Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0889020	04/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
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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	An entrance conference was held with the laboratory representative. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 494.1230 General Laboratory Systems 493.1250 Analytic Systems 493.1441 Laboratory Director, (high complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and confirmed in interview, the laboratory failed to meet the requirements of general laboratory systems as evidenced by: 1. The

	laboratory failed to verify the accuracy of KOH (potassium hydroxide) (unregulated) testing at least twice annually for 1 of 2 years (2019). This is a repeat deficiency from the previous survey conducted on 01/03/2019. Refer to D5217.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, laboratory proficiency testing records for 2019-2020 and confirmed in interview, the laboratory failed to verify the accuracy of KOH (potassium hydroxide) (unregulated) testing at least twice annually for 1 of 2 years (2019). Findings Included: 1. Review of the laboratory's procedure manual did not include procedures for the KOH test and did not include a procedure for verifying twice annual accuracy. 2. Review of laboratory KOH proficiency testing records for 2019-2020 revealed the laboratory failed to perform twice annual accuracy assessment for KOH in 2019 The laboratory was unable to provide documentation of twice annual verification of accuracy for KOH testing in 2019. 3. Review of laboratory records revealed the laboratory's annual patient test volume was 68 KOH tests performed. 4. During an interview on 04/01/2021 at 11:09 AM, the surgical technician confirmed the laboratory failed to perform twice annual verification of KOH (potassium hydroxide) for 1 of 2 years (2019). This is a repeat deficiency from the previous survey conducted on 01/03/2019.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policy, laboratory records, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements, as evidenced by: 1. The laboratory failed to follow its own written policy for labeling Mohs slides for 6 of 6 sets of slides reviewed from 11/2019 through 12/2020 (random sampling). Refer to D5401, I. 2. The laboratory failed to follow their own written policy for the changing, filtering and rotating of Hematoxylin and Eosin stain on the Linistat Linear Stainer (Serial #LS1605A1301) in use for 13 of 15 days in January 2021, 9 of 15 days in February 2021 and 17 of 19 days in March 2021. Refer to D5401, II. 3. The laboratory procedure manual, KOH (potassium hydroxide) logs, and confirmed in staff interview, the laboratory failed to establish a procedure for performing KOH testing. Refer to D5403. 4. The laboratory failed to follow manufacturer's staining instructions for the NovoDiax ihcDirect Mart 1 Kit. Refer to D5411, I. 5. The laboratory failed to follow manufacturer's instructions for storage of prepared Novodiax ihc Wash Buffer reagent. Refer to D5411, II. 6. The laboratory failed to

	define acceptable room temperature and humidity ranges in accordance with Leica CM1510-S Cryostat manufacturer's specifications for 9 of 15 months in 2020(1/2020-12/2020) and 2021(1/2021-3/2021). Refer to D5413. 7. The laboratory failed to ensure prepared Novodiax ihc Wash Buffer reagent had documentation of preparation date and expiration date. Refer to D5415. 8. The laboratory failed to ensure reagents had not exceeded their expiration dates. Refer to D5417. 9. The laboratory failed to perform daily maintenance on Leica CM1510S (Serial # 22505200) Cryostat #1 and Leica CM1510S (Serial # 22489092001) Cryostat #2 for 156 of 156 days in 2020 (09 /2020-12/2020) and 86 of 86 days in 2021(01/2021- 03/2021). Refer to D5429. 10. The laboratory failed to have an effective QA (quality assessment) in place to identify and correct problems for the analytical phase of testing. Refer to D5793.