Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2244940	01/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dolehide Dermatology At Silver Cross	1851 Silver Cross Blvd - Ste 150, New Lenox, IL	

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 recertification certification survey was completed on 01/15/2026. The following condition level deficiencies were dicovered: D5028 - 42 CFR 493.1219 - Condition: Histopathology D6076 - 42 CFR 493.1441 - Condition: Laboratories performing high complexity testing; laboratory director D6108 - 42 CFR 493.1447 - Condition: Laboratories performing high complexity testing; technical supervisor
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 direct observation, review of laboratory policies and procedures, manufacturer's instructions for use, laboratory records, lack of documentation, and interviews with testing personnel (TP) #2; the laboratory failed to perform biannual method accuracy (proficiency testing/peer reviewed Mohs micrographic carcinoma exclusion results) for four of four Mohs events performed (see D5217a), failed to perform and document biannual method accuracy (proficiency testing/peer reviewed histopathology cases) for histopathology interpretations for four of four events (see D5217b), failed to evaluate results of bi-annual method accuracy (proficiency testing /peer reviewed Mohs micrographic carcinoma exclusion results) for four of four Mohs events (see D5221), failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for 24 of 24 months (see D5291), failed to outline control procedures for two of three stains utilized for histopathology testing (see D5403), failed to perform and document maintenance as defined by the manufacturer (see D5429), failed to establish and document a preventative maintenance protocol that ensures equipment, instrument, and test system performance for accurate and reliable test results for eight of eight instruments and

	microscopes utilized for the histopathology testing (see D5433), failed to exam and document the quality control (intended reactivity) of Hematoxylin and Eosin staining material used for 4 of 11 histopathology interpretations reviewed (see D5473), and failed to document histopathology special stain known reactivity and immunohistochemical (IHC) stain positive and negative reactivity for 11 of 11 patients reviewed in the subspecialty of histopathology in 2024 and 2025 (see D5601).
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: a) Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to perform biannual method accuracy (proficiency testing/peer reviewed Mohs micrographic carcinoma exclusion results) for four of four Mohs events performed in 2024 and 2025 in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Proficiency Testing Policy", which stated, under "Procedures:", "Twice annually 4-5 patients will be randomly chosen from our Mohs cases for review by an outside lab/reviewer for accuracy." 2. Review of biannual method accuracy documentation for Mohs micrographic cases revealed the diagnostic interpretation of the carcinoma was peer-reviewed by an outside reviewer, not the accuracy of the Mohs micrographic carcinoma exclusion procedure. Year/Event: Date: Mohs Case #: Diagnosis: 2024/1st Event 01/08/2024 SM24-003 BCC* 2024/1st Event 04/10/2024 SM24-054 BCC 2024 /1st Event 04/10/2024 SM24-056 BCC 2024/1st Event 04/29/2024 SM24-063 BCC 2024/2nd Event 08/16/2024 SM24-138 BCC 2024/2nd Event 10/16/2024 SM24-174 BCC 2024/2nd Event 11/15/2024 SM24-205 BCC 2024/2nd Event 11/20/2024 SM24-210 BCC 2025/1st Event 01/20/2025 SM25-012 BCC 2025/1st Event 02/17/2025 SM25-022 BCC 2025/1st Event 04/09/2025 SM25-051 BCC 2025/1st Event 05/05 /2025 SM25-069 BCC 2025/2nd Event 06/23/2025 SM25-106 BCC 2025/2nd Event 06/30/2025 SM25-113 BCC 2025/2nd Event 07/14/2025 SM25-122 BCC 2025/2nd Event 10/31/2025 SM25-195 BCC *BCC = Basal Cell Carcinoma 3. Review of biannual method accuracy documentation for Mohs micrographic cases revealed the laboratory sent slides out for peer review one time each year in 2024 and 2025. Year /Event: Date(s) of testing: Date of review: 2024/1st Event 01/08/2024 - 04/29/2024 01 /13/2025 2024/2nd Event 08/16/2024 - 11/20/2024 01/13/2025 2025/1st Event 01/20 /2025 - 05/05/2025 01/12/2026 2025/2nd Event 06/23/2025 - 10/31/2025 01/12/2026 4. Interview with TP #2 on 01/15/2026, at 11:29 am, confirmed the laboratory failed to perform biannual method accuracy (proficiency testing/peer reviewed Mohs micrographic carcinoma exclusion results) for four of four Mohs events performed in 2024 and 2025 in the subspecialty of histopathology. b) Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to perform and document biannual method accuracy (proficiency testing/peer reviewed histopathology cases) for histopathology interpretations for four of four events in 2024 and 2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Dolehide Dermatology Laboratory Manual", which stated, under "Proficiency Testing", "Twice annually 4-5 cases will be randomly chosen for review by an outside lab/reviewer for accuracy." 2. Review of laboratory records revealed a lack of bi-

