reports, and receipt log, the laboratory failed to meet the requirements for preanalytic systems, as evidenced by: 1. The laboratory failed to ensure patient test requisitions solicited the name and address of the authorized person requesting the test for patients. Refer to D5305. 2. The laboratory failed to establish written policies for storage, stability and preservation requirements for the specimen type (toenails) accepted and processed. Refer to D5311, I. 3. The laboratory failed to ensure specimen containers were labeled with the patient's name or a unique patient identifier to ensure integrity for specimens. Refer to D5311, II. 4. The laboratory failed to ensure clients followed instructions for filling out all patient and insurance information, as required by their policy for patients. Refer to D5311, III. 5. The laboratory failed to follow their own written policy for labeling patient slides with all components for patients. Refer to D5311, IV. 6. The laboratory failed to document the time 2,087 patient specimens were received into the laboratory for processing and testing. Refer to D5313. 7. The laboratory failed to ensure complete written instructions were available to clients sending specimens for testing. Refer to D5317.
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 direct observation, review of the laboratory's procedure manual, patient requisitions, and confirmed in interview, the laboratory failed to ensure patient test requisitions solicited the name and address of the authorized person requesting the test for 11 out of 20 patients in 2017 and 2018 (random sampling from 09/2017, 12/2017 and 01/2018). Findings included: 1. Review of the laboratory's procedure manual included a "Specimen Receiving" policy and stated, "4. Then each patient's biopsy bottle and requisitions are QA to assure that each label affixed matches the requisition and that the following information is correct: a. patient name, b. patient account number, c. patient sex, d. patient date of birth, e. patient biopsy site, f. patient accession number." The procedure did not include ensuring the test requisition solicited the name and address of the authorized person requesting the test. 2. During a tour of the facility on 01/09/2018 at 4:50 pm, the COO provided UPS (united parcel service) bags of specimens that were being held for testing. The requisitions of the following patient specimens observed did not include the name and address of the authorized person requesting the test (this was a random sampling): UPS bag #1 - Patient #2 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09 /20/2017. Patient #3 requisition collection date was 09/13/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #5 requisition collection date was 09/18/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. UPS bag #2 - Patient #6 requisition collection date was 12/21/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #7 requisition collection date was 12/20/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #8 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #10 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #12 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #13 requisition

	collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #14 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #17 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Received dates for the above mentioned specimens in UPS bag #2 were not documented in the receipt log. All requisitions for patients mentioned above (UPS bag #1 and #2) included a section "Ordering Physician" and were all blank. During an interview on 01 /09/2018 at 4:55 pm, the COO (chief operating officer) was asked how the laboratory knew the name of the authorized person ordering the above tests, she stated, "By the signature (physician) on the requisition." The laboratory did not ensure the requisitions solicited the name and address of the authorized person ordering the tests, as required. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver H&E - Haematoxylin & Eosin
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory's procedure manual, patient requisitions, final test reports, receipt log and confirmed in interview, the laboratory failed to establish written policies for storage, stability and preservation requirements for the specimen type (toenails) accepted and processed. Findings included: 1. Review of the laboratory's procedure manual included a "Specimen Receiving" policy and stated, "The biopsies are submitted in 10% formalin fixative specimen bottles." Review of the policy distributed to clients stated, "Place biopsy inside pre-filled 10% NBF bottles with patient's name, date, location, for specimen preservation." The laboratory received and processed toenails that were not submitted in formalin. The procedure was not applicable to the specimen type. The laboratory did not establish written policies of toenail storage, preservation, acceptability, rejection, and processing. During an interview on 01/09/2018 at 4:50 pm, the Chief Operating Officer (COO) confirmed the 10% formalin policy was not applicable to the toenails received. Procedures applicable to the toenails were not provided. 2. Review of patient requisitions, final test reports, and receipt log from 04/2017 and 06/2017 revealed the laboratory received, processed and reported patient specimens/results without established written policies of specimen handling: Requisition for Patient #PHD17-01712 collection date was 06/19/2017; receipt log for the patient included received date 06/27/2017; the final test report included collection date 06/19/2017, received date 12/20/2017 and report date was 12/29/2017 at 1:36 pm. Requisition for Patient #PHD17-01479 collection date was 04/12/2017; receipt log for the patient included received date 04/17/2017; final test report included collection date 04/12 /2017, received date 12/20/2017 and report date was 01/02/2018 at 10:12 pm. Requisition for Patient #PHD17-01366 collection date was 06/22/2017; receipt log for

the patient included received date 06/23/2017; final report included collection date 06 /22/2017, received date 12/202/107 and report date was 01/02/2018 at 9:39 pm. Requisition for Patient #PHD17-01474 collection date was 04/10/2017; receipt log for the patient included received date 04/17/2017; final report included collection date 04 /10/2017, received date 12/20/2017 and report date was 01/02/2018 at 10:08 pm. PAS, GMS and H&E stains were used for above patient specimens. During an interview on 01/09/2018 at 4:50 pm, the COO was asked about the specimens collected from 04 /2017 and 06/2017 and processing occurring in 12/2017, she stated, "The specimens were still being received even though we were not testing. We held on to the specimens until we were able to test. Doctors (clients) were notified that the toenails would be processed later due to no testing. They were held in their UPS bags and we document the received date in a spreadsheet. We had specimens from 04/2017 through 12/2017. Right now we are processing 08/2017 specimens." During an interview on 01/09/2018 at 4:50 pm, the COO was asked if there was documentation of notifying their clients of the delay in testing, she stated, "No, I went to them in person and let them know and they said that was ok." During an interview on 01/09 /2018 at 4:50 pm, the COO was asked if the laboratory had established written policies defining the storage, stability, handling and inclusion of pertinent clinical literature references of the toenails, she stated, "No." The laboratory did not have written established policies and procedures of the toenail preanalytical requirements to ensure integrity of the specimens from the time of collection to report date. 3. During a tour of the facility on 01/09/2018 at 4:50 pm, the COO provided UPS (united parcel service) bags of the following specimens that were being held for testing (this was a random sampling): UPS bag #1 - Patient #1 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #2 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #3 requisition collection date was 09/13/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #4 requisition collection date was 09/12/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #5 requisition collection date was 09/18/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. The specimen containers mentioned above were not labeled with a patient name or a unique patient identifier, as required. Patient requisitions mentioned above included "Precise Diagnostics" on the top part of the page and at the bottom "Precise Diagnostics 1510 Randolph St. #603, Carrollton, TX 75006, Phone: (214) 619-5632, Fax: (888) 548-2767." (Precise Diagnostics is the sister laboratory of Pro Health Diagnostics) UPS bag #2 - Patient #6 requisition collection date was 12/21/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #7 requisition collection date was 12/20/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #8 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #9 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained

4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #10 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #11 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #12 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #13 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #14 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #15 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #16 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #17 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #18 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #19 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #20 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The specimen containers mentioned above were not labeled with a patient name or a unique patient identifier, as required and received dates were not documented in the receipt log. Patient requisitions mentioned above included "Precise Diagnostics" on top part of page and at the bottom "Precise Diagnostics 1510 Randolph St. #603, Carrollton, TX 75006, Phone: (214) 619-5632, Fax: (888) 548-2767." (Precise Diagnostics is the sister laboratory of Pro Health Diagnostics) During an interview on 01/09/2018 at 4:55 pm, the COO was asked why there was a different laboratory name (Precise Diagnostics) on the patient requisitions, she stated, "Precise is not testing at this time, so the specimens are sent here and we are processing and testing the specimens." 4. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver H&E - Haematoxylin & Eosin II. Based on direct observation, review of the laboratory's policies, requisitions, and confirmed in interview, the laboratory failed to ensure specimen containers were labeled with the patient's name or a unique patient identifier to ensure integrity for 20 of 20 specimens collected in 09/2017, 12/2017 and 01/2018. Findings included: 1. Review of the laboratory's procedure manual included a "Specimen Receiving" policy and stated, "5. The person receiving the specimen verifies that the specimen is indeed inside the container and that the patient's name, date of birth and biopsy site is written clearly on the bottle. 6. The name on the bottle is compared to the name on the patient requisition. The requisition must be completely and accurately filled out." Review of the "Requirement for Specimen Collection to all offices" for clients stated, "Place patient biopsy inside pre-filled 10% NBF bottles with patient's name, date, location, for specimen preservation." 2. During a tour of the facility on 01/09/2018 at 4:50 pm,