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of laboratory's procedure manual, review of patient Mohs slides, and confirmed in interview, the laboratory failed to follow its own written policy for labeling Mohs slides for 6 of 6 sets of slides reviewed from 11/2019 through 12/2020 (random sampling). Findings Included: 1. Review of the laboratory's Mohs Surgery-Histopathology policy stated "3.4.8 ...Slides are labeled with number, full patient name and date." 2. A random review of Mohs slides from 11/2019-12/2020 revealed the following: a. Patient DOB 2/10/47- slides were labeled with only the patient last name and birthdate. The laboratory failed to label slides with full patient name. The laboratory failed to follow its own written policy for the proper labeling of Mohs slides. Corrective action was not documented. b. Patient DOB 10/18/29- slides were labeled with only the patient last name and birthdate. The laboratory failed to label slides with full patient name. The laboratory failed to follow its own written policy for the proper labeling of Mohs slides. Corrective action was not documented. c. Patient DOB 6/19/33- slides were labeled with only the patient last name and birthdate. The laboratory failed to label slides with full patient name. The laboratory failed to follow its own written policy for the proper labeling of Mohs slides. Corrective action was not documented. d. Patient DOB 1/23/42 - slides were labeled with only the patient last name and birthdate. The laboratory failed to label slides with full patient name. The laboratory failed to follow its own written policy for the proper labeling of Mohs slides. Corrective action was not documented. e. Patient DOB 9/30/47 - slides were labeled with only the patient last name and birthdate. The laboratory failed to label slides with full patient name. The laboratory failed to follow its own written policy for the proper labeling of Mohs slides. Corrective action was not documented. f. Patient DOB 3/28/48 - slides were labeled with only the patient last name and birthdate. The slides were not labeled with full patient name. The laboratory failed to follow its own written policy for the proper labeling of Mohs slides. Corrective action was not documented. 3. During the exit interview on 04/01/2021 at 1:45 PM, the surgical technician confirmed the above findings. This is a repeat deficiency from the previous survey conducted on 01/03/02019. Word Key DOB-Date of Birth II. Based on review of automated stainer maintenance logs, and confirmed in staff interview, the laboratory failed to follow their own written policy for the changing, filtering and

	rotating of Hematoxylin and Eosin stain on the Linistat Linear Stainer (Serial #LS1605A1301) in use for 13 of 15 days in January 2021, 9 of 15 days in February 2021 and 17 of 19 days in March 2021. Findings Included: 1. Review of "Automatic Stainer Maintenance"(Updated 03/07/2013 CM) log stated the following: "Filter Hematoxylin and Eosin Weekly Change entire stain line at the beginning of each week Change and/or rotate all other solutions as needed C = Changed F = Filtered R = Rotated" The laboratory failed to provide meaning of "T" on the maintenance form. 3. Review of the laboratory maintenance logs revealed: a. The following days in January 2021 did not have documentation of changing, filtering and rotating of stain being performed on the stainer, but instead listed "T" as performed: Bluing: 4,5,7,8,11,12,14,15,18,19,22 100% Alcohol-4,5,6,7,8,12,13,14,15,19,20,22,26 Eosin-4,5,6,7,8,12,13,14,15,19,20,22,26 Citra Clear- 4,5,6,7,8,12,13,14,15,19,20,22,26 b. The following days in February 2021 did not have documentation of changing, filtering and rotating of stain being performed on the stainer, but instead listed "T" as performed: Bluing: 1,2,4,5,8,9,19,22,23,25 100% Alcohol- 2,3,4,5,9,10, 22,23,25 Eosin-2,3,4,5,9,10, 22,23,25 Citra Clear-2,3,4,5,9,10, 22,23,25 c. The following days in March 2021 did not have documentation of changing, filtering and rotating of stain being performed on the stainer, but instead listed "T" as performed: Bluing-1,2,4,5,8,9,11,12,13,14, 16,18,19, 22, 23,30, 31. 100% Alcohol- 2,3,4,5,9,10,11,12,14, 16, 17, 18,19,22, 23,19, 31. Eosin- 2,3,4,5,9,10,11,12,14, 16, 17, 18,19,22, 23,19, 31. Citra Clear- 2,3,4,5,9,10,11,12,14, 16, 17, 18,19,22, 23,19, 31. The laboratory failed to follow its own procedure for maintenance on the Linistat Linear Stainer for 13 of 15 days in January 2021, 9 of 15 days in February 2021 and 17 of 19 days in March 2021. 2. During an interview on 04/01/2021 at 11:14 AM the surgical technician stated the Hematoxylin and Eosin stain was not filtered daily, the "T" was for stain "topped off" and verified there was no indication for "T" on the maintenance form. This confirmed the above findings. This is a repeat deficiency from the previous survey conducted on 01/03/02019.