	annual method accuracy documentation at least twice annually for histopathology interpretations. 3. Interview with TP #2 on 01/15/2026, at 11:29 am, confirmed the laboratory failed to document biannual method accuracy (proficiency testing/peer reviewed histopathology cases) for histopathology interpretations for four of four events in 2024 and 2025.
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 policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed Mohs micrographic carcinoma exclusion results) for four of four Mohs events performed in 2024 and 2025 in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Proficiency Testing Policy", which stated, under "Procedures:", "Twice annually 4-5 patients will be randomly chosen from our Mohs cases for review by an outside lab/reviewer for accuracy. The results of the proficiency testing (PT) will be forwarded to the laboratory director within one week of their return from the outsides reviewer. The director will carefully evaluate any unacceptable, unsatisfactory or unsuccessful proficiency testing results in an effort to identify the cause of the failure." 2. Review of laboratory policies and procedures revealed the policy titled "Competency /Evaluation Program", which stated, under "Laboratory Proficiency Testing", "Proficiency testing results are reviewed by the Lab Director." 3. Review of laboratory records revealed a lack of documentation of review by the laboratory director for four of four Mohs histopathology bi-annual method accuracy events performed in 2024 and 2025. 4. Interview with TP #2 on 01/15/2026, at 11:29 am, confirmed the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed Mohs micrographic carcinoma exclusion results) for four of four Mohs events performed in 2024 and 2025 in the subspecialty of histopathology.
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 laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for 24 of 24 months in the subspecialty of histopathology in the years of 2024 and 2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Quality Assurance [QA] Policy", which stated, under "QA Checklist", "1. Using the Quality Assurance (QA) Monthly Checklist, pre-

	analytic, analytic and post-analytic processes are monitored in order to identify problems, failures or unacceptable results in specimen processing or patient care." 2. Review of laboratory policies and procedures revealed the procedure titled "Quality Assessment Procedures", which stated, under "3. Ongoing Assessment:", "The Laboratory Director will review, monitor and sign the Monthly QA Checklist in order to assess and correct problem identified in the general laboratory systems." 3. Review of laboratory records revealed a lack of documentation of monthly quality assurance checks performed in laboratory for the previous 24 months reviewed. 4. Interview with TP #2 on 01/15/2026, at 10:31 am, confirmed the laboratory failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for 24 of 24 months in the subspecialty of histopathology in the years of 2024 and 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 laboratory policies and procedures, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to outline control procedures for two of three stains utilized for histopathology testing in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Dolehide Dermatology Laboratory Manual", which stated, under "Procedure Manual", "This laboratory maintains a procedure manual that includes all tests performed." 2. Review of laboratory policies and procedures for histopathology testing failed to outline control procedures for Periodic acid-Schiff (PAS) stain material and immunohistochemical (IHC) stain material. 3. Interview with TP #3 on 01/15/2026, at 11:40 am, confirmed the laboratory failed to outline control procedures for two of three stains utilized for histopathology testing in the subspecialty of histopathology.
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 direct observation, review of manufacturer's instructions for use (IFU), laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to perform and document preventative maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for histopathology testing in the years of 2024 and 2025. Findings include: 1. Upon a tour of the laboratory on 01/15/2026, at 10:10 am, the surveyor observation a Leica Cryostat CM1520 (Serial Number: 00000002222) and a Leica Bond-Max immunohistochemical (IHC) stainer (Serial Number: M496703). 2. Review of the manufacturer IFU for the Leica Cryostat CM1520 revealed, on page 67, under "9.3.1 General maintenance instructions", "At least once a year, have the instrument inspected by a qualified service engineer authorized by Leica." 3. Review of the manufacturer IFU for the Leica Bond-Max IHC stainer revealed, on page 235, under "2.8.0.1 Preventative Maintenance", "BOND notifies you to organize a preventative maintenance service for each processing module once a year or every 15600 slides (whichever comes first)." 4. Review of laboratory policies and procedures revealed the policy titled "General Laboratory Policies", which stated, under "11. Maintenance and Function Checks", "We follow the manufacturer's instructions for maintenance and function checks." 5. Review of laboratory records revealed a lack of documentation of maintenance as defined by the manufacturer for histopathology testing. 6. Interview with TP #2 on 01/15/2026, at 11: 40 am, confirmed the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for histopathology testing in the years of 2024 and 2025.
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: Based on direct observation, review of laboratory policies and procedures, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to establish and document a preventative maintenance (PM) protocol that ensures equipment, instrument, and test system performance for accurate and reliable test results for eight of eight instruments and microscopes utilized for the histopathology testing process. Findings include: 1. Upon a tour of the laboratory on 01/15/2026, at 10:10 am, the surveyor observed the following eight instruments and microscopes utilized for the histopathology testing process: i. Sakura VIP Tissue Processor Model: VIP 5A-F1 Serial Number: 52150479 ii. Epredia Embedding Center a) Cold Module Serial Number: HS7425C1808 b) Embedding Module Serial Number: HS7980A1902 iii. Leica Microtome Model: Histocore BioCut Serial Number: 00243 iv. Thermo Scientific Stainer Model: Linistat Serial Number: LS5532A1811 v. Leica Immunohistochemical Stainer (see D5429) Model: Bond-Max Serial Number: M496703 vi. Leica Cryostat (see D5429) Model: CM1520 Serial Number:

	00000002222 vii. Olympus Microscope Model: BX41 Serial Number: 001720 viii. Amscope Microscope Model: T360B Serial Number: 1272071 2. Review of laboratory policies and procedures revealed the laboratory lacked an established PM protocol that ensures equipment, instrument, and test system performance for accurate and reliable test results. 3. Interview with TP #2 on 01/15/2026, at 11:40 am, confirmed the laboratory failed to establish and document a PM protocol that ensures equipment, instrument, and test system performance for accurate and reliable test results for eight of eight instruments and microscopes utilized for the histopathology testing process in the subspecialty of histopathology.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to exam and document the quality control (intended reactivity) of Hematoxylin and Eosin (H&E) staining material used for 4 of 11 histopathology interpretations reviewed. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Hematoxylin & Eosin Stain [Quality Assurance] QA Policy", which stated, under "Procedures", "1. A daily log sheet is maintained for hematoxylin and eosin stained slides whereby the Lab Director documents the acceptability of the stain produced. "2. The first surgical case of the day serves as the hematoxylin and eosin quality control sample." 2. Review of 4 of 11 patient testing dates revealed a lack of documentation of the examinations for the quality control (intended reactivity) of the H&E stain. Date: Case Number: 10/11/2024 D24-2071 12/02/2024 D24-2406 01/22 /2025 D25-0121 01/24/2025 D25-0125 3. Interview with TP #2 on 01/15/2026, at 11: 47 am, confirmed the laboratory failed to exam and document the quality control (intended reactivity) of H&E staining material used for 4 of 11 histopathology interpretations reviewed.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: a) Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to document special stain known reactivity quality control (QC) for five of five patient Periodic acid-Schiff (PAS) stain testing dates reviewed in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Dolehide Dermatology Laboratory Manual", which stated,

	under "General QC Requirements", "To detect failures in the testing system and to monitor the accuracy of testing over time, every day that patient samples are tested, every laboratory procedure used to test samples will undergo ...QC analysis." 2. Review of patient testing records for dermatopathological interpretations revealed five of five patients tested failed to document special stain known reactivity with each patient slide or group of patient slides. Date: Case #: Special Stain: 11/13/2024 D24-2222 PAS 11/24/2024 D24-2264B PAS 02/24/2025 D25-0313 PAS 02/28/2025 D25-0252 PAS 03/04/2025 D25-0287 PAS 3. Interview with TP #2 on 01/15/2026, at 10: 20 am, confirmed the laboratory failed to document special stain known reactivity QC for five of five patient PAS stain testing dates reviewed in the subspecialty of histopathology. b) Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to document immunohistochemical (IHC) stain quality control (QC) for positive and negative reactivity for six of six patient IHC stain testing dates reviewed in the subspeciality of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Dolehide Dermatology Laboratory Manual", which stated, under "General QC Requirements", "To detect failures in the testing system and to monitor the accuracy of testing over time, every day that patient samples are tested, every laboratory procedure used to test samples will undergo ...QC analysis." 2. Review of patient testing records for dermatopathological interpretations revealed six of six patients tested failed to document IHC stain positive and negative reactivity each time of use. Date: Case #: IHC Stain(s): 10/15/2024 D24-1913 SOX-10 10/30/2024 D24-2071 SOX-10 12/20 /2024 D24-2406 SOX-10 02/10/2025 D25-0125 SOX-10 02/17/2025 D25-0121 SOX-10 02/20/2025 D25-0241 SOX-10 3. Interview with TP #2 on 01/15/2026, at 10:20 am, confirmed the laboratory failed to document IHC stain QC for positive and negative reactivity for six of six patient IHC stain testing dates reviewed in the subspeciality of histopathology.
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 observation, review of manufacturer's instructions for use (IFU), laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory director (LD) failed to ensure the testing systems developed and used for histopathology testing provide quality laboratory services (see D6082), failed to ensure that quality control and quality assessment programs are maintained to assure the quality of laboratory services provided (see D6093) and failed to ensure that quality control was performed by an individual qualified to perform histopathology interpretations (see D6102).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) 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 direct observation, review of manufacturer's instructions for use (IFU), laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory director failed to ensure the performance and documentation of preventative maintenance as defined by the manufacturer (see D5429) and failed to establish and document a preventative maintenance protocol that ensures equipment, instrument, and test system performance for accurate and reliable test results for eight of eight instruments and microscopes utilized for the histopathology testing process (see D5433).
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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory director (LD) failed to ensure biannual method accuracy was performed and evaluated in order to assure the quality of laboratory results (see D5217 and D5221), failed to follow written policies and procedures for monitoring, assessing, and correcting problems identified for 24 of 24 months in the subspecialty of histopathology in the years of 2024 and 2025 (see D5291), and failed to ensure quality control of stains utilized for histopathology interpretations were performed and documented (see D5473 and D5601).
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 policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory director (LD) failed to ensure that Hematoxylin & Eosin (H&E) stain quality control (QC) was performed by a TP qualified to perform histopathology interpretations for 11 of 11 patient testing dates reviewed. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Hematoxylin & Eosin Stain [Quality Assurance] QA Policy", which stated, under "Procedures", "1. A daily log sheet is maintained for hematoxylin and eosin stained slides whereby the Lab Director documents the acceptability of the stain produced. "2 .... The surgeon interprets the quality of the stain." 2. Review of the document titled "H&E Quality Control Log Sheet" revealed lack of documentation identifying the individual evaluating H&E stain quality on 11

	of 11 patient testing dates reviewed. 3. Interview with TP #2 on 01/15/2026, confirmed that they were performing and documenting the daily H&E QC despite not being qualified to perform histopathology interpretations.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, competency records, lack of documentation, and interview with testing personnel (TP) #2; the technical supervisor (TS) failed to evaluate the competency of one of two TP performing histopathological tissue grossing in 2024 and 2025 (see D6120) and failed to ensure semi-annual competency assessments were completed for one of one new TP during the first year the TP performed histopathological grossing (see D6127).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, competency records, lack of documentation, and interview with testing personnel (TP) #2; the technical supervisor (TS) failed to evaluate the competency of one of two TP performing histopathological tissue grossing in 2024 and 2025. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form, signed by the laboratory director (LD) on 01/12/2026, revealed the LD served as the TS. 2. Review of laboratory policies and procedures revealed the policy titled "Competency/Evaluation Program", which stated, under "Policies", "1. The Director is responsible for evaluating the competency of all testing personnel and assuring that the staff maintains their competency to perform test procedures and report test results promptly, accurately and proficiently." 3. Review of laboratory policies and procedures revealed the policy titled "Technical Competency Evaluation Policy", which stated, under "Procedures ...for nonwaived testing:", "After an individual has performed his/her duties for one year, competency must be assessed at least annually." 4. Review of competency records revealed one of two TP (TP #2) failed to have competency assessments completed by the TS in 2024 and 2025. 5. Interview with TP #2 on 01/15/2026, at 1:05 pm, confirmed the TS failed to ensure the competency of one of two TP performing histopathological tissue grossing in 2024 and 2025.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high 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 the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, competency records, lack of documentation, and interview with testing personnel (TP) #2; the technical supervisor (TS) failed to ensure semi-annual competency assessments were completed for one of one new TP during the first year the TP performed histopathological grossing. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form, signed by the laboratory director (LD) on 01/12/2026, revealed the LD served as the TS. 2. Review of laboratory policies and procedures revealed the policy titled "Competency/Evaluation Program", which stated, under "Policies", "1. The Director is responsible for evaluating the competency of all testing personnel and assuring that the staff maintains their competency to perform test procedures and report test results promptly, accurately and proficiently." 3. Review of laboratory policies and procedures revealed the policy titled "Technical Competency Evaluation Policy", which stated, under "Procedures ... for nonwaived testing:", "During the first year of an individual's (TP) duties, competency must be assesses at least semiannually". 4. Review of competency records revealed one of one new TP failed to have competency assessments completed semi-annually in the first year of patient testing. TP #3 Date of Hire: 08/21/2023 Dates of Competency Evaluations: 08/24/2023 09/09/2024 03/11/2025 5. Interview with TP #2 on 01/15/2026, at 1:05 pm, confirmed the TS failed to ensure semi-annual competency assessments were completed for one of one new TP during the first year the TP performed histopathological grossing.