Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2176553	09/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Nikko Dermatology	27150 Us-290 Suite 100, Cypress, 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	An announced survey of the laboratory was conducted on 09/08/2023. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D5028 - 42 C. F.R. 493.1219 Condition: Histopathology D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory's random patient test records and staff interview, the laboratory failed to retain patient's Mohs maps for 2 of 25 patient test records reviewed. Note: This is a repeat deficiency from the survey conducted on 09/21/2021. Findings included: 1. Review of laboratory's random patient test records for 2022 and 2023 revealed the following 2 of 25 reviewed case numbers did not have Mohs maps available for review: Case number: M20-115 Mohs Performed: 01/11/2023 Case number: M20-119 Mohs Performed: 01/12/2023 2. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document), stated that the Mohs maps were scanned into the system, but could not find them. No paper copies were available for review. This confirmed the findings.
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 laboratory's proficiency test (PT) records, policies/procedures, quality control (QC) records, maintenance records, patient test records, surveyor's observations and staff interview the laboratory failed to meet the requirements for the specialty of histopathology as evidenced by: 1. The laboratory failed to document evaluation of PT results. Refer to D5221. 2. The laboratory failed to follow its own policy/procedure for reagent maintenance. Refer to D5401. 3. The laboratory failed to ensure no expired reagents were used. Refer to D5417. 4. The laboratory failed to ensure cryostat maintenance was performed. Refer to D5429. 5. The laboratory failed to document Hematoxylin and Eosin stain quality control. Refer to D5473. 6. The laboratory failed to document corrective actions for out-of-range temperatures. Refer to D5785. 7. The laboratory failed to establish and follow analytic system's quality assurance (QA) program. Refer to D5791. 8. The laboratory failed to ensure patients' test documents/reports were accurately documented and transcribed. Refer to D5801. 9. The laboratory's post-analytic QA failed to identify and correct issues in documentation and transcription of results. Refer to D5891.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's twice annual test accuracy verification records, review of laboratory's policies/procedures and staff interview, the laboratory failed to document evaluation of test accuracy verification results for two of two 2022 events reviewed. Findings included: 1. The laboratory was asked to provide twice annual test accuracy verification records for September 2021 to August 2023. Review of the provided records revealed the laboratory only had records for the following events in 2022: Event 1 2022 Verification performed: 12/23/2022 Case: M20-079 Diagnosed during: October Event 2 2022 Verification performed: 12/30/2022 Case: Number not documented (Name of patient listed and date of Mohs procedure listed did not match patient test log) Diagnosed during: July Note: There were no identifiers (name /signature) of the test accuracy verifying party for either of the above events. 2. Further review of the above records revealed no documentation of laboratory's evaluation of its performance against the assessment of the test accuracy verifying party to see if the laboratory's performance was acceptable or if corrective action was necessary. 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place addressing twice annual test accuracy verification, evaluation of results and corrective action for failures/diagnostic discrepancies. 4. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document), after review of data, confirmed the findings.
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: Based on review of laboratory's Hematoxylin and Eosin (H&E) stain reagent maintenance summary and logs, policies/procedures and staff interview the laboratory failed to follow its own policy for reagent maintenance documentation for 12 of 32 days the stain reagents were in use. Findings included: 1. Review of laboratory's H&E stain reagent maintenance summary "Manual Hematoxylin and Eosin Stain" (posted above the stain containers) revealed: "DAILY CHANGE FIXATIVE AND SCOTTS BLUIN DAILY EMPTY FIRST 95% (percent) ALCOHOL, MOVE SECOND 95% ALCOHOL TO EMPTY SPACE, FILL FRESH 95% ALCOHOL DAILY EMPTY FIRST 100% ALCOHOL, MOVE SECOND 100% ALCOHOL TO EMPTY STATIONS, REPLACE FRESH 100% ALCOHOL CHANGE ALL ALCOHOLS AD XYLENE WEEKLY CHANGE HEMATOXILIN AND EOSIN MONTHLY" 2. Review of laboratory's H&E stain reagent maintenance logs for 2022 and 2023 revealed there was no documentation of H&E stain reagent maintenance for the following 12 of 32 reviewed days the reagents were in use: Date: Last maintenance documented: 03/04/2022 02/16/2022 06/15/2022 05/18/2022 06/21/2022 05/18/2022 07/15/2022 05/18/2022 08/17/2022 05/18/2022 08/19/2022 05/18/2022 08/26/2022 05 /18/2022 02/17/2023 02/10/2023 02/22/2023 02/10/2023 03/24/2023 03/22/2023 