

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2314040	(X3) Date Survey Completed 08/19/2026
Name of Provider or Supplier Dermatology Solutions	Street Address, City, State 5796 East Highway 114 Suite 2b, Haslet, 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 onsite initial certification survey was conducted on 08/19/2026. The laboratory was found to be in compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on direct observation and confirmed in staff interview, the laboratory failed to retain the operator's manual for one of one slide stainer and one of one microscope used in dermatopathology slide interpretations. Findings included: 1. During a tour of the laboratory on 08/19/2026 at 12:35 PM, the surveyor observed the following: 1 HistoPro414 Linear Slide Stainer, Serial # LS0559 1 Unico microscope, serial # 1722533 On 08/19/2026 at 10:14 AM in the laboratory, the surveyor requested the operator's manual for the slide stainer and microscope, and none were provided. 2. During an interview in the laboratory on 08/19/2026 at 10:36 AM, the office manager stated she could not find the operator's manuals for the slide stainer and microscope. This confirmed that the laboratory failed to retain the operator's manual for one of one slide stainer and one of one microscope used in dermatopathology slide interpretations.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure

positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, direct observation, patient dermatopathology slides, and confirmed in interview, the laboratory failed to ensure positive identification and optimum integrity of patient specimens from the time of collection and receipt of the specimen through completion of testing and reporting of results for one of one patient dermatopathology slides from October 20, 2025. Findings included: 1. Review of the laboratory's "Mohs Laboratory Policy & Procedure Manual" stated: "5. Specimen Handling & Documentation Proper specimen handling and documentation are essential to maintaining the accuracy, reliability, and traceability of patient results. All frozen section specimens must be managed according to the following policies and procedures ... 5.2 Accessioning and Labeling Each specimen must be assigned a unique accession number upon receipt. All cassettes, tissue molds, and slides must be labeled with: Patient name Site/location Accession number Stage (I, 11, 111, etc.) Labels must be clear, legible, and resistant to staining reagents and freezing temperatures ... 5.5 Documentation and Tracking ... All stages and slides must be traceable from receipt through final interpretation." 2. On 08/19/2026 at 11:10 AM in the laboratory, the surveyor observed patient dermatopathology slides were stored in a slide storage box in the cabinet. 3. Review of patient slides from October 20, 2025 revealed one patient dermatopathology slide that was not labeled any patient identification. The slide was not labeled with "patient name, site/location, accession number or stage". The laboratory did not ensure positive identification and integrity of the unlabeled patient slide from time of collection through completion of testing and reporting of results. 4. During an interview in the laboratory on 08/19/2026 at 11:10 AM, the office manager, after a review of the slides, confirmed the laboratory failed to ensure positive identification and optimum integrity of patient specimens from the time of collection and receipt of the specimen through completion of testing and reporting of results for one of one patient dermatopathology slides from October 20, 2025.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, direct observation, patient dermatopathology slides, and confirmed in interview, the laboratory failed to establish a Quality Assessment program to monitor, assess, identify and correct problems in the general laboratory systems. Findings included: 1. Review of the laboratory's procedure manual revealed the laboratory failed to have documentation of a quality assessment program to identify, monitor, and assess problems in the general laboratory's systems. 2. The laboratory was asked to provide documentation of a quality assessment plan, and none was provided. 3. The laboratory failed to have a policy for twice annual accuracy assessments that outlined how the accuracy of