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: Based on review of the laboratory procedure manual, KOH (potassium hydroxide)

	logs, and confirmed in staff interview, the laboratory failed to establish a procedure for performing KOH testing. Findings Included: 1. Review of the laboratory's procedure manual did not include a written policy for KOH (potassium hydroxide) testing with the following components: a) The microscopic examination of KOH test, including interpretation of results. b) Requirements for patient preparation, specimen collection, labeling and handling. c) Preparation of slides and solutions used in testing. d) The laboratory's system for entering results in the patient record and reporting patient results. 2. According laboratory records, the laboratory's annual patient test volume was 68 KOH tests performed. 3. During an interview on 04/01 /2021 at 11:09 AM, the surgical technician confirmed there was no procedure for performing KOH (potassium hydroxide) testing. This is a repeat deficiency from the previous survey conducted on 01/03/02019.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory policy, and confirmed in staff interview, the laboratory failed to follow manufacturer's staining instructions for the NovoDiax ihcDirect Mart 1 Kit. Findings Included: 1. Review of manufacturer's instructions for the NovoDiax ihcDirect Mart 1 Kit (Revised March 2019) revealed the following steps in the frozen tissue staining procedure: " Fixation, use acetone or ihc fixative Incubation Time- 30 seconds- 1 minute ihc Wash Incubation Time - 15 Seconds ..Mart 1 phrp Incubation Time - 3 minutes ihc Wash Incubation Time - 15 Seconds DAB working solution Incubation Time - 1-3 Minutes ihc Wash Incubation Time - 15 Seconds" 2. Review of the laboratories IHC Frozen Tissue staining procedure (Modified CM:3/25/2019) stated the following steps: "Fixation ...fix for 1 minute in reagent grade acetone 1st wash (wash buffer)- use spray bottle to wash tissue on the slides. (Manufacturer's instructions defined a wash time of 15 seconds. The laboratory failed to define a wash time) ..Apply antibody(covering entire tissue) and incubate for 3 minutes 2nd wash (wash buffer)- use spray bottle to wash tissue on the slides. (Manufacturer's instructions defined a wash time of 15 seconds. The laboratory failed to define a wash time) ..Apply DAB working solution (covering entire tissue) and incubate for 3 minutes. 3rd wash (DI or distilled water)-use spray bottle to wash tissue on the slides." (Manufacturer's instructions defined a wash time of 15 seconds. The laboratory failed to define a wash time) The laboratory failed to follow manufacturer's instructions for the NovoDiax ihcDirect Mart 1 frozen tissue staining procedure. 3. In the exit interview on 4/01/2021 at 1:48 PM, after presentation of findings, the surgical technician confirmed the laboratory failed to follow manufacturer's staining instructions for the NovoDiax ihcDirect Mart 1 Kit. This confirmed the above findings. II. Based on review of manufacturer's instructions, direct observation, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for storage of prepared Novodiax ihc Wash Buffer reagent. Findings Included: 1. Review of manufacturer's instructions for the Novodiax ihc Wash Buffer (Revised March 2019) revealed the following: "Storage: Upon reconstitution, store solution 2-8C to inhibit growth of microbes." 2. During a tour of the lab on 4/01/2021 at 12:40 PM the surveyor observed a wash bottle in the overhead