04/07 /2023 03/22/2023 04/28/2023 03/22/2023 06/02/2023 03/22/2023 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place for performing H&E stain and/or H&E stain reagent maintenance other than the posted "Manual Hematoxylin and Eosin Stain" summary. The summary did not have documentation of laboratory director's approval into use. 4. In an interview on 09/08 /2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Exit Conference document) confirmed the 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 surveyor's observations, review of laboratory's test logs and staff interview, the laboratory failed to ensure two of four marking dyes used for Mohs histopathology procedures were not used after exceeding their expiration date. Findings included: 1. Surveyor's observations on 09/08/2023 at 1520 hours in the laboratory revealed the following marking dyes used for laboratory procedures exceeded their expiration date: Avantic Green Tissue Marking Dye Lot: 090707 Expired: 2021-11-30 Avantic Black Tissue Marking Dye Lot: 091345 Expired: 2021-12-31 2. Review of laboratory's test logs revealed the laboratory performed 25 Mohs histopathology procedures annually. 3. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document), after review of the expired products, confirmed the findings.
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 surveyor's observations in the laboratory, review of manufacturer instructions for use for the Leica CM 1510 S Cryostat, review of laboratory's cryostat maintenance records, policies/procedures and staff interview, the laboratory failed to follow/document required Cryostat maintenance from June to September of 2023. Findings included: 1. Surveyor's observations on 09/08/2023 at 1645 hours in the laboratory revealed the Leica CM 1510 S Cryostat (serial number 5767/10.2007) used by the laboratory was turned on, had approximately one and a half inch of frost/ice accumulated around its cooling system and ice particles and paraffin debris dispersed on the bottom platform. Temperature reading was -16C (degrees Celsius). 2. An interview with the Medical Assistant (as indicated on the submitted Survey Entrance Conference document) on 09/08/2023 at 1645 hours in the laboratory revealed the last Mohs case was processed on the instrument in June 2023. She also stated the instrument was always on, it was not set to defrost automatically, and defrosting was done manually by the staff. She could not remember the last date/time defrosting cycle was performed. 3. An attempted review of the manufacturer instructions for use for the Leica CM 1510 S Cryostat revealed the laboratory did not have a user manual or instructions for use for the cryostat instrument. 4. Review of the "Leica CM1510 S - Cryostat Instruction Manual" (V 1.4 - 04/2010) available online (www.manualslib.com/manual/1909118/Leica-Cm1510s.html) revealed: "Always keep this manual near the instrument. Read carefully prior to operating the instrument." And, "6.5 Defrosting Defrosting the cryochamber actually means defrosting the evaporator to prevent excessive frost buildup." And, "After defrosting, drops of water remaining on the surface of the quick-freeze shelf need to be wiped off manually with an absorbent cloth to prevent new frost buildup." And, "6.5.3 Manual defrosting of the quick-freeze shelf If heavy frost builds up on the quick-freeze shelf, especially after spray disinfection ..., a manual defrost cycle ... should be started." 5. Review of the laboratory's cryostat maintenance records for 2022 and 2023 revealed the following instructions: "4. The machines are wiped out daily with dry gauze, to collect waste material. Then wiped with gauze containing 100% isopropyl alcohol, to disinfect. Wiped again with dry gauze and ready for the next day. 5. The defrost cycle is done every night at 2300 hours." 6. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place for Cryostat use and maintenance other than the instructions on the cryostat maintenance sheet. The maintenance sheet did not have documentation of laboratory director's approval into use. 7. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Exit Conference document) confirmed the 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 laboratory's quality control records (QC) for the Hematoxylin and Eosin (H&E) stain for 2022 and 2023, review of patient test logs, H&E stain reagent maintenance summary, policies/procedures and staff interview, the laboratory failed to document H&E stain QC for 14 of 32 days the stain reagents were used in patient testing. Findings included: 1. Review of the laboratory's 2022 and 2023 H&E stain QC records revealed the following 14 of 32 days patient testing was performed did not have documentation of H&E stain QC: 03/04/2022 06/15/2022 06/21/2022 07/15 /2022 08/17/2022 08/19/2022 12/02/2022 01/11/2023 01/12/2023 02/22/2023 04/07 /2023 04/28/2023 06/02/2023 06/23/2023 2. Review of laboratory's test logs revealed the following patients' samples were tested with H&E stain on the days H&E stain QC was not documented: On 03/04/2022, case number: M20-097 On 06/15/2022, case number: M20-099 On 06/21/2022, case number: M20-100 On 07/15/2022, case number: M20-101 On 