dermatopathology slide interpretations would be verified. 4. The laboratory failed to ensure positive identification and optimum integrity of patient specimens from the time of collection and receipt of the specimen through completion of testing and reporting of results for one of one patient dermatopathology slides from October 20, 2025. Refer to D5203. 5. During an interview in the laboratory on 08/19/2026 at 10:50 AM, the office manager, after a review of the records, confirmed the laboratory failed to establish a Quality Assessment program to monitor, assess, identify and correct problems in the laboratory for analytical phase of testing.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observations, operator's manual, environmental logs, and confirmed in staff interview, the laboratory failed to ensure room humidity was maintained according to manufacturer's instructions for one of one cryostat and one of one automatic slide stainer used to process dermatopathology specimens for 21 of 21 days in 2025 and 2026. Findings included: 1. During a tour of the laboratory on 08/19/2026 at 12:35 PM, the surveyor observed: 1 Leica CM1860 UV Cryostat, Serial #4960 1 HistoPro414 Linear Slide Stainer, Serial # LS0559 The back of the stainer had a manufacture's sticker that read: Operating Ranges Temperature 15C to 30C Humidity 20%-80% 2. Review of the Leica CM1860 UV Cryostat operator's manual page 19 stated: "3. Technical Data Note Operating temperature range (ambient temperature): 18 C to 35 C. All specifications related to temperature of the cooling unit are valid only for an ambient temperature of 22 C and a relative humidity of not more than 60 %." 3. Review of the laboratory's daily environmental logs from 10/20/2025 through 07/17/2026 revealed the laboratory documented humidity for 21 days without a defined acceptable humidity range. Without a defined acceptable humidity range the laboratory could not ensure the documented room humidity did not exceed the manufacturers' requirements for operating ranges for the cryostat and slide stainer. 4. During an interview in the laboratory on 08/19/2026 at 10:50 AM, the office manager, after a review of the records, confirmed the laboratory failed to ensure room humidity was maintained according to operator's manual for one of one cryostat and one of one automatic slide stainer used to process dermatopathology specimens for 21 of 21 days in 2025 and 2026. Word Key: C - Celsius II. Based on direct observation, manufacturer's instructions, environmental logs, and confirmed in interview, the laboratory failed to ensure the proper storage conditions were maintained for two of two Eosin-Y stains and two of two Hematoxylin stains used in the preparation of dermatopathology specimens for three of three months in 2025 (October-December) and seven of seven months in 2026 (January-July). Findings included: 1. During a tour of the laboratory on 08/19/2026 at 12:35 PM, the following were found to be stored in the flammable storage cabinet down the hall from the laboratory: 1 opened bottle of Eosin-Y stain, lot# 239073, expiration date 03/31/2027 Manufacture's label

	stated: "Store at room temperature (20-30C)." 1 sealed bottle of Eosin-Y stain, lot# 247437, expiration date 06/30/2027 Manufacture's label stated: "Store at room temperature (20-30C)." 1 sealed bottle of Hematoxylin stain, lot# 244531, expiration date 05/31/2027 Manufacture's label stated: "Store at room temperature (20-30C)." 1 opened bottle of Hematoxylin stain, lot# 239072, expiration date 03/31/2027 Manufacture's label stated: "Store at room temperature (20-30C)." The laboratory did not have a thermometer in the hallway or flammable storage cabinet. The laboratory failed to ensure temperatures did not exceed manufacturer's instructions for Eosin-Y and Hematoxylin stains. 2. Review of the laboratory's environmental logs from October 2025 through July 2026 revealed the laboratory did document the temperature for the hallway or flammable storage cabinet where the Eosin-Y and Hematoxylin stains were stored. 3. During an interview in the laboratory on 08/19/2026 at 1:00 PM, the office manager, after a review of the records, confirmed the laboratory failed to ensure the proper storage conditions were maintained for two of two Eosin-Y stains and two of two Hematoxylin stains used in the preparation of dermatopathology specimens for three of three months in 2025 (October-December) and seven of seven months in 2026 (January-July). Word Key: C - Celsius
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 review of operator's manual, laboratory maintenance logs, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance on one of one Leica CM1860 UV Cryostat for 13 of 13 weeks (October 2025 through July 2026). Findings included: 1. Review of the Leica CM1860 UV Cryostat operator's manual page 72 stated: "9.3 Maintenance ... 9.3.1 General maintenance instructions ... Weekly Note Before the following parts can be lubricated, all section waste and deposits must be carefully removed. Lubricate the plastic coupling (--> Fig. 58-6) with a drop of cryo oil. Lubricate the specimen cylinder (--> Fig. 56-1): Push the appropriate coarse feed button to move the specimen cylinder out to the front stop position, apply a drop of cryo oil and move the specimen cylinder back to the home position by pressing the appropriate coarse feed button." 2. Review of the laboratory's maintenance logs for the cryostat from 10/20/2025 - 07/17/2026 revealed the laboratory failed to document the required weekly maintenance for 13 of 13 weeks when the cryostat was used in the processing of dermatopathology specimens. 3. During an interview in the laboratory on 08/19/2026 at 12:16 PM, the office manager, after a review of the records, confirmed the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance on one of one Leica CM1860 UV Cryostat for 13 of 13 weeks (October 2025 through July 2026). Word Key: Fig - figure cryo - cryostat
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of the laboratory's policy manual, maintenance logs, patient specimen logs, and confirmed in interview, the laboratory failed to establish maintenance protocols for one of one microscope in use and failed to document the microscope maintenance activities necessary for accurate and reliable test result reporting for three of three months in 2025 (October-December) and seven of seven months in 2026 (January-July). Findings included: 1. During a tour of the laboratory on 08/19/2026 at 12:35 PM, the surveyor observed on the desk one Unico microscope, serial # 1722533, used for dermatopathology slide interpretations. 2. Review of laboratory policy manual stated: "4. Equipment and Maintenance ... 4.3 Microscope - To Be Specified Used for interpretation of stained frozen sections by the physician. Instrument specifications, maintenance procedures, and QC protocols will be added once the model is confirmed." 3. Review of the laboratory's maintenance logs revealed no documentation of microscope maintenance performance from October 2025 through July 2026. 4. Review of the laboratory's patient specimen logs from October 2025 through July 2026 identified 79 patients in 2025 and 205 patients in 2026 who had dermatopathology slide interpretations performed. 5. During an interview in the laboratory on 08/19/2026 at 12:16 PM, the office manager, after a review of the records, confirmed the laboratory failed to establish maintenance protocols for one of one microscope in use and failed to document the microscope maintenance activities necessary for accurate and reliable test result reporting for three of three months in 2025 (October-December) and seven of seven months in 2026 (January-July). II. Based on review of laboratory policy, laboratory maintenance logs, patient specimen logs, and confirmed by staff interview, the laboratory failed to have documentation of performing monthly maintenance for the cryostat for three of three months in 2025 and seven of seven months in 2026 and failed to have documentation of replacing the cryostat's air filter for one of one six month period between October 2025 through July 2026. Findings included: 1. Review of the laboratory's policy manual stated: "4. Equipment & Maintenance 4.1 Cryostat - Leica CM1860 UV ... Monthly Maintenance: Inspect and clean internal components and check for wear. Every 6 Months: Replace air filter and document change. All maintenance activities must be documented on the Cryostat Maintenance Log." 2. Review of the laboratory's maintenance log from October 2025 through July 2026 revealed the laboratory failed to document monthly maintenance on the cryostat as required per laboratory policy. Further review of the maintenance log revealed a column titled "Clean Air Filter 6 months" everyday the laboratory performed patient testing from October 2025 through July 2026 the "Clean Air Filter 6 months" was marked off with a "checkmark". The "checkmark" did not indicate if the air filter was changed. 3. During an interview in the laboratory on 08/19/2026 at 12:16 PM, the office manager, after a review of the records, confirmed the laboratory failed to have documentation of performing monthly maintenance for the cryostat for three of three months in 2025 and seven of seven months in 2026 and failed to have documentation of replacing the cryostat's air filter for one of one six month period between October 2025 through July 2026.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of

specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of patient Mohs maps, patient final reports, CMS 209 form, and confirmed in interview, the laboratory failed to accurately record the identity of the personnel performing Mohs procedures for dermatopathology slide interpretations for 11 of 11 patients in 2025 (random review October and December) and 10 of 10 patients in 2026 (random review June and July) on the patient Mohs maps and patient final reports. Findings included: 1. A random review of patient Mohs maps from October and December 2025 and June and July 2026 identified the following 21 patient Mohs maps which did not include the identity of the personnel performing the Mohs procedures for dermatopathology slide interpretations: Test date: 10/20/2025 Mohs Case #s: DR1-2025, DR2-2025, DR3-2025, DR4-2025, DR5-2025 Test date: 12/18/25 Mohs Case #s: DR68-2025, DR69-2025, DR70-2025, DR71-2025, DR72-2025, DR73-2025 Test date: 06/20/2026 Mohs Case #s: DR165-2026, DR166-2026 Test date: 06/26/2026 Mohs Case #s: DR167-2026, DR168-2026, DR169-2026 Test date: 07/18/2026 Mohs Case #s: DR194-2026, DR195-2026, DR196-2026, DR197-2026, DR198-2026 2. Review of Mohs patient final reports revealed the following patients whose final reports were listed as "performed by" and "electronically signed" the laboratory director: Test date: 10/20/2025 Mohs Case #s: DR1-2025, DR2-2025, DR3-2025, DR4-2025, DR5-2025 Test date: 12/18/25 Mohs Case #s: DR68-2025, DR69-2025, DR70-2025, DR71-2025, DR72-2025, DR73-2025 The laboratory director was NOT delegated as a high complexity testing person on the CMS 209 form submitted by the laboratory on the date of the survey. Further review of Moh's patient final reports revealed the following patients whose final reports were listed as "performed by" and "electronically signed" by testing person 1, as delegated on the CMS 209 form. These patient final reports were also "electronically cosigned" by the laboratory director: Test date: 06/20/2026 Mohs Case #s: DR165-2026, DR166-2026 Test date: 06/26/2026 Mohs Case #s: DR167-2026, DR168-2026, DR169-2026 Test date: 07/18/2026 Mohs Case #s: DR194-2026, DR195-2026, DR196-2026, DR197-2026, DR198-2026 3. During an interview in the laboratory on 08/19/2026 at 11:40 AM, the office manager, after a review of the records, stated that testing person 1 was the only provider who performed the Mohs procedures for dermatopathology slide interpretations. She further stated that the laboratory director did NOT perform any testing in the laboratory, confirming the laboratory failed to accurately record the identity of the personnel performing Moh's procedures for dermatopathology slide interpretations for 11 of 11 patients in 2025 (random review October and December) and 10 of 10 patients in 2026 (random review June and July) on the patient Mohs maps and patient final reports. Word Key: CMS - Center for Medicare & Medicaid Services

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.

This STANDARD is not met as evidenced by:

Based on direct observations, review of laboratory procedure manual, manufacturer's instructions, environmental logs, maintenance logs, patient records (specimen logs, Mohs maps, and final reports), CMS 209 form, and confirmed in staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems, as evidenced by: 1. Review of the laboratory's procedure manual revealed the laboratory failed to have documentation of a quality assessment program to identify, monitor, and assess problems in the analytic systems. 2. The laboratory was asked to provide documentation of a quality assessment plan, and none was provided. 3. The laboratory failed to ensure room humidity was maintained according to manufacturer's instructions for one of one cryostat and one of one automatic slide stainer used to process dermatopathology specimens for 21 of 21 days in 2025 and 2026. Refer to D5413-I. 4. The laboratory failed to ensure the proper storage conditions were maintained for two of two Eosin-Y stains and two of two Hematoxylin stains used in the preparation of dermatopathology specimens for three of three months in 2025 (October-December) and seven of seven months in 2026 (January-July). Refer to D5413-II. 5. The laboratory failed to follow the manufacturer's instructions for performing weekly maintenance on one of one Leica CM1860 UV Cryostat for 13 of 13 weeks (October 2025 through July 2026). Refer to D5429. 6. The laboratory failed to establish maintenance protocols for one of one microscope in use and failed to document the microscope maintenance activities necessary for accurate and reliable test result reporting for three of three months in 2025 (October-December) and seven of seven months in 2026 (January-July). Refer to D5433-I. 7. The laboratory failed to have documentation of performing monthly maintenance for the cryostat for three of three months in 2025 and seven of seven months in 2026 and failed to have documentation of replacing the cryostat's air filter for one of one six month period between October 2025 through July 2026. Refer to D5433-II. 8. The laboratory failed to accurately record the identity of the personnel performing Mohs procedures for dermatopathology slide interpretations for 11 of 11 patients in 2025 (random review October and December) and 10 of 10 patients in 2026 (random review June and July) on the patient Mohs maps and patient final reports. Refer to D5787.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient Mohs maps and confirmed in interview, the laboratory failed to include the testing facility address on the patient Moh's maps for 11 of 11 patients in 2025 (random review October and December) and 10 of 10 patients in 2026 (random review June and July). Findings included: 1. A random review of patient Mohs maps from October and December 2025 and June and July 2026 identified the following 21 patient Mohs maps which did not include the testing

	facility address: 10/20/2025 Mohs Case #: DR1-2025, DR2-2025, DR3-2025, DR4-2025, DR5-2025 12/18/25 Mohs Case #: DR68-2025, DR69-2025, DR70-2025, DR71-2025, DR72-2025, DR73-2025 06/20/2026 Mohs Case #: DR165-2026, DR166-2026 06/26/2026 Mohs Case #: DR167-2026, DR168-2026, DR169-2026 07/18/2026 Mohs Case #: DR194-2026, DR195-2026, DR196-2026, DR197-2026, DR198-2026 2. During an interview in the laboratory on 08/19/2026 at 12:02 PM, the office manager, after a review of the records, confirmed the laboratory failed to include the testing facility address on the patient Moh's maps for 11 of 11 patients in 2025 (random review October and December) and 10 of 10 patients in 2026 (random review June and July).
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual, patient Mohs maps and confirmed in interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the post-analytic systems, as evidenced by: 1. Review of the laboratory's procedure manual revealed the laboratory failed to have documentation of a quality assessment program to identify, monitor, and assess problems in the post-analytic systems. 2. The laboratory was asked to provide documentation of a quality assessment plan, and none was provided. 3. The laboratory failed to include the testing facility address on the patient Moh's maps for 11 of 11 patients in 2025 (random review October and December) and 10 of 10 patients in 2026 (random review June and July). Refer to D5805.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 direct observations, review of laboratory procedure manual, manufacturer's instructions, environmental logs, maintenance logs, patient records (dermatopathology slides, specimen logs, Mohs maps, and final reports), CMS 209 form, and confirmed in staff interview, the laboratory director failed to ensure a quality assessment program was developed and followed to provide quality laboratory services as evidenced by: 1. The laboratory failed to establish a Quality Assessment program to monitor, assess, identify and correct problems in the general laboratory systems. Refer to D5291. 2. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems. Refer to D5791. 3. The laboratory failed

	to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the post-analytic systems. Refer to D5893.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files and confirmed in interview, the laboratory director failed to ensure documentation of site-specific training for one of one testing personnel (TP-1) performing high complexity testing- dermatopathology slide interpretations (Mohs). Findings included: 1. Review of the laboratory's "Mohs Laboratory Policy & Procedure Manual" stated: "2. Responsibilities 2.1 Lab Director The Lab Director is responsible for the overall operation and administration of the Mohs laboratory. This includes ensuring that the laboratory is in compliance with all applicable federal, state, and local regulations, as well as CUA standards. The Lab Director must ... Ensure that personnel are qualified, adequately trained, and competent to perform assigned tasks." 2. A review of the laboratory's personnel records revealed TP-1 had NO documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) to perform high complexity testing- dermatopathology slide interpretations (Mohs). 3. During an interview in the laboratory on 08/19/2026 at 10:50 AM, the office manager, after a review of the records, confirmed that the laboratory director failed to ensure documentation of site-specific training for one of one testing personnel (TP-1) performing high complexity testing- dermatopathology slide interpretations (Mohs).
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the CMS 209 form, laboratory policies, and confirmed in interview, the laboratory director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 1 of 1 testing person (TP-1), 1 of 1 technical supervisor (TS-1) and 1 of 1 general supervisor (GS-1) performing and supervising high complexity testing. Findings included: 1. Review of the CMS 209 form identified one testing person performing high complexity testing, one technical supervisor and one general supervisor supervising high complexity testing. 2. Review of the laboratory's "Mohs Laboratory Policy & Procedure Manual" stated: "2. Responsibilities 2.1 Lab Director The Lab Director is responsible for the overall

operation and administration of the Mohs laboratory. This includes ensuring that the laboratory is in compliance with all applicable federal, state, and local regulations, as well as CUA standards. The Lab Director must ... Approve and periodically review all laboratory policies, procedures, and quality assurance measures. Ensure that personnel are qualified, adequately trained, and competent to perform assigned tasks." Further review of the policy manual revealed there was no policy established to assess, monitor, and maintain competency for personnel involved in the testing or supervising of high complexity testing. 3. During an interview in the laboratory on 08/19/2026 at 10:50 AM, the office manager, after a review of the records, confirmed the laboratory director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 1 of 1 testing person (TP-1), 1 of 1 technical supervisor (TS-1) and 1 of 1 general supervisor (GS-1) performing and supervising high complexity testing. Word Key: CMS - Center for Medicare & Medicaid Services