the COO provided UPS (united parcel service) bags of the following specimens that were being held for testing and containers were not labeled with the patient's name or a unique patient identifier (this was a random sampling): UPS bag #1 - Patient #1 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #2 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09 /20/2017. Patient #3 requisition collection date was 09/13/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #4 requisition collection date was 09/12/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #5 requisition collection date was 09/18/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. UPS bag #2 - Patient #6 requisition collection date was 12/21/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #7 requisition collection date was 12/20/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #8 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #9 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #10 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #11 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #12 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #13 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #14 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #15 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #16 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #17 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #18 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #19 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #20 requisition collection date was 01/03/2018 and

order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The date and time of receipt into the laboratory for the specimens mentioned above was not documented. 3. During an interview on 01/09/2018 at 4:55 pm, the COO (chief operating officer) confirmed the above findings. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver H&E - Haematoxylin & Eosin III. Based on direct observation, review of the laboratory's procedure manual, patient requisitions, and confirmed in interview, the laboratory failed to ensure clients followed instructions for filling out all patient and insurance information, as required by their policy for 24 of 24 patients from 04/2017. 06/2017, 09/2017, 12/2017 and 01/2018. Findings included: 1. Review of the laboratory's procedure manual included a "Specimen Receiving" policy and stated, "4. Then each patient's biopsy bottle and requisitions are QA to assure that each label affixed matches the requisition and that the following information is correct: a. patient name, b. patient account number, c. patient sex, d. patient date of birth, e. patient biopsy site, f. patient accession number." Review of the "Requirement for Specimen Collection to all offices" for clients stated, "1. Fill out patient requisition form with all patient and insurance information." 2. Review of patient requisitions, final test reports, and receipt log from 04/2017 through 06/2017 revealed the laboratory received, processed and reported patient specimens/results without ensuring all patient and insurance information was filled out on requisitions: Requisition for Patient #PHD17-01712 collection date was 06/19/2017; receipt log for the patient included received date 06/27/2017; the final test report included collection date 06/19/2017, received date 12/20/2017 and report date was 12/29/2017 at 1:36 pm. The requisition included a "Patient Information" section and street address, city, state, zip were blank. "Billing Information" section that was blank. Requisition for Patient #PHD17-01479 collection date was 04/12/2017; receipt log for the patient included received date 04/17/2017; final test report included collection date 04/12 /2017, received date 12/20/2017 and report date was 01/02/2018 at 10:12 pm. The requisition included a "Patient Information" section and street address, city, state, zip were blank. "Billing Information" section that was blank. Requisition for Patient #PHD17-01366 collection date was 06/22/2017; receipt log for the patient included received date 06/23/2017; final report included collection date 06/22/2017, received date 12/202/107 and report date was 01/02/2018 at 9:39 pm. The requisition included a "Patient Information" section and street address, city, state, zip were blank. "Billing Information" section that was blank. Requisition for Patient #PHD17-01474 collection date was 04/10/2017; receipt log for the patient included received date 04/17/2017; final report included collection date 04/10/2017, received date 12/20/2017 and report date was 01/02/2018 at 10:08 pm. The requisition included a "Patient Information" section and street address, city, state, zip were blank. "Billing Information" section that was blank. During a tour of the facility on 01/09/2018 at 4:50 pm, the COO provided UPS (united parcel service) bags of the following specimens that were being held for testing (this was a random sampling): UPS bag #1 - Patient #1 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #2 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #3 requisition collection date

was 09/13/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #4 requisition collection date was 09/12/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #5 requisition collection date was 09/18/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. UPS bag #2 - Patient #6 requisition collection date was 12/21/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #7 requisition collection date was 12/20/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #8 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #9 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #10 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #11 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #12 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #13 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #14 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard

bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #15 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #16 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #17 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #18 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #19 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. Patient #20 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The requisition included a "Patient Information" section and social security, phone number, street address, city, state, zip were blank. "Billing Information" section that was blank. 3. During an interview on 01/09/2018 at 4:55 pm, the COO (chief operating officer) confirmed the above findings. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver H&E - Haematoxylin & Eosin IV. Based on direct observation, review of the laboratory's policy, and confirmed in interview, the laboratory failed to follow their own written policy for labeling patient slides with all components for 13 of 13 patients in 2017. Findings included: 1. Review of the laboratory's policy "Slide Preparation" stated, "Slides are labeled as follows: Patient's accession number across the very top of the white portion of the slide at the end of the accession number the site letter is to be written, directly underneath the patients last name is to be written and finally the name of the stain being done is to be written on the far right bottom corner of the white portion of the slide with a slide labeler or labeling marker." 2. During a tour of the laboratory on 01/09/2018 at 3:44 pm, the following labeled patient slides were observed: Last name was not included - PHD17-2330 A GMS PHD17-2330 B GMS PHD17-2330 C GMS PHD17-2330 D GMS PHD17-2328 D GMS PHD17-2329 A GMS PHD17-2329 B GMS PHD17-2331 A GMS PHD17-2331 B GMS PHD17-2324 A GMS PHD17-2324 B GMS PHD17-2325 A GMS PHD17-2325 B GMS PHD17-2325 C GMS PHD17-2325 D GMS PHD17-2327 A GMS PHD17-2327 B GMS PHD17-2328 A GMS PHD17-2328 C GMS PHD17-1675 B PAS PHD17-1653 A PAS Stain and last name was not included - PHD17-1650 A PHD17-1651 B PHD17-1652 B The laboratory did not follow their own written policy for labeling patient slides. 3. During an interview on 01/09/2018 at 4:50 pm, the Chief Operating Officer confirmed the above findings. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver

D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of patient specimen receipt log, final test reports, and confirmed in interview, the laboratory failed to document the time 2,087 patient specimens were received into the laboratory for processing and testing from 04/03/2017 through 12/20/2017. Findings included: 1. The laboratory provided the patient specimen receipt log via electronic mail on 01/10/2018 and final test reports via drop-off on 01/12/2018. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017 and had not documented the receipt time. The following is a random sampling of patients from the receipt log and their corresponding final test reports: Specimens collected 03/2017 - Receipt log for Patient #PHD17-01213 included a documented received date of 04/05/2017; the final patient test report received date was 12/18/2017. Receipt log for Patient #PHD17-01272 included a documented received date of 04/11/2017; the final patient test report received date was 12/18/2017. Receipt log for Patient #PHD17-01104 included a documented received date of 04/24/2017; the final patient test report received date was 12/18/2017. Receipt log for Patient #PHD17-01249 included a documented received date of 04/05/2017; the final patient test report received date was 12/18/2017. Receipt log for Patient #PHD17-01229 included a documented received date of 04/15/2017; the final patient test report received date was 12/18/2017. Specimens collected 04/2017 - Receipt log for Patient #PHD17-01511 included a documented received date of 05/25/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01483 included a documented received date of 04/17/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01596 included a documented received date of 05/25/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01505 included a documented received date of 04/17/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01639 included a documented received date of 04/20/2017; the final patient test report received date was 12/20/2017. Specimens collected 05/2017 - Receipt log for Patient #PHD17-01336 included a documented received date of 05/22/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01563 included a documented received date of 05/09/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01657 included a documented received date of 05/09/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01703 included a documented received date of 06/05/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01655 included a documented received date of 05/09/2017; the final patient test report received date was 12/20/2017. Specimens collected 06/2017 - Receipt log for Patient #PHD17-02047 included a documented received date of 06/27/2017; the final patient test report received date was 01/05/2018. Receipt log for Patient #PHD17-01875 included a documented received date of 07/03/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-01358 included a documented received date of 06/07/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01378 included a documented received date of 06/29/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-02058 included a documented received date of 06/27/2017; the final patient test report received date was 01/05