	cabinet stored at room temperature and labeled as "Wash Buffer". The surveyor asked the surgical technician about the contents of the bottle, and the surgical technician stated it was the prepared Novodiax "kit wash buffer". The laboratory failed to follow manufacturer's instructions for the 2-8C storage temperature specifications of the prepared Novodiax ihc Wash Buffer reagent. 3.During the exit interview on 04/01/21 at 1:30 PM, the surgical technician confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory environmental logs (08 /2020-03/2021), and staff interview, the laboratory failed to define acceptable room temperature and humidity ranges in accordance with Leica CM1510-S Cryostat manufacturer's specifications for 8 of 15 months in 2020 and 2021. Findings included: 1. Review of Leica CM1510-S instructions (Version V 1.4 04/2010) stated the following: "3.2 Technical Data Operating temperature range from +18C to +35C. All specifications related to temperature are based on an ambient temperature of +22C and a maximum air humidity of 60%" 2. Review of the laboratory's environmental logs for Cryostat #1 and #2 (Updated 03/07/2013 CM) from 8/2020 through 3/2021 revealed the following months the laboratory failed to include a defined room temperature and humidity range to ensure temperatures and humidity were within manufacturer's operating conditions: 08/2020; 09/2020; 10/2020; 11/2020; 12/2020; 01 /2021; 02/2021; 03/2021 3. In an interview on 4/01/2021 at 10:59 AM, the surgical technician verified acceptable temperature and humidity ranges were not defined on the environmental logs. This confirmed the above findings. This is a repeat deficiency from the previous survey conducted on 01/03/02019.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in staff interview, the laboratory failed to ensure prepared Novodiax ihc Wash Buffer reagent had documentation of reagent lot number, preparation date and expiration date. Findings Included: 1. During a tour of the lab on 4/01/2021 at 12:40 PM the surveyor observed a wash bottle in the overhead cabinet labeled as "Wash Buffer". The surveyor asked the surgical technician about

	the contents of the bottle, and the surgical technician replied it was the prepared Novodiax ihc "kit wash buffer". Upon inspection of the bottle, it was revealed the laboratory failed to document the reagent lot number, preparation date and expiration date of the prepared Novodiax ihc Wash Buffer reagent. 2. During the exit interview on 04/01/21 at 1:30 PM, the surgical technician 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 and confirmed in staff interview, the laboratory failed to ensure reagents had not exceeded their expiration dates. Findings Included: 1. During a tour of the laboratory on 04/01/2020 at 12:48 PM, it was revealed the following reagents had exceeded their expiration date: a. Located on top of the flammable cabinet: Blue Tissue Marking Dye, Lot #072646, expiration date 11/2020 Orange Tissue Marking Dye Lot #054039, expiration date 5/2019 b. Located in the flammable reagents cabinet: Hydrochloric Acid, Lot #8331, expiration date 11/2020 c. The following reagent was handed directly to the inspector on 04/01/2021 at 11:07 AM by the surgical technician in the conference room: KOH (potassium hydroxide), Lot #K183J2, expiration date 3/31/21 2. During the exit interview on 04/01/2021 at 1:30 PM, the surgical technician confirmed the above findings. This is a repeat deficiency from the previous survey conducted on 01/03/02019.
