Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D2227795	02/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ascent Surgery Center	4889 Munson St, Nw, Suite A, Canton, OH	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the laboratory failed to establish and follow written policies and procedures to assess the competency of the General Supervisors (GS), based on the responsibilities of the position and at a frequency determined by the laboratory. The laboratory also failed to establish and follow written policies and procedures to assess the competency of testing personnel (TP) as specified in the personnel requirements in subpart M for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Pathology Policies" manual, provided on the date of the inspection, did not find any mention of competency assessment procedures for the GS based on the responsibilities of the position, at a frequency determined by the laboratory and TP utilizing the six required components. 2. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02/03/2023, revealed four individuals listed and qualified by the Laboratory Director to function as a GS and TP. 3. The Inspector requested the laboratory's policy and procedure for the competency assessment of the GS's and TP's and the competency assessment documentation for GS#1, GS#2, GS#3, GS#4 based on the responsibilities of the position and for TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a policy and procedure for the assessment of the GS's and TP's, did not assess the competency of the GS's based on the responsibilities of the position, at a

	frequency determined by the laboratory, did not assess the competency of the TP's and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 8:00 AM.
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 record review and an interview with the Clinical Director (CD), the laboratory failed to establish and conduct blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02 /06/2023. Findings Include: 1. Review of the laboratory's "Pathology Policies" policy and procedure, provided on the date of the inspection, did not find any instructions to conduct blind TAV activities for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections performed, at least twice annually. 2. The Inspector requested the laboratory's TAV policy and procedure and documentation of blind TAV from the CD. The CD confirmed the laboratory did not establish and follow a policy and procedure for blind TAV activities at least twice annually for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 11:09 AM.
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 record review and an interview with the Clinical Director (CD), the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems with the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02 /06/2023. Findings Include: 1. The Laboratory Director failed to ensure that policies and procedures for high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology were approved via signature and date before implementation. (Refer to D5407) 2. The laboratory failed to label the secondary containers of reagents, solutions and stains in

	the slide stain station with their contents, lot numbers and expiration dates which were utilized for high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D5415) 3. The laboratory failed to establish and demonstrate, before reporting patient test results, performance specifications for the cryostat, slide staining station and microscope to include accuracy, precision and any other performance characteristics required for accurate and reliable high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D5423) 4. The laboratory failed to establish a maintenance policy and procedure that ensures temperature, humidity and microscope test system performance necessary for accurate and reliable high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D5435) 5. The laboratory failed to establish a hematoxylin and eosin (H&E) quality control (QC) policy and procedure, including the criteria of acceptability, and document H&E stain quality control (QC) activities corresponding to the intended stain reactivity to ensure predictable staining characteristics each day of use for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D5469) 6. The laboratory failed to perform and document hematoxylin and eosin (H&E) stain quality control (QC) for the intended reactivity to ensure predictable staining characteristics each day of use for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D5473)
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the Laboratory Director failed to ensure that policies and procedures for high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology were approved via signature and date before implementation. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Pathology Policies" manual, provided on the date of the inspection, revealed the following procedures were approved by the Laboratory Director on 11/01/2022, after the testing was implemented on 08/11/2022. "Section 1.0 Frozen Section" "Section 1.2 Labeling /Expiration Dates/Storage of Reagents and Stains" "Section 1.3 Storage of Flammable Liquids" "Section 1.5 Cryostat Decontamination" "Section 1.6 Xylene Safety Program" "Section 1.7 Formaldehyde and Xylene Environmental Monitoring" "Section 1.8 Recommended Precautions for Mycobacterium Tuberculosis" "Section 1.9 Daily Logs" "Section 1.10 Use of Flammable Freezing Spray Inside the Cryostat" 2. Further review of the laboratory's "Pathology Policies" manual, revealed the following policies and procedures were on a hospital laboratory's letterhead and had not been approved by the Laboratory Director. "Transcription of Pathology Reports" "QAP Reports" "Frozen Sections" "Reporting Frozen Sections" 3. The CD confirmed the Laboratory Director did not approve the laboratory's policies and procedures prior to implementing the high complexity tissue biopsy grossing and slide interpretation