	/2018. Specimens collected 07/2017 - Receipt log for Patient #PHD17-01831 included a documented received date of 07/12/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-02286 included a documented received date of 08/03/2017; the final patient test report received date was 01/03 /2018. Receipt log for Patient #PHD17-02289 included a documented received date of 08/03/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-02294 included a documented received date of 08/03/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-01847 included a documented received date of 07/12/2017; the final patient test report received date was 01/03/2018. PAS, GMS and H&E stains were used for above patient specimens. The laboratory failed to ensure the actual received date was transcribed accurately to the final test reports. Refer to D5801. 3. During an interview on 01/09/2018 at 4:50 pm, the COO (chief operating officer) had confirmed the laboratory documented the received date for specimens in a spreadsheet. The laboratory did not document the time. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver H&E - Haematoxylin & Eosin
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's procedure manual, patient test requisitions, final test reports and confirmed in interview, the laboratory failed to ensure complete written instructions were available to clients sending specimens for testing. Findings included: 1. Review of the laboratory's procedure manual included a "Requirement for Specimen Collection to all offices" and did not include the following components: a) Specimen storage and preservation for toenails b) Conditions for specimen transportation c) Specimen processing d) Specimen acceptability and rejection e) Specimen referral 2. Review of the "Requirement for Specimen Collection to all offices"policy distributed to clients stated, "Place biopsy inside pre-filled 10% NBF bottles with patient's name, date, location, for specimen preservation." The laboratory received and processed toenails that were not submitted in formalin. The procedure was not applicable to the specimen type. The laboratory did not provide a client services manual that was applicable to the specimen type received. During an interview on 01/09/2018 at 4:50 pm, the Chief Operating Officer (COO) confirmed the 10% formalin policy was not applicable to the toenails received. Procedures applicable to the toenails were not provided. 3. Review of patient requisitions, final test reports, and receipt log from 04/2017 and 06/2017 revealed the laboratory received, processed and reported patient specimens/results: Requisition for Patient #PHD17-01712 collection date was 06/19/2017; receipt log for the patient included received date 06/27/2017; the final test report included collection date 06/19 /2017, received date 12/20/2017 and report date was 12/29/2017 at 1:36 pm. . Requisition for Patient #PHD17-01479 collection date was 04/12/2017; receipt log for the patient included received date 04/17/2017; final test report included collection date 04/12/2017, received date 12/20/2017 and report date was 01/02/2018 at 10:12 pm. Requisition for Patient #PHD17-01366 collection date was 06/22/2017; receipt log for the patient included received date 06/23/2017; final report included collection date 06/22/2017, received date 12/202/107 and report date was 01/02/2018 at 9:39

	pm. Requisition for Patient #PHD17-01474 collection date was 04/10/2017; receipt log for the patient included received date 04/17/2017; final report included collection date 04/10/2017, received date 12/20/2017 and report date was 01/02/2018 at 10:08 pm. PAS, GMS and H&E stains were used for above patient specimens. The laboratory did not provide their clients with a services manual that included specimen storage and preservation for toenails and specimen acceptability and rejection. During an interview on 01/09/2018 at 4:50 pm, the COO was asked about the specimens collected from 04/2017 and 06/2017 and processing occurring in 12/2017, she stated, "The specimens were still being received even though we were not testing. We held on to the specimens until we were able to test. Doctors (clients) were notified that the toenails would be processed later due to no testing. They were held in their UPS bags and we document the received date in a spreadsheet. We had specimens from 04/2017 through 12/2017. Right now we are processing 08/2017 specimens." The laboratory did not have written established policies and procedures of the toenail preanalytical requirements to ensure integrity of the specimens from the time of collection to report date. Refer to D5311, I. 4. During a tour of the facility on 01/09/2018 at 4:50 pm, the COO provided UPS (united parcel service) bags of the following specimens with requisitions that were being held for testing (this was a random sampling) (Refer to D5311, I, II): UPS bag #1 contained patient toenails in plastic containers in biohazard bags. There was a total of 5 patient specimens and the containers were not labeled with the patient's name or a unique patient identifier. The specimens were collected 09 /2017. UPS bag #2 contained patient toenails in plastic containers in biohazard bags. There was a total of 15 patient specimens and the containers were not labeled with the patient's name or a unique patient identifier. The specimen were collected 12/2017 and 01/2018. The laboratory did not provide their clients with a services manual that included specimen storage and preservation for toenails, specimen acceptability and rejection, conditions for specimen transportation, and specimen processing. 5. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13 /2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver H&E - Haematoxylin & Eosin
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, patient requisitions, final test reports, and receipt log, the laboratory failed to follow their own written policy for performing and documenting monthly quality assessment (QA) activities for an ongoing mechanism to monitor, assess, and correct problems identified in preanalytic system for 11/2017 and 12/2017. Findings included: 1. Review of the laboratory's "Pathology Monthly Quality Assurance Checklist" included: "Our Patient Test Management System was followed as written: _Specimens were logged in correctly. _Lab reports contain correct information. _Specimens were handled and collected according to protocol. _Specimens were labeled legible prior to receipt in the laboratory. _Tests referred to a reference laboratory were reported when expected. _Testing records identify the technician performing the gross. _Patient final report

	identifies location of all testing." The laboratory did not perform and document QA activities; the "Pathology Monthly Quality Assurance Checklist" forms for 11/2017 and 12/2017 were blank. The above checklist did not include all components to identify all problems in preanalytic systems, as identified on survey. 2. The laboratory's QA system did not include an ongoing mechanism to monitor, assess, and correct the following problems identified in the preanalytic systems: a) Based on direct observation, review of the laboratory's procedure manual, patient requisitions, and confirmed in interview, the laboratory failed to ensure patient test requisitions solicited the name and address of the authorized person requesting the test for patients. Refer to D5305. b) Based on direct observation, review of laboratory's procedure manual, patient requisitions, final test reports, receipt log and confirmed in interview, the laboratory failed to establish written policies for storage, stability and preservation requirements for the specimen type (toenails) accepted and processed. Refer to D5311, I. c) Based on direct observation, review of the laboratory's policies, requisitions, and confirmed in interview, the laboratory failed to ensure specimen containers were labeled with the patient's name or a unique patient identifier to ensure integrity for specimens. Refer to D5311, II. d) Based on direct observation, review of the laboratory's procedure manual, patient requisitions, and confirmed in interview, the laboratory failed to ensure clients followed instructions for filling out all patient and insurance information, as required by their policy for patients. Refer to D5311, III. e) Based on direct observation, review of the laboratory's policy, and confirmed in interview, the laboratory failed to follow their own written policy for labeling patient slides with all components for patients. Refer to D5311, IV. f) Based on review of patient specimen receipt log, final test reports, and confirmed in interview, the laboratory failed to document the time 2,087 patient specimens were received into the laboratory for processing and testing. Refer to D5313. g) Based on direct observation, review of the laboratory's procedure manual, patient test requisitions, final test reports and confirmed in interview, the laboratory failed to ensure complete written instructions were available to clients sending specimens for testing. Refer to D5317. 3. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. 4. During an interview on 01/09/2018 at 4:50, Chief Operating Officer confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
I. Based on review of the laboratory's procedure manual, quality control logs, and confirmed in interview, the laboratory failed to implement a written procedure for the GMS (Grocott's Methenamine Silver) special stain. Findings included: 1. Review of the laboratory's procedure manual did not include a procedure for the GMS special stain. The following components were not included for the stain: a) Step-by-step procedure, including interpretation of results b) Microscopic examination, including detection of inadequately prepared slides c) Preparation of slides, solutions, reagents and stains d) Control procedures e) Corrective actions to take for unacceptable stain quality and results f) Limitations g) Imminently life-threatening test results 2. Review of quality control logs from 12/2017 and 01/2018 revealed the laboratory used the GMS special stain and a control slide of known reactivity was not documented for each patient or group of patient slides (random sampling from 12/2017 and 01/2018): 12/28/2017 - Case #PHD17-1084-1104, PHD17-1105-1212, PHD17-1213-1227, "Adequate" was circled and next to "GMS" was documented "Stains okay." 01/02 /2018 - Case #PHD17-1209-1317, "Adequate" was circled and next to "GMS Control" was documented "Ok." 01/02/2018 - Case #PHD17-1587-1590, PHD17-1593-1596, PHD17-1598, PHD17-1600-1604, "GMS Control" was circled and "adequate" was documented in the space next to a blank space below "GMS Control." 01/02/2018 - Case #PHD17-1378-1480, "Adequate" and "GMS Control" were circled. 01/02/2018 - Case #PHD-1481-1486, "Adequate" and "GMS Control" were circled. 01/02/2018 - Case #PHD-1359-1377, "Adequate" and "GMS Control" were circled. 01/02/2018 - Case #PHD17-1318-1336, "Adequate" and "GMS Control" were circled and a line was drawn through the space next to "GMS Control." 01/02/2018 - Case #PHD17-1530-1538, PHD17-1540-1542, PHD17-15444-1549, "GMS Control" was circled and next to it was documented "adequate." 01/02/2018 - No case # was documented, "GMS Control" was circled and next to it was documented "Adequate." 01/02/2018 - Case #PHD17-1337-1358, "Adequate" and "GMS Control" were circled. The laboratory did not define the reactivity of the GMS special stain and did not document the reactivity of a control slide. 3. During an interview on 01/09/2018 at 11:30 am, Testing Person 2 and the Chief Operating Officer confirmed the above findings. II. Based on review of the laboratory's procedure manual, H&E (hematoxylin & eosin) stain worksheets, daily quality control logs, and confirmed in interview, the laboratory failed to implement a written procedure that defined the intended reactivity of the H&E stain to ensure predictable characteristics. Findings included: 1. Review of the laboratory's procedure manual included an "Hematoxylin and Eosin Staining (H&E)" that was a step-by-step procedure. The procedure did not define the intended reactivity of the stain. 2. Review of "Hematoxylin & Eosin Staining Quality Control Worksheet" logs included a column for the identification of the "Tech," the "Date," "Control Slide" and "Doctor Signature." At the bottom of the log included a check mark that was defined as "Good Quality." The logs were blank and did not include documentation of H&E intended reactivity. The laboratory did not define the intended reactivity to ensure predictable staining characteristics. A random sampling of days with patient from 12/2017 and 01/2018 revealed the laboratory did not define "Adequate" for documentation of H&E stain review and did not properly document the intended reactivity of H&E stain. Refer to D5473. 3. During an interview on 01/09 /2018 at 11:45 am, Testing Person 2 and the Chief Operating Officer confirmed the above findings. III. Based on direct observation, review of the laboratory's procedure manual, records and confirmed in interview, the laboratory failed to implement