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: Based on manufacturer's instructions, maintenance logs, and confirmed in staff interview, the laboratory failed to perform daily maintenance on Leica CM1510S (Serial # 22505200) Cryostat #1 and Leica CM1510S (Serial # 22489092001) Cryostat #2 for 156 of 156 days in 2020 (09/2020-12/2020) and 86 of 86 days in 2021 (01/2021- 03/2021). Findings included: 1. Review of manufacturer's instructions for the Leica CM1510S-Cryostat (Version V 1.4 04/2010) stated the following: "8.1 General maintenance instructions ... Clean the instrument every day." 2. Review of laboratory Leica CM1510S-Cryostat #1 and Leica CM1510S-Cryostat #2 maintenance logs revealed the following: The laboratory failed to document daily cleaning of cryostat #1 on the following days in September 2020: 1, 2, 3,4,7, 8, 9, 10,11, 14,15,16, 17,18,21, 22, 23,24,25,29,30. The laboratory failed to document daily cleaning of cryostat #2 on the following days in September 2020: 1, 2, 3,4,7, 8, 9, 10,11, 14,15,16, 17,18,21, 22, 23,24,25,29,30. The laboratory failed to document daily cleaning of cryostat #1 on the following days in October 2020: 1, 2, 5, 6, 7, 8, 9, 12,13, 14,15,16, 19,20,21, 22, 23,26,27,28 ,29,30. The laboratory failed to document daily cleaning of cryostat #2 on the following days in October 2020: 1, 2, 5, 6, 7, 8, 9,

	12,13, 14,15,16, 19,20,21, 22, 23,26,27,28 ,29,30. The laboratory failed to document daily cleaning of cryostat #1 on the following days in November 2020: 2, 3,4,5,6, 9, 10,11,12,13, 16, 17,18,19,20, 23,24,25,26,27,30. The laboratory failed to document daily cleaning of cryostat #2 on the following days in November 2020: 2, 3,4,5,6, 9, 10,11,12,13, 16, 17,18,19,20, 23,24,25,26,27,30. The laboratory failed to document daily cleaning of cryostat #1 on the following days in December 2020:1, 2,3,4,7,8, 9, 10,11,14,15 16, 17, 18 The laboratory failed to document daily cleaning of cryostat #2 on the following days in December 2020:1, 2,3,4,7,8, 9, 10,11,14,15 16, 17, 18 The laboratory failed to document daily cleaning of cryostat #1 on the following days in January 2021:4,5,6,7,8, 11,12,13,14,15 18,19,20,22,26 The laboratory failed to document daily cleaning of cryostat #2 on the following days in January 2021: 4,5,6,7,8, 11,12,13,14,15 18,19,20,22,26 The laboratory failed to document daily cleaning of cryostat #1 on the following days in February 2021: 1, 2, 3,4,5, 8, 9, 10, 19, 22, 23. The laboratory failed to document daily cleaning of cryostat #2 on the following days in February 2021: 1, 2, 3,4,5, 8, 9, 10, 19, 22, 23. The laboratory failed to document daily cleaning of cryostat #1 on the following days in March 2021: 1, 2, 3,4,5, 8, 9, 10, 11,12,15,16,17,18,19, 22, 23. The laboratory failed to document daily cleaning of cryostat #2 on the following days in March 2021: 1, 2, 3,4,5, 8, 9, 10, 11,12,15,16,17,18,19, 22, 23. The laboratory failed to have documentation of manufacturer required daily maintenance on cryostat #1 and cryostat #2 for 156 of 156 days in 2020 (09/2020-12/2020) and 86 of 86 days in 2021(01/2021- 03/2021). 3. During the exit interview on 04/01/2021 at 1:30 PM, the surgical technician confirmed the above findings. This is a repeat deficiency from the previous survey conducted on 01/03/02019.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, manufacturer's instructions, environmental logs, maintenance records, patient records, and confirmed in interview, the laboratory failed to have an effective QA (quality assessment) in place to identify and correct problems for the analytical phase of testing. Findings Included: 1. Review of the laboratory record titled, "Quarterly Quality Assurance Checklist" from 03/2019, 06 /2019, 9/2019, 12/2019,03/2020, 9/2020 and 12/2020 revealed the following: "Our quality control policies were performed as specified: All laboratory Quality Control Logs(Cryostat Maintenance log, Automatic Stainer Log, Eyewash Station Log, Laboratory Refrigerator Log, Olympus Microscope Log and the Slide Review Log) are reviewed for any deficiencies. All slides were reviewed for proper slide labeling. All required temperatures were taken and recorded. All reagents, controls, kits, etc., that exceeded their expiration date were discarded. All instruments maintenance was performed and documented. All necessary remedial action was performed and documented ... Our Quality Assurance Program is monitored for compliance: The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies and procedures." All entries were marked with a "Y" indicating the quality control policies were performed as specified