	testing procedures for frozen sections. The interview occurred on 02/06/2023 at 8:30 AM.
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 record review, direct observation and an interview with the Clinical Director (CD), the laboratory failed to label the secondary containers of reagents, solutions and stains in the slide stain station with their contents, lot numbers and expiration dates, which were utilized for high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Section 1.2 Labeling/Expiration Dates /Storage of Reagents and Stains" policy and procedure, approved by the Laboratory Director via signature and date on 11/01/2022 and provided on the date of the inspection, revealed the following information: "Policy Reagents, stains, chemicals, and solutions are properly labeled in the Pathology Frozen Section room. If any container is missing a label or required information, corrective action must be taken. GUIDELINES FOR LABELING * Content and quantity; concentration or titer * Storage requirements * Date prepared, filled or reconstituted * Expiration date" 2. Direct observation of the secondary containers in the slide stain station on 02/06/2023 at 11:35 AM, did not find each container labeled with their contents, lot number and expiration date. 3. The Inspector requested the laboratory's reagent log documentation and the stock bottles of the reagents, solutions and stains utilized in the slide stain station, the lot numbers and the expiration dates from the CD. The CD stated the original reagents, solutions and stains received upon implementing frozen section testing were still in use. Direct observation of the stock bottles found them to be labeled and within the manufacturer's expiration dates. The CD confirmed the secondary containers were not labeled as required, the laboratory did not establish a reagent log and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 3:55 PM.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any

	other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the laboratory failed to establish and demonstrate, before reporting patient test results, performance specifications for the cryostat, slide staining station and microscope to include accuracy, precision and any other performance characteristics required for accurate and reliable high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Pathology Policies" policy and procedure manual, provided on the date of the inspection, did not find any instructions for performance specification studies on the cryostat, slide stain station and the microscope. 2. The Inspector requested the laboratory's policy and procedure for performance specification activities and the performance specification documentation prior to reporting patient test results for the cryostat, slide stain station and microscope from the CD. The CD confirmed the laboratory did not establish a performance specification policy and procedure for the cryostat, slide stain station and microscope, did not conduct and document any performance specification activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 8:25 AM.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the laboratory failed to establish a maintenance policy and procedure that ensures temperature, humidity and microscope test system performance necessary for accurate and reliable high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Pathology Polices" procedure manual, provided on the date of the inspection, did not find any mention of a temperature, humidity or microscope maintenance policy and procedure. 2. The Inspector requested the laboratory's temperature, humidity and microscope maintenance policy and procedure and microscope maintenance documentation for each day of stain use between 08/11 /2022 through 02/06/2023 from the CD. The CD stated the laboratory did not establish

	a temperature, humidity and microscope policy and procedure, did not document any microscope maintenance and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:55 AM.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the laboratory failed to establish a hematoxylin and eosin (H&E) quality control (QC) policy and procedure, including the criteria of acceptability, and document H&E stain quality control (QC) activities corresponding to the intended stain reactivity to ensure predictable staining characteristics each day of use for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11 /2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Pathology Polices" procedure manual, provided on the date of the inspection, did not find any mention of an H&E stain quality control policy and procedure. 2. The Inspector requested the laboratory's H&E stain QC policy and procedure and QC documentation for each day of stain use between 08/11/2022 through 02/06/2023 from the CD. The CD stated the laboratory did not establish an H&E stain QC policy and procedure, did not document the intended stain characteristics or any stain QC and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:43 AM.
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 record review and an interview with the Clinical Director (CD), the laboratory failed to perform and document hematoxylin and eosin (H&E) stain quality