	written procedures for the specimen type accepted and processed. Findings included: 1. During a tour of the laboratory on 01/09/2018 at 1:50 pm, the following was observed to be stored in a cabinet: Nair Hair Remover Lotion - Softening Baby Oil 9.0 oz (2 bottles) Suave Professional Honey Infusion Strengthening Condition 28 oz (2 bottles) During an interview on 01/09/2018 at 1:55 pm, Testing Person 2 (TP-2) was asked what was the purpose of the observed bottles (mentioned above), she stated, "They are used for the toe nails, it makes cutting easier. I mix the Nair and Suave together in a container and the toenails are placed in there. Then they are washed off and are ready to be cut." The laboratory did not have a written procedure for preparation and processing of the toenails. 2. Review of the laboratory's procedure manual included a "Specimen Receiving" and stated, "All biopsies are submitted to the laboratory for gross and microscopic examination by lab staff. The biopsies are submitted in 10% formalin fixative specimen bottles." "Requirements for Specimen Collection to all Offices" stated, "Place patient biopsy inside pre-filled 10% NBF bottles with patient's name, date, location, for specimen preservation." The above procedure did not apply to the toenail specimens received by the laboratory. The laboratory failed to implement written procedure for processing toenail specimens. 3. Review of the receipt log revealed the laboratory had received 2,087 specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13 /2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. 4. During an interview on 01/09/2018 at 1:55 pm, TP-2 was asked where the verbal procedure for processing toenails with conditioner was obtained, she stated, "We saw it on the Internet." The laboratory failed to implement written procedures for processing toenails and failed to include pertinent clinical literature references.
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: I. Based on direct observation, review of manufacturer's instructions, the laboratory's policy, temperature charts, and confirmed in interview, the laboratory failed to define the room temperature range in accordance with manufacturer's storage requirements; and failed to ensure reagents were stored in accordance with manufacturer's storage requirements for 21 of 24 days documented in 2017 (11/2017, 12/2017). Findings included: 1. Review of the laboratory's policy for "Reagent Quality Control" stated, "The reagent must be properly stored." 2. Review of temperature charts "Daily Quality Control - Room Temperature" from 11/17/2017 through 12/22/2017 revealed the defined temperature range was "60 - 78F" (15.5 - 25.5C). During a tour of the laboratory on 01/09/2018 at 1:45 pm, the following reagents/solutions were observed to be stored in a cabinet under the Thermo Scientific Microm EC 350-1 and included manufacturer's storage requirements: Borax Solution by STAT Lab, Lot #45646, expiration date 05/2019 and storage requirement was "18-25C." Borax Solution by STAT Lab, Lot #44500, expiration date 02/2019 and storage requirement was "18-

25C." Fast Green Solution by STAT Lab, Lot #41306, expiration date 06/2018 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #40535, expiration date 09/2018 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #42953, expiration date 04/2019 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #41046, expiration date 11/2018 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #42486, expiration date 03/2019 and storage requirement was "18-25C." The laboratory's defined temperature of "60 - 78F" (15.5 - 25.5C) was not in accordance with the above manufacturer's storage requirement of 18-25C. 3. Review of the temperature charts from "Daily Quality Control - Room Temperature" from 11/17/2017 through 12/22/2017 revealed the following days were not within reagents/solutions manufacturer's storage requirements of 18-25C (64.4 - 77F): 11/17/2017: 60F 11/20/2017: 60F 11/21/2017: 60F 11/22/2017: 60F 11/27/2017: 60F 11/28/2017: 60F 11/29/2017: 60F 11/30/2017: 60F 12/01/2017: 60F 12/04/2017: 60F 12/05/2017: 60F 12/06/2017: 60F 12/07/2017: 60F 12/08/2017: 62F 12/11/2017: 63F 12/14/2017: 64F 12/18/2017: 61F 12/19/2017: 63F 12/20/2017: 60F 12/21/2017: 60F 12/22/2017: 60F 4. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. 5. During an interview on 01/09/2018 at 3:00 pm, the Chief Operating Officer (COO) confirmed the above findings. II. Based on direct observation, review of laboratory's policy, temperature charts, manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure reagents and solutions were stored in accordance with manufacturer's requirements. Findings included: 1. Review of the laboratory's policy for "Reagent Quality Control" stated, "The reagent must be properly stored." 2. Review of temperature charts "Daily Quality Control - Room Temperature" from 11/17/2017 through 12/22/2017 revealed the defined temperature range was "60 - 78F" (15.5 - 25.5C). During a tour of the laboratory on 01/09/2018 at 1:45 pm, the following reagent was observed to be stored in a cabinet under the Thermo Scientific Microm EC 350-1 and included manufacturer's storage requirements: Silver Nitrate by STAT Lab, Lot #44869, expiration date 03/2019 and storage requirement was "2-8C." The laboratory did not ensure the above reagent was stored in proper conditions of 2-8C. 3. Review of temperature charts "Function Verification - Refrigerator" from 11/17/2017 through 12/22/2017 revealed the defined temperature range was "2 - 8 Celsius." During a tour of the laboratory on 01/09/2018 at 1:45 pm, the following solutions were observed to be stored in a "Magic Chef" refrigerator and included manufacturer's storage requirements: Chromic Acid Solution by STAT Lab (2 bottles), Lot #42342, expiration date 08/2018 and storage requirement was "18-25C." Chromic Acid Solution by STAT Lab (2 bottles), Lot #41977, expiration date 08/2018 and storage requirement was "18-25C." The laboratory did not ensure the above solutions were stored in proper conditions of 18-25C. (Note: It was observed the refrigerator did not include a thermometer to monitor the temperature, Refer to D5413, III.) 4. During an interview on 01/09/2018 at 1:55 pm, Testing Person 2 confirmed the above findings. III. Based on direct observation, review of the laboratory's policy, temperature charts, manufacturer's instructions, and confirmed in interview, the laboratory failed to have a mechanism in place to monitor the storage conditions of reagents stored in the refrigerator. Findings included; 1. Review of the laboratory's policy for "Reagent Quality Control" stated, "The reagent must be properly stored." 2. Review of temperature charts "Function Verification - Refrigerator" from 11/17/2017 through 12/22/2017 revealed the defined temperature range was "2 - 8 Celsius." For the 24 documented days, the temperature documented was 4C. During a tour on 01/09/2018 at 1:45 pm, a "Magic Chef" refrigerator was