08/17/2022, case number: M20-102 On 08/19/2022, case number: M20-103 On 12/02/2022, cases number: M20-112 M20-113 On 01/11/2023, cases number: M20-114 M20-115 M20-116 On 01/12/2023, cases number: M20-117 M20-118 M20-119 On 02/22/2023, cases number: M20-123 M20-124 On 04/07/2023, case number: M20-130 On 04/28/2023, case number: M20-131 On 06/02/2023, case number: M20-132 On 06/23/2023, case number: M20-133 3. Review of laboratory's H&E stain reagent maintenance summary "Manual Hematoxylin and Eosin Stain" (posted above the stain containers) revealed: "Quality Assurance: The first case submitted to the Mohs lab which consists of NORMAL tissue will be stained for H&E and documented on the control sheet as the QA." 4. Review of laboratory's policies /procedures revealed the laboratory did not have in place protocols addressing H&E stain procedure or QC, other than the posted summary. The summary did not have documentation of laboratory director's approval into use. 5. In an interview on 09/08 /2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document), after review of the data, confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of laboratory's temperature logs, corrective action documents, policies/procedures and staff interview the laboratory failed to document corrective action for five of five instances laboratory's room temperature was out of its defined range. Findings included: 1. Review of laboratory's temperature logs for 2022 and 2023 revealed the laboratory defined room temperature as 68-76F (degrees Fahrenheit). 2. Further review of temperature logs revealed the following instances the room temperature was documented as outside of the 68-76F range: Date: Temperature: 12/02/2022 66.0F 01/12/2023 67.2F 02/22/2023 67.0F 04/28/2023 67.0 F 06/02/2023 67.3F 3. Review of laboratory corrective action documentation revealed there was no documentation of corrective action for the above instances the room temperature was out of laboratory's defined range. 4. Review of laboratory's policies /procedures revealed there were no protocols in place addressing corrective action for

	out-of-range temperatures. 5. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance /Exit Conference document), after review of the data, confirmed the findings.
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 laboratory's records, policies/procedures and staff interview, the laboratory failed to establish and document quality assurance activities for 20 of 20 months reviewed. Findings included: 1. Review of laboratory's records revealed the laboratory had a blank copy of a "Monthly Quality Assurance Checklist". 2. The laboratory was asked to provide documentation for quality assurance activities for 2022 and 2023 and no such documentation was available for review prior to survey exit. 3. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place addressing quality assurance activities. 4. In an interview on 09 /08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document) confirmed the 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 laboratory's manual patient test logs, Mohs surgery maps, Mohs procedure notes, laboratory's policies/procedures and staff interview, the laboratory failed to have an adequate system in place to ensure the accuracy and reliability of results transcribed into the practice electronic medical record for 2 of 25 Mohs patient test records reviewed. Findings included: 1. Review of laboratory's manual patient test logs, MOHS surgery maps, and corresponding Mohs procedure notes from the electronic system revealed the following discrepancies: a. Discrepant case number annotation as evidenced by: Patient: 26392163 Test log (manual entry) data: Case number M20-097 Test date: 03/04/2022 Surgery location: L (left) 3rd finger Diagnosis: SCC (squamous cell carcinoma) Versus Mohs map data: Case number: M20-094 Test date: 03/04/2022 Surgery location: L 3rd finger Diagnosis: SCC And, No Mohs procedural notes could be located in laboratory's electronic system for this patient for the visit on 03/04/2022 for case number M20-097 (Mohs of L 3rd finger) M20-2094 was assigned to the same patient for Mohs of R tear through on 02/09

	/2022. b. Discrepant test date, surgery location and diagnosis annotation as evidenced by: Case number M20-112 Patient: 26395006 Test log data: Test date: 12/02/2022 Surgery location: Forehead Diagnosis: SCC Versus Mohs map data: Test date: 12/09 /2022 Surgery location: L glabella/eyebrow Diagnosis: BCC (basal cell carcinoma) Versus Mohs Procedure Notes data: Test date: 12/2/2022 Surgery location: R (right) forehead Diagnosis: SCC 2. Review of laboratory's policies/procedures revealed the laboratory did not have protocols in place to ensure accurate documentation and transcription of Mohs procedures. 3. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of laboratory's manual patient test logs, Mohs surgery maps, Mohs procedure notes, laboratory's policies/procedures and staff interview, the laboratory's quality assurance (QA) failed to identify and correct issues with the accuracy and reliability of test documentation and transcription of results for one of one test performed by the laboratory, Mohs. Refer to D5801.