	and the quality assurance program was monitored for compliance. The laboratory's QA assessments failed to identify and correct problems for the analytical phase of testing. 2. The laboratory failed to follow its own written policy for labeling Mohs slides for 6 of 6 sets of slides reviewed from 11/2019 through 12/2020 (random sampling). This is a repeat deficiency from the previous survey conducted on 01/03 /02019. Refer to D5401, I. 3. The laboratory failed to follow their own written policy for the changing, filtering and rotating of Hematoxylin and Eosin stain on the Linistat Linear Stainer (Serial #LS1605A1301) in use for 13 of 15 days in January 2021, 9 of 15 days in February 2021 and 17 of 19 days in March 2021. This is a repeat deficiency from the previous survey conducted on 01/03/02019. Refer to D5401, II. 4. The laboratory procedure manual, KOH (potassium hydroxide) logs, and confirmed in staff interview, the laboratory failed to establish a procedure for performing KOH testing. This is a repeat deficiency from the previous survey conducted on 01/03 /02019. Refer to D5403. 5. The laboratory failed to follow manufacturer's staining instructions for the NovoDiax ihcDirect Mart 1 Kit. Refer to D5411, I. 6. The laboratory failed to follow manufacturer's instructions for storage of prepared Novodiax ihc Wash Buffer reagent. Refer to D5411, II. 7. The laboratory failed to define acceptable room temperature and humidity ranges in accordance with Leica CM1510-S Cryostat manufacturer's specifications for 9 of 15 months in 2020(1/2020-12/2020) and 2021(1/2021-3/2021). This is a repeat deficiency from the previous survey conducted on 01/03/02019. Refer to D5413. 8. The laboratory failed to ensure prepared Novodiax ihc Wash Buffer reagent had documentation of preparation date and expiration date. Refer to D5415. 9. The laboratory failed to ensure reagents had not exceeded their expiration dates. This is a repeat deficiency from the previous survey conducted on 01/03/02019. Refer to D5417. 10. The laboratory failed to perform daily maintenance on Leica CM1510S (Serial # 22505200) Cryostat #1 and Leica CM1510S (Serial # 22489092001) Cryostat #2 for 156 of 156 days in 2020 (09 /2020-12/2020) and 86 of 86 days in 2021(01/2021- 03/2021). This is a repeat deficiency from the previous survey conducted on 01/03/02019. Refer to D5429.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, personnel records, and interview with staff, the Technical Consultant (TC) failed to evaluate and document performance of 1 of 1 Testing Persons responsible for moderate complexity testing (KOH) at least semiannually during the first year that testing persons analyze patient specimens. Findings Included: 1. Review of the submitted CMS 209 form revealed Testing Person 2 listed to perform moderate complexity testing. 2. Review of personnel records from 2017 through 2019 revealed the following: a. Testing Person #2; Date of Hire: 09/17/2017 No other documentation of semiannual evaluation during the first year of patient testing was provided. The TC failed to evaluate and document performance at least semiannually during the first year of patient testing. 3. In an interview on 04/01/2021 at 1:30 PM in the conference room, the surgical technician was asked to provide documentation of semiannual competency assessment. No documentation was provided. This confirmed the above findings.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, personnel records, and staff interview, the Technical Consultant (TC) failed to evaluate competency annually in 2019 for 1 of 1 Testing Persons who perform moderate complexity testing. Findings Included: 1. Review of the submitted CMS 209 form revealed Testing Person 2 listed to perform moderate complexity testing(KOH testing). 2. Review of personnel records from 2017 through 2019 revealed the following: a. Testing Person #2; Date of Hire: 09/17/2017 No documentation of 2019 annual competency was provided for KOH testing. The Technical Consultant had not performed and documented competency assessment for Testing Person 2 to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem solving skills. 3. In an interview on 04/01/2021 at 1:30 PM in the conference room, the surgical technician was asked to provide documentation of annual competency assessment. No documentation was provided. This confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of the laboratory's personnel records, and in interview with staff, it was revealed the laboratory failed to have documentation of training for the following 1 of 1 testing persons to qualify them to perform moderate complexity testing(KOH). Findings Included: 1. Review of the submitted CMS 209 form revealed Testing Person 2 listed to perform moderate complexity testing. 2. Review of personnel records from 2017 through 2019 revealed the following: Testing Person #2; Date of Hire: 09/17/2017 No other documentation of initial training for KOH testing was provided. The TC failed to evaluate and document initial training for KOH testing. 3. During the exit interview on 04/01/21 at 1:30 PM, the surgical technician confirmed the above findings.