observed to be stored in the corner of the laboratory. Inside of the refrigerator there was no thermometer to monitor the conditions in which reagents were stored. The inside of the refrigerator was not cold to the touch. The following reagents were observed to be stored in the refrigerator and included manufacturer's storage requirements: Schiff's Reagent by STAT Lab (brown bottle), Lot #40809, expiration 04/2018 and storage requirement was "2-8C." Schiff's Reagent by STAT Lab (colorless bottle), Lot #059432, expiration 10/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #41545, expiration date 06/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #42021, expiration date 08/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #40276, expiration date 03/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #40919, expiration date 04/2018 and storage requirement was "2-8C." Methanamine Solution by STAT Lab, Lot #45373, expiration date 04/2019 and storage requirement was "2-8C." The laboratory did not ensure the reagents above were stored according to manufacturer's instructions and did not have a mechanism in place to monitor storage conditions. 3. During an interview on 01/09/2018 at 1:55 pm, Testing Person 2 (TP-2) confirmed there was no thermometer in the refrigerator. During a telephone interview on 01/09/2018 at 4:30 pm, when TP-2 was asked how temperatures were documented 11/17/2017 through 12/22/2017 for the refrigerator if there was no thermometer, she stated, "There was one in there, but I must have thrown it away." The laboratory could not provide documentation of discarding the thermometer and corrective action. IV. Based on direct observation, review of temperature charts, manufacturer's instructions, and confirmed in interview, the laboratory failed to document room and refrigerator temperatures in which reagents were stored with condition requirements from 12/23/2017 through 01/09/2018. Findings included: 1. During a tour of the laboratory on 01/09/2018 at 1:45 pm, the following reagents were stored in a cabinet and a refrigerator that included manufacturer's storage requirements: In cabinet - Borax Solution by STAT Lab, Lot #45646, expiration date 05/2019 and storage requirement was "18-25C." Borax Solution by STAT Lab, Lot #44500, expiration date 02/2019 and storage requirement was "18-25C." Fast Green Solution by STAT Lab, Lot #41306, expiration date 06/2018 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #40535, expiration date 09/2018 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #42953, expiration date 04/2019 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #41046, expiration date 11/2018 and storage requirement was "18-25C." Sodium Metabisulfite Solution by STAT Lab, Lot #42486, expiration date 03/2019 and storage requirement was "18-25C." In refrigerator - Schiff's Reagent by STAT Lab (brown bottle), Lot #40809, expiration 04/2018 and storage requirement was "2-8C." Schiff's Reagent by STAT Lab (colorless bottle), Lot #059432, expiration 10/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #41545, expiration date 06/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #42021, expiration date 08/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #40276, expiration date 03/2018 and storage requirement was "2-8C." Gold Chloride Solution by STAT Lab, Lot #40919, expiration date 04/2018 and storage requirement was "2-8C." Methanamine Solution by STAT Lab, Lot #45373, expiration date 04/2019 and storage requirement was "2-8C." 2. Review of temperature charts "Daily Quality Control - Room Temperature" from 11/17/2017 through 12/22/2017 revealed the defined temperature range was "60 - 78F" (15.5 - 25.5C). (Note: The defined temperature was not in accordance with the manufacturer of reagents stored in the laboratory. Refer to D5413, I.) Review of temperature charts "Function Verification - Refrigerator" from 11/17/2017 through 12/22/2017 revealed the defined temperature

range was "2 - 8 Celsius." (Note: There was no thermometer observed in the refrigerator for monitoring the conditions of the stored reagents. Refer to D5413, III.) There were no temperatures documented from 12/22/2017 through 01/09/2018 for the laboratory and refrigerator in which reagents were stored with manufacturer's requirements. 3. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. 4. During an interview on 01/09/2018 at 4:50 pm, the Chief Operating Officer confirmed the above findings. V. Based on direct observation, review of test requisitions, temperature charts, receipt logs, and confirmed in interview, the laboratory failed to document the storage room temperature in which patient samples were stored. Findings included: 1. Review of temperature charts "Daily Quality Control - Storage Room Temperature" for 2017 revealed no temperatures were documented. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20 /2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17 /2017. Specimens continued to be received and held until testing began. 2. During a tour of the facility on 01/09/2018 at 4:50 pm, the COO provided UPS (united parcel service) bags of the following specimens that were being held for testing in the storage room across the hall from the laboratory (this was a random sampling): UPS bag #1 - Patient #1 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #2 requisition collection date was 09/12/17 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #3 requisition collection date was 09/13/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #4 requisition collection date was 09/12/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. Patient #5 requisition collection date was 09/18/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Receipt log for the patient included received date was 09/20/2017. UPS bag #2 - Patient #6 requisition collection date was 12/21/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #7 requisition collection date was 12/20/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #8 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #9 requisition collection date was 12/15/2017 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #10 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #11 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #12 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #13 requisition

	collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #14 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #15 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #16 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #17 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #18 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #19 requisition collection date was 01/02/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. Patient #20 requisition collection date was 01/03/2018 and order was for PAS and GMS stain. The biohazard bag contained 4 small plastic containers (no preservatives) that each had a piece of toenail. The laboratory did not document the temperature of the room in which the above specimens were stored awaiting processing. 3. During an interview on 01/09/2018 at 4: 50 pm, the Chief Operating Officer confirmed the above findings. VI. Based on direct observation, review of the laboratory's policy, temperature charts and confirmed in interview, the laboratory failed to ensure the defined temperature range on precision oven charts reflected the range in their own written policy; and failed to ensure the precision oven temperatures were within the range in their policy for 23 of 23 days in 2017 (11/2017 and 12/2017). Findings included: 1. Review of the the laboratory's policy "Precision Oven" stated, "The Precision Oven is used as a slide dryer. Temperatures are maintained daily to ensure a range of 56C to +/- 4C." 2. Review of "Oven QC Log" temperature charts from 11/17/2017 through 12/21/2017 included a defined temperature of "77 +/- 3 Celsius." The temperature range did not reflect the range in the written policy (56C +/-4C). Review of the temperatures documented for the precision oven revealed the following days were not within 56 +/- 4C: 11/17/17: 78C 11/20/17: 78C 11/21/17: 78C 11/22/17: 78C 11/27/17: 78C 11/28/17: 78C 11/29 /17: 78C 11/30/17: 78C 12/01/17: 78C 12/04/17: 78C 12/05/17: 78C 12/06/17: 78C 12 /07/17: 78C 12/08/17: 78C 12/11/17: 77C 12/12/17: 78C 12/13/17: 78C 12/14/17: 78C 12/15/17: 78C 12/18/17: 77C 12/19/17: 78C 12/20/17: 78C 12/21/17: 78C 3. During a tour of the laboratory on 01/09/2018 at 2:00 pm, a Boekel Scientific Model 107800 oven was observed to be stored in the laboratory. The thermometer of the oven read as 55 degrees Celsius. The laboratory failed to ensure the temperature range on the charts reflected the temperature range of the written policy. 4. During an interview on 01/09/2018 at 2:00 pm, the Chief Operating Officer confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on direct observation, review of laboratory's policy, and confirmed in interview, the laboratory failed to ensure reagents did not exceed their expiration date. Findings included: 1. Review of the laboratory's policy for "Reagent Quality Control" stated, "Reagents that have expired or are no longer suitable for use must be disposed of properly." 2. During a tour of the laboratory on 01/09/2018 at 1:45 pm, Leica Hemtoxylin Gill II, Lot #041818, expiration date 11/17/2016 was observed to be stored in the refrigerator. The laboratory did not ensure the reagent stored had not exceeded its expiration date. 3. During an interview on 01/09/2018 at 1:55 pm, Testing Person 2 stated, "That reagents is not longer in use." The laboratory did not dispose of the expired reagent as stated in their policy.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, maintenance logs, and confirmed in interview, the laboratory failed to perform and document maintenance for the Tissue Processor at the frequency defined in the logs in 11/2017 and 12/2017. Findings included: 1. Review of the laboratory's policy "Equipment Monitoring" stated, "Routine maintenance and checks of all equipment parameters, alert the technologist to any equipment failures or the potential for failure." 2. Review of Tissue Processor Maintenance Logs from 11/17/2017 and 12/22/2017 revealed the following maintenance was not performed and documented: 11/2017 - Weekly 3: Clean Drain; Paraffin Temp 1; Paraffin Temp 2; Paraffin Temp 3; Paraffin Temp 4 - no documentation of cleaning drain and temperatures of paraffin. Weekly 4: Clean Drain; Paraffin Temp 1; Paraffin Temp 2; Paraffin Temp 3; Paraffin Temp 4 - no documentation of cleaning drain and temperatures of paraffin. "Paraffin baths: 60 degrees Celsius +/- 4 degrees." - documentation of paraffin temperatures to ensure within defined range were not documented. Monthly included: Change Charcoal; Inspect Gaskets/Caps; Check - no documentation of monthly "Monthly Supervisor Review" - no documentation (Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017.) 12/2017 - Daily: Clean Retort; Clean Gasket; Change Fume H2O; (1) 10% Formalin; (2) 10% Formalin; (3) 70% Alcohol; (4) 80% Alcohol; (5) 95% Alcohol; (6) 95% Alcohol; (7) 100% Alcohol; (8) 100% Alcohol; (9) Xylene; (10) Xylene; (11) Paraffin; (12) Paraffin; (13) Paraffin; (14) Paraffin; Xylene Purge; Alcohol Purge - no documentation of daily from 12/23/2017 through 12/31/2017. Weekly 1: Clean Drain; Warm Water Flush; Paraffin Temp 1; Paraffin Temp 2; Paraffin Temp 3; Paraffin Temp 4 - no documentation of cleaning drain and temperatures of paraffin. Weekly 2: Clean Drain; Warm Water Flush; Paraffin Temp 1; Paraffin Temp 2; Paraffin Temp 3; Paraffin Temp 4 - no documentation of cleaning drain and temperatures of paraffin. Weekly 3: Clean Drain; Warm Water Flush; Paraffin Temp 1; Paraffin Temp 2; Paraffin Temp 3; Paraffin Temp 4 - no documentation of cleaning drain and temperatures of paraffin. Weekly 4: Clean Drain; Warm Water Flush; Paraffin Temp 1; Paraffin Temp 2; Paraffin Temp 3; Paraffin Temp 4 - no documentation of cleaning drain and temperatures of paraffin. "Paraffin baths: 60 degrees Celsius +/- 4 degrees." - documentation of paraffin temperatures to ensure within defined range were not documented. Monthly included: Change Charcoal; Inspect Gaskets/Caps; Check - no documentation of monthly "Monthly