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 laboratory's proficiency test (PT) records, policies/procedures, quality control (QC) records, maintenance records, patient test records, surveyor's observations and staff interview, the Laboratory Director failed to provide overall management and direction as evidenced by: 1. Laboratory Director Failed to ensure the laboratory was in compliance with applicable regulations. Refer to D6079. 2. Laboratory Director Failed to ensure the laboratory provided quality lab services for all aspects of testing. Refer to D6082. 3. Laboratory Director Failed to ensure the laboratory's PT results were reviewed by appropriate personnel. Refer to D6091. 4. Laboratory Director Failed to ensure the laboratory's QC was established and maintained. Refer to D6093. 5. Laboratory Director Failed to ensure the laboratory's quality assurance was established and maintained. Refer to D6094. 6. Laboratory Director Failed to ensure the laboratory had an approved written procedure manual available to all personnel. Refer to D6106. 7. Laboratory Director Failed to ensure the responsibilities and duties of each individual and/or consultant employed by the laboratory were specified in writing. Refer to D6107.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory's twice annual test verification records, policies /procedures, quality control (QC) records, maintenance records, patient test records, surveyor's observations and staff interview, the Laboratory Director failed to ensure the laboratory was in compliance with applicable regulations for one of one test performed by the laboratory, Mohs. Refer to D5028.
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 laboratory's policies/procedures, patient test records, surveyor's observations and staff interview, the Laboratory Director failed to ensure laboratory provided quality lab services for preanalytic, analytic and post-analytic aspects of testing for one of one tests performed by the laboratory, Mohs. Refer to D5801.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of laboratory's twice annual test accuracy verification records, policies/procedures and staff interview, the Laboratory Director failed to ensure twice annual test accuracy verification was evaluated by appropriate personnel for 20 of 20 months reviewed. Refer to D5221.
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 laboratory's quality control records, equipment and reagent maintenance records, policies/procedures and staff interview, the Laboratory Director failed to ensure quality control was established and maintained for one of one stain performed by the laboratory, Hematoxylin and Eosin stain. Refer to D5473.
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 laboratory's proficiency test (PT) records, policies/procedures, quality control records, maintenance records, quality assurance records, patient test records and staff interview, the Laboratory Director failed to ensure quality assurance was established and maintained for one of one test performed by the laboratory, Mohs. Refer to D5791 and D5891.
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 laboratory's policies/procedures and staff interview, the Laboratory Director failed to ensure a written approved procedure manual was available to all three of three personnel involved in processing patient samples and/or testing. Findings included: 1. The laboratory was asked to provide a policy/procedure manual describing protocols related to patient/staff safety, staff qualifications and competency assessment, twice annual test accuracy verification, preanalytic test aspects (specimen collection, processing, etc.), analytic processes (Mohs testing , quality control requirements, interpretation, etc.), post-analytic processes (result documentation, reporting, etc.), storage and retention of samples/slides /records, and overall laboratory's quality assurance. 2. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document) confirmed the laboratory did not have an approved policy/procedure manual available for review.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which

	examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's records and staff interview, the Laboratory Director failed to specify in writing responsibilities and duties for three of three individuals and /or consultants employed by the laboratory. Findings included: 1. Review of laboratory's records revealed the laboratory did not have documentation specifying responsibilities and duties of the three individuals employed by the laboratory. 2. In an interview on 09/08/2023 at 1730 hours in the laboratory, the facility's Medical Assistant (as identified on submitted Survey Entrance/Exit Conference document), confirmed the findings.