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 direct observations, review of laboratory policies, manufacturer's instructions, laboratory records, patient records, CMS 209 form, and confirmed in staff interview, it was revealed the laboratory director failed to provide overall management and direction in accordance with 493.1441 of this subpart, as evidenced by: 1. The laboratory director failed to ensure requirements were met for high complexity analytical phase of testing. Refer to D6082. 2. The laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The laboratory failed to have a quality assessment system in place for ongoing mechanism to monitor, assess, and when indicated, correct problems identified. Refer to D6094.
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 policies, laboratory records, and in interview with staff, the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance, as evidenced by: 1. The laboratory failed to follow its own written policy for labeling Mohs slides for 6 of 6 sets of slides reviewed from 11/2019 through 12/2020 (random sampling). Refer to D5401, I. This is a repeat deficiency from the previous survey conducted on 01/03/02019. 2. The laboratory failed to follow their own written policy for the changing, filtering and rotating of Hematoxylin and Eosin stain on the Linistat Linear Stainer (Serial #LS1605A1301) in use for 13 of 15 days in January 2021, 9 of 15 days in February 2021 and 17 of 19 days in March 2021. Refer to D5401, II. This is a repeat deficiency from the previous survey conducted on 01/03/02019. 3. The laboratory procedure manual, KOH (potassium hydroxide) logs, and confirmed in staff interview, the laboratory failed to establish a procedure for performing KOH testing. Refer to D5403. This is a repeat deficiency from the previous survey conducted on 01/03/02019. 4. The laboratory failed to follow manufacturer's staining instructions for the NovoDiax ihcDirect Mart 1 Kit. Refer to D5411, I. 5. The laboratory failed to follow manufacturer's instructions for storage of prepared Novodiax ihc Wash Buffer reagent. Refer to D5411, II. 6. The laboratory failed to define acceptable room temperature and humidity ranges in accordance with Leica CM1510-S Cryostat manufacturer's specifications for 9 of 15 months in 2020(1/2020-12/2020) and 2021(1/2021-3/2021). Refer to D5413. This is a repeat deficiency from the previous survey conducted on 01/03/02019. 7. The laboratory failed to ensure prepared Novodiax ihc Wash Buffer reagent had documentation of preparation date and expiration date. Refer to D5415. 8. The laboratory failed to ensure reagents had not exceeded their expiration dates. Refer to D5417. This is a repeat deficiency from the previous survey conducted on 01/03/02019. 9. The laboratory failed to perform

	daily maintenance on Leica CM1510S (Serial # 22505200) Cryostat #1 and Leica CM1510S (Serial # 22489092001) Cryostat #2 for 156 of 156 days in 2020 (09/2020-12/2020) and 86 of 86 days in 2021(01/2021- 03/2021). Refer to D5429. This is a repeat deficiency from the previous survey conducted on 01/03/02019.
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 quality assurance records and staff interview, it was revealed the laboratory director failed to ensure quality assurance programs maintained the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D5793