	Supervisor Review" - no documentation 3. During an interview on 01/09/2018 at 11: 30 am, Testing Person 2 confirmed the above findings. II. Based on review of the laboratory's policy, maintenance logs, receipt logs, and confirmed in interview, the laboratory failed to perform and document microscope maintenance in 2017. Findings included: 1. Review of "Microscope Maintenance" policy stated, "Routine maintenance of the microscope is very important and should be a part of the routine quality assurance program." 2. Review of "Microscope Verification & Maintenance" monthly logs included: Daily Check: Alignment, Slide Visualization; Clean: Optical Surfaces, Exterior Surfaces, Lubricate Slides/Gears, Cover if not use, Initial. Maintenance was not performed and documented; the logs were blank. 3. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04 /03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. Testing included staining patient slides with Periodic Acid Schiff, Grocott's Methenamine Silver, and Haematoxylin & Eosin; and reviewing slides for acceptability of stain performance characteristics by microscopic examination. The laboratory did not perform and document microscope maintenance to ensure proper function. 4. During an interview on 01/09/2018 at 4:50 pm, the Chief Operating Officer 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: Based on review of the laboratory's procedure manual, H&E (hematoxylin & eosin) stain worksheets, daily quality control logs, and confirmed in interview, the laboratory failed to document H&E intended reactivity to ensure predictable staining characteristics each day of use in 12/2017 and 01/2018. Findings included: 1. Review of the laboratory's procedure manual included an "Hematoxylin and Eosin Staining (H&E)" that was a step-by-step procedure. The procedure did not define the intended reactivity of the stain. Refer to D5403. Review of "Monitoring of Quality Control Testing" stated, "Quality Control Testing is performed for all types of staining procedures. Prior to patient specimen testing, a slide is prepared (stained) and reviewed by the laboratory Director. This slide is labeled as 'QC' Quality Control and maintained with the patient's slide of the day. If the Laboratory Director find a problem with the stain, the stain solutions are corrected, and the QC slide is repeated." 2. Review of "Hematoxylin & Eosin Staining Quality Control Worksheet" logs included a column for the identification of the "Tech," the "Date," "Control Slide" and "Doctor Signature." At the bottom of the log included a check mark that was defined as "Good Quality." The logs were blank and did not include documentation of H&E intended reactivity. The laboratory did not define the intended reactivity to ensure predictable staining characteristics. There was no documentation of review by the laboratory director for control slides of H&E stain. 3. Review of daily quality control logs for each patient's case from 12/2017 and 01/2018 revealed H&E stain was used and not documented for intended reactivity for the following sampling of days: 12/19 /2017 - Case #PHD1230-1271, next to "Histology Technical Quality" stated

	"Adequate" and a line was drawn through the space next to "H&E" stain. 12/22/2017 - Case #PHD17-1487-1563, next to "Histology Technical Quality" stated "Adequate" and a line was drawn through the space next to "H&E" stain. 12/28/2017 - Case #PHD17-1737-1758, next to "Histology Technical Quality" stated "Adequate" and a line was drawn through the space next to "H&E" stain. 12/28/2017 - Case #PHD17-1773-1786, next to "Histology Technical Quality" and "H&E Stain" a line was drawn through the spaces. No date was documented - Case #PHD17-1606-1643, PHD17-1678-2062, next to "Histology Technical Quality" stated "Adequate" and a line was drawn through the space next to "H&E" stain. 01/03/2018 - Case #PHD17-1978-1983, PHD17-2281-2323, "H&E Stain" was circled and next to "Histology Technical Quality" was documented "Adequate." 01/03/2018 - Case #PHD17-1382-1400, PHD17-1787-1800, PHD17-1831-1836, "Adequate" was circled, a line was drawn through the space next to "H&E Stain" and was documented "Reviewed-Adequate." The laboratory did not define "Adequate" for documentation of H&E stain review. The laboratory did not properly document the intended reactivity of H&E stain. The above histology daily quality control logs provided by the laboratory did not include the laboratory director's documentation of review. 4. Review of the receipt log revealed the laboratory had received 2,087 specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. 5. During an interview on 01/09/2018 at 11:45 am, when Testing Person 2 was asked about lack of documentation on the "Hematoxylin & Eosin Staining Quality Control Worksheet" logs, she stated, "I did not know about those sheets." The COO (chief operating officer) reviewed the above findings and confirmed.
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: Based on review of the laboratory's procedure manual, review of special stains quality control sheets, histology daily quality control logs and confirmed in interview, the laboratory failed to document the reactions of control slides with PAS (Periodic Acid Schiff) and GMS (Grocott's Methenamine Silver) stains for 5 of 5 days in 12/2017 and 01/2018 (random sampling). Findings included: 1. Review of the laboratory's procedure manual included a "PAS (Periodic Acid Schiff) Staining Procedure" included "Results: Glycogen, mucin and some basement membranes ---------- red/purple; Fungi ---------- red/purple; Background ---------- green." The procedure did not include documentation of reactions of control slides for PAS stain. The procedure manual did not include a written GMS policy/procedure. Refer to D5403, I. Review of the "Special Stains Quality Control Sheet" included sections "Month:," "Year:," "Tech Initials," "Date," "Case #," "Special Stain," "QC check (check mark) + or -," "Doctor initials," and at the bottom "QC: Positive = (check mark) +; Negative = (check mark) -." The laboratory did not define "Positive" and "Negative" in their written procedures for PAS and GMS special stains. Review of "Monitoring of Quality Control Testing" stated, "Quality Control Testing is performed

for all types of staining procedures. Prior to patient specimen testing, a slide is prepared (stained) and reviewed by the laboratory Director. This slide is labeled as 'QC' Quality Control and maintained with the patient's slide of the day. If the Laboratory Director find a problem with the stain, the stain solutions are corrected, and the QC slide is repeated." 2. Review of the "Special Stains Quality Control Sheet" logs for PAS and GMS stains were blank. The laboratory had not documented the reactions of control slides for each patient slide or group of patient slides. There was no documentation of review by the laboratory director for control slides of special stains. 3. Review of quality control logs from 12/2017 and 01/2018 revealed the laboratory used the GMS special stain and a control slide of known reactivity was not documented for each patient or group of patient slides (random sampling from 12 /2017 and 01/2018): 12/28/2017 - Case #PHD17-1084-1104, PHD17-1105-1212, PHD17-1213-1227, "Adequate" was circled and next to "GMS" was documented "Stains okay." 01/02/2018 - Case #PHD17-1209-1317, "Adequate" was circled and next to "GMS Control" was documented "Ok." 01/02/2018 - Case #PHD17-1587-1590, PHD17-1593-1596, PHD17-1598, PHD17-1600-1604, "GMS Control" was circled and "adequate" was documented in the space next to a blank space below "GMS Control." 01/02/2018 - Case #PHD17-1378-1480, "Adequate" and "GMS Control" were circled. 01/02/2018 - Case #PHD-1481-1486, "Adequate" and "GMS Control" were circled. 01/02/2018 - Case #PHD-1359-1377, "Adequate" and "GMS Control" were circled. 01/02/2018 - Case #PHD17-1318-1336, "Adequate" and "GMS Control" were circled and a line was drawn through the space next to "GMS Control." 01/02/2018 - Case #PHD17-1530-1538, PHD17-1540-1542, PHD17-15444-1549, "GMS Control" was circled and next to it was documented "adequate." 01/02/2018 - No case # was documented, "GMS Control" was circled and next to it was documented "Adequate." 01/02/2018 - Case #PHD17-1337-1358, "Adequate" and "GMS Control" were circled. Review of quality control logs from 12/2017 and 01 /2018 revealed the laboratory used the PAS special stain and a control slide of known reactivity was not documented for each patient or group of patient slides (random sampling from 12/2017 and 01/2018): 12/19/2017 - Case #PHD17-1230-1271, "Adequate" was documented next to "Special Stain Control" with a line drawn through the space next to "PAS." 12/19/2017 - Case #PHD17-1084-1229, "Adequate" was circled, next to "PAS" was documented "Ok." 12/22/2017 - Case #PHD17-1487-1563, "Adequate" was documented next to "Special Stain Control" with a line drawn through the space next to "PAS." 12/28/2017 - Case #PHD17-1773-1786, under "Adequate/Inadequate" was a line drawn through the space next to "PAS." 12/28/2017 - Case #PHD17-1230-1255, PHD17-1550-1563, next to "Histology Technical Quality" was documented "Adequate." 12/28/2017 - Case #PHD17-1759-1772, "Adequate" was circled, next to "PAS" was documented "stains ok." 01/03/2018 - Case #PHD17-1837-1875, PHD17-1961-1977, "Adequate" was circled and next to "PAS Control" was documented "Ok." 01/03/2018 - Case #PHD17-1382-1400, PHD17 -1787-1800, PHD17-1831-1836, "Adequate" was circled and next to "PAS Control" was documented "Reviewed - Adequate." 01/03/2018 - Case #PHD17-1978-1983, PHD17-2281-2323, "Adequate" was documented next to "Histology Technical Quality," PAS Control" was circled. No date was documented - Case #PHD17-1606-1643, PHD17-1678-2062, "Adequate" was documented next to "PAS." "Ok" and "Adequate" were not defined in the laboratory's procedure for PAS and GMS special stains. The laboratory did not document the reactivity for controls slides of the special stains. The above histology daily quality control logs provided by the laboratory did not include the laboratory director's documentation of review. 4. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing

	began. 5. During an interview on 01/09/2018 at 11:45 am, when Testing Person 2 was asked about lack of documentation on the "Special Stains Quality Control Sheet" logs for PAS and GMS stains, she stated, "I did not know about those sheets." The COO (chief operating officer) reviewed the above findings and confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, H&E (hematoxylin & eosin) stain worksheets, quality control logs, manufacturer's instructions, temperature charts, test requisitions, receipt logs, special stains quality control sheets, and histology daily quality control logs, the laboratory failed to follow their own written policy for performing and documenting monthly quality assessment (QA) activities for an ongoing mechanism to monitor, assess, and correct problems identified in histopathology for 11/2017 and 12/2017. Findings included: 1. Review of the laboratory's "Pathology Monthly Quality Assurance Checklist" included: "Our Quality Control Policies were performed as specified: _All required temperatures were taken and recorded. _All reagents, controls, kits, etc. that exceeded their expiration date were discarded. _All instrument maintenance was performed and documented. _Any necessary remedial action was performed and documented. _All quality controls /calibrations were performed and were within acceptable limits before test results were reported. _Quality Control results were examined for possible problems. _All Quality control logs were reviewed for accuracy and completeness." The laboratory did not perform and document QA activities; the "Pathology Monthly Quality Assurance Checklist" forms for 11/2017 and 12/2017 were blank. The above checklist did not include all components to identify all problems in histopathology, as identified in the survey. 2. The laboratory's QA system did not include an ongoing mechanism to monitor, assess, and correct the following problems identified in the specialty of histopathology: a) Based on review of the laboratory's procedure manual, quality control logs, and confirmed in interview, the laboratory failed to implement a written procedure for the GMS (Grocott's Methenamine Silver) special stain. Refer to D5403, I. b) Based on review of the laboratory's procedure manual, H&E (hematoxylin & eosin) stain worksheets, daily quality control logs, and confirmed in interview, the laboratory failed to implement a written procedure that defined the intended reactivity of the H&E stain to ensure predictable characteristics. Refer to D5403, II. c) Based on direct observation, review of the laboratory's procedure manual, records and confirmed in interview, the laboratory failed to implement written procedures for the specimen type accepted and processed. Refer to D5403, III. d) Based on direct observation, review of manufacturer's instructions, the laboratory's policy, temperature charts, and confirmed in interview, the laboratory failed to define the room temperature range in accordance with manufacturer's storage requirements; and failed to ensure reagents were stored in accordance with manufacturer's storage requirements for days documented. Refer to D5413, I. e) Based on direct observation, review of laboratory's policy, temperature charts, manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure reagents and solutions were stored in accordance with manufacturer's requirements. Refer D5413, II. f) Based on

	direct observation, review of the laboratory's policy, temperature charts, manufacturer's instructions, and confirmed in interview, the laboratory failed to have a mechanism in place to monitor the storage conditions of reagents stored in the refrigerator. Refer to D5413, III. g) Based on direct observation, review of temperature charts, manufacturer's instructions, and confirmed in interview, the laboratory failed to document room and refrigerator temperatures in which reagents were stored with condition requirements from 12/23/2017 through 01/09/2018. Refer to D5413, IV. h) Based on direct observation, review of test requisitions, temperature charts, receipt logs, and confirmed in interview, the laboratory failed to document the storage room temperature in which patient samples were stored. Refer to D5413, V. i) Based on direct observation, review of the laboratory's policy, temperature charts and confirmed in interview, the laboratory failed to ensure the defined temperature range on precision oven charts reflected the range in their own written policy; and failed to ensure the precision oven temperatures were within the range in their policy. Refer to D5413, VI. j) Based on direct observation, review of laboratory's policy, and confirmed in interview, the laboratory failed to ensure reagents did not exceed their expiration date. Refer to D5417. k) Based on review of the laboratory's policy, maintenance logs, and confirmed in interview, the laboratory failed to perform and document maintenance for the Tissue Processor at the frequency defined in the logs in 11/2017 and 12/2017. Refer to D5429, I. l) Based on review of the laboratory's policy, maintenance logs, receipt logs, and confirmed in interview, the laboratory failed to perform and document microscope maintenance in 2017. Refer to D5429, II. m) Based on review of the laboratory's procedure manual, H&E (hematoxylin & eosin) stain worksheets, daily quality control logs, and confirmed in interview, the laboratory failed to document H&E intended reactivity to ensure predictable staining characteristics each day of use in 12/2017 and 01/2018. Refer to D5473. n) Based on review of the laboratory's procedure manual, review of special stains quality control sheets, histology daily quality control logs and confirmed in interview, the laboratory failed to document the reactions of control slides with PAS (Periodic Acid Schiff) and GMS (Grocott's Methenamine Silver) stains. Refer to D5601. 3. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. 4. During an interview on 01/09/2018 at 4:50, Chief Operating Officer confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient specimen receipt log, final test reports, and confirmed in interview, the laboratory failed to ensure the actual received date was transcribed accurately to the final test reports for 25 of 25 patients in 2017 (random sampling was

from 03/2017 through 07/2017). Findings included: 1. Review of specimen receipt log and final test reports from 03/2017 through 07/2017 revealed the laboratory did not ensure received dates were accurately transcribed to patient final test reports for the following patients (random sampling): Specimens collected 03/2017 - Receipt log for Patient #PHD17-01213 included a documented received date of 04/05/2017; the final patient test report received date was 12/18/2017. Receipt log for Patient #PHD17-01272 included a documented received date of 04/11/2017; the final patient test report received date was 12/18/2017. Receipt log for Patient #PHD17-01104 included a documented received date of 04/24/2017; the final patient test report received date was 12/18/2017. Receipt log for Patient #PHD17-01249 included a documented received date of 04/05/2017; the final patient test report received date was 12/18 /2017. Receipt log for Patient #PHD17-01229 included a documented received date of 04/15/2017; the final patient test report received date was 12/18/2017. Specimens collected 04/2017 - Receipt log for Patient #PHD17-01511 included a documented received date of 05/25/2017; the final patient test report received date was 12/20 /2017. Receipt log for Patient #PHD17-01483 included a documented received date of 04/17/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01596 included a documented received date of 05/25/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01505 included a documented received date of 04/17/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01639 included a documented received date of 04/20/2017; the final patient test report received date was 12/20/2017. Specimens collected 05/2017 - Receipt log for Patient #PHD17-01336 included a documented received date of 05/22/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01563 included a documented received date of 05/09/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01657 included a documented received date of 05/09/2017; the final patient test report received date was 12/20 /2017. Receipt log for Patient #PHD17-01703 included a documented received date of 06/05/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01655 included a documented received date of 05/09/2017; the final patient test report received date was 12/20/2017. Specimens collected 06/2017 - Receipt log for Patient #PHD17-02047 included a documented received date of 06/27 /2017; the final patient test report received date was 01/05/2018. Receipt log for Patient #PHD17-01875 included a documented received date of 07/03/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-01358 included a documented received date of 06/07/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-01378 included a documented received date of 06/29/2017; the final patient test report received date was 12/20/2017. Receipt log for Patient #PHD17-02058 included a documented received date of 06/27/2017; the final patient test report received date was 01/05 /2018. Specimens collected 07/2017 - Receipt log for Patient #PHD17-01831 included a documented received date of 07/12/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-02286 included a documented received date of 08/03/2017; the final patient test report received date was 01/03 /2018. Receipt log for Patient #PHD17-02289 included a documented received date of 08/03/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-02294 included a documented received date of 08/03/2017; the final patient test report received date was 01/03/2018. Receipt log for Patient #PHD17-01847 included a documented received date of 07/12/2017; the final patient test report received date was 01/03/2018. PAS, GMS and H&E stains were used for above patient specimens. During an interview on 01/09/2018 at 4:50 pm, the COO was asked about the specimens received and processing occurring at a later date, she

	stated, "The specimens were still being received, even though we were not testing. We held on to the specimens until we were able to test. Doctors (clients) were notified that the toenails would be processed later due to no testing. They were held in their UPS (united parcel service) bags and we document the received date in a spreadsheet. We had specimens from 04/2017 through 12/2017. Right now we are processing 08/2017 specimens." 2. Review of the receipt log revealed the laboratory had received 2,087 patient specimens from 04/03/2017 through 12/20/2017. Note: The laboratory had ceased testing on 02/13/2017 and began testing 11/17/2017. Specimens continued to be received and held until testing began. Word Key: PAS - Periodic Acid Schiff GMS - Grocott's Methenamine Silver H&E - Haematoxylin & Eosin
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, patient requisitions, final test reports, H&E (hematoxylin & eosin) stain worksheets, daily quality control logs, and special stains quality control sheets, manufacturer's instructions, temperature charts and receipt log, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure the testing systems developed provided quality laboratory services for the preanalytic and analytic phases of testing. Refer to D6082 2. The laboratory director failed to ensure quality control programs were established and maintained to assure quality of laboratory services. Refer to D6093. 3. The laboratory director failed to ensure that the quality assessment (QA) programs were established and maintained to assure the quality of laboratory services and to identify failures. Refer to D6094. 4. The laboratory director failed to ensure an approved procedure manual with all procedures was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, patient requisitions, final test reports, and receipt log, the laboratory director failed to ensure the testing systems developed provided quality laboratory services for the preanalytic and analytic phases of testing, as evidenced by: 1. The laboratory failed to ensure patient test requisitions solicited the name and address of the authorized person requesting the test for patients. Refer to D5305. 2. The laboratory failed to establish written policies for storage, stability and preservation requirements for the specimen type (toenails) accepted and processed. Refer to D5311, I. 3. The laboratory failed to ensure

	specimen containers were labeled with the patient's name or a unique patient identifier to ensure integrity for specimens. Refer to D5311, II. 4. The laboratory failed to ensure clients followed instructions for filling out all patient and insurance information, as required by their policy for patients. Refer to D5311, III. 5. The laboratory failed to follow their own written policy for labeling patient slides with all components for patients. Refer to D5311, IV. 6. The laboratory failed to document the time 2,087 patient specimens were received into the laboratory for processing and testing. Refer to D5313. 7. The laboratory failed to ensure complete written instructions were available to clients sending specimens for testing. Refer to D5317. 8. The laboratory failed to define the room temperature range in accordance with manufacturer's storage requirements; and failed to ensure reagents were stored in accordance with manufacturer's storage requirements for days documented. Refer to D5413, I. 9. The laboratory failed to ensure reagents and solutions were stored in accordance with manufacturer's requirements. Refer to D5413, II. 10. The laboratory failed to have a mechanism in place to monitor the storage conditions of reagents stored in the refrigerator. Refer to D5413, III. 11. The laboratory failed to document room and refrigerator temperatures in which reagents were stored with condition requirements. Refer to D5413, IV. 12. The laboratory failed to document the storage room temperature in which patient samples were stored. Refer to D5413, V. 13. The laboratory failed to ensure the defined temperature range on precision oven charts reflected the range in their own written policy; and failed to ensure the precision oven temperatures were within the range in their policy. Refer to D5413, VI. 14. The laboratory failed to ensure reagents did not exceed their expiration date. Refer D5417. 15. The laboratory failed to perform and document maintenance for the Tissue Processor at the frequency defined in the logs. Refer to D5429, I. 16. The laboratory failed to perform and document microscope maintenance in 2017. Refer to D5429, II.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, H&E (hematoxylin & eosin) stain worksheets, daily quality control logs, and special stains quality control sheets, the laboratory director failed to ensure quality control programs were established and maintained to assure quality of laboratory services, as evidenced by: 1. The laboratory failed to document H&E intended reactivity to ensure predictable staining characteristics each day of use in 12/2017 and 01/2018. Refer to D5473. 2. The laboratory failed to document the reactions of control slides with PAS (Periodic Acid Schiff) and GMS (Grocott's Methenamine Silver) stains for 5 of 5 days in 12/2017 and 01/2018 (random sampling). Refer to D5601.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, patient requisitions, final test reports, receipt log, H&E (hematoxylin & eosin) stain worksheets, quality control logs, manufacturer's instructions, temperature charts, special stains quality control sheets, and histology daily quality control logs, the laboratory director failed to ensure that the quality assessment (QA) programs were established and maintained to assure the quality of laboratory services and to identify failures, as evidenced by: 1. The laboratory failed to follow their own written policy for performing and documenting monthly QA activities for an ongoing mechanism to monitor, assess, and correct problems identified in preanalytic system for 11/2017 and 12/2017. Refer to D5391. 2. The laboratory failed to follow their own written policy for performing and documenting monthly QA activities for an ongoing mechanism to monitor, assess, and correct problems identified in histopathology for 11/2017 and 12/2017. Refer to D5791.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, quality control logs, H&E (hematoxylin & eosin) stain worksheets, daily quality control logs, the laboratory director failed to ensure an approved procedure manual with all procedures was available to all personnel responsible for any aspect of the testing process, as evidenced by: 1. The laboratory failed to implement a written procedure for the GMS (Grocott's Methenamine Silver) special stain. Refer to D5403, I. 2. The laboratory failed to implement a written procedure that defined the intended reactivity of the H&E stain to ensure predictable characteristics. Refer to D5403, II. 3. The laboratory failed to implement written procedures for the specimen type accepted and processed. Refer to D5403, III.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review CMS 209 form and personnel records, the laboratory failed to ensure all individuals employed met the qualification requirements for the complexity of testing performed. The laboratory failed to ensure 1 of 4 Testing Persons (TP-2) were qualified to perform grossing (high complexity testing). Refer to D6171. Word Key: CMS - Centers for Medicare & Medicaid Services
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

	This STANDARD is not met as evidenced by: Based on review CMS 209 form, personnel records, and confirmed in interview, the laboratory failed to ensure 1 of 4 Testing Persons (TP-2) were qualified to perform grossing (high complexity testing). Findings included: 1. Review of the CMS 209 form revealed TP-2 was listed as performing high complexity testing. TP-2 performed grossing of specimens received and processed. 2. Review of TP-2 personnel records revealed an American Society for Clinical Pathology board of certification for Histotechnician, awarded 06/01/1998. TP-2 did not have any other educational documents to qualify to perform high complexity. 3. During an interview on 01/09 /2018 at 11:00 am, the Chief Operating Officer confirmed the above findings. Word Key: CMS - Centers for Medicare & Medicaid Services