	control (QC) for the intended reactivity to ensure predictable staining characteristics each day of use for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Pathology Polices" procedure manual, provided on the date of the inspection, did not find any mention of an H&E stain quality control policy and procedure. 2. The Inspector requested the laboratory's H&E stain QC policy and procedure and QC documentation for each day of stain use between 08/11/2022 through 02/06/2023 from the CD. The CD stated the laboratory did not establish an H&E stain QC policy and procedure, did not document the intended stain characteristics or any stain QC and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:43 AM.
D5805	TEST REPORT CFR(s): 493.1291(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: Item 1 Based on record review and an interview with the Clinical Director (CD), the laboratory failed to indicate positive patient identification (ID), either by name and ID or a unique patient identifier and ID number that correlated to the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections conducted in the subspecialty of Histopathology on the final test report. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of 13 out of 41 of the laboratory's final patient test reports revealed 13 out of 13 final test reports did not indicate positive patient ID for the high complexity tissue biopsy grossing and slide interpretation testing procedures for the frozen section testing conducted. The patient name is the only identifier that correlates between the "Frozen Section Requisition" and the final "Laboratory Report" issued by the reference laboratory when reporting the permanent biopsy result. 2. The CD confirmed the laboratory did not indicate positive ID of the patient utilizing either name and ID or a unique patient identifier and ID number for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen section testing that were conducted and correlated to the final patient test report. The interview occurred on 02/06/2023 at 11:30 AM. Item 2 Based on record review and an interview with the Clinical Director (CD), the laboratory failed to consistently indicate the correct address of the laboratory location where the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections performed in the subspecialty of Histopathology were conducted on the final test report. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023.

	Findings Include: 1. Review of 13 out of 41 of the laboratory's final patient test reports revealed three final test reports did not indicate the name and address of the laboratory location where the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections laboratory testing was conducted. 2. The CD confirmed the laboratory did not consistently indicate the name and address of the laboratory location where the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections laboratory testing were conducted on the final patient test report. The interview occurred on 02/06/2023 at 11: 30 AM.
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 record review and an interview with the Clinical Director (CD), the Laboratory Director failed to ensure that a quality assessment program was established and maintained to assure the quality of the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections provided in the subspecialty of Histopathology and to identify failures in quality as they occur. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's "Pathology Policies" policy and procedure manual provided on the date of the inspection did not find any mention of a quality assessment policy and procedure. 2. The Inspector requested the laboratory's quality assessment policy and procedure and their quality assessment documentation from the CD. The CD confirmed that the laboratory did not establish a quality assessment policy and procedure, did not document any quality assessment activities and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 11:09 AM.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 record review and an interview with the Clinical Director (CD), the Laboratory Director failed to ensure that, prior to testing patients' specimens, four out of four testing personnel (TP) were trained and had documentation as evidence that they could perform all testing operations reliably to provide and report accurate results for the high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since

	the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02 /03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and documentation of training and demonstration that TP#1, TP#2, TP#3 and TP#4 could perform all testing operations reliably to provide and report accurate results for the high complexity tissue biopsy grossing and slide interpretation testing procedures, prior to testing patients' specimens, from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, did not conduct and document competency assessments for the TP, prior to testing patients' specimens, did not document that the TP were trained and demonstrated they could perform all testing operations reliably to provide and report accurate results for the high complexity tissue biopsy grossing and slide interpretation testing procedures performed and was not able to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:25 AM.
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 record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to provide technical supervision to evaluate and ensure four out of four testing personnel (TP) maintained their competency to perform high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. The TS failed to include direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D6121) 2. The TS failed to include monitoring the recording and reporting of test results in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D6122) 3. The TS failed to include the review of intermediate test results or worksheets, quality control records, test accuracy verification results and preventive maintenance records in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D6123) 4. The TS failed to include direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing

	and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D6124) 5. The TS failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D6125) 6. The TS failed to include the assessment of problem solving skills in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D6126) 7. The TS failed to evaluate and document the six month competency assessment during the first year of testing patients for four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. (Refer to D6127)
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to include direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02 /06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02/03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation of the competency of TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, did not conduct and document competency assessments for the TP, therefore did not include direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing in the evaluation of the TP competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:25 AM.
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii)

	The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to include monitoring the recording and reporting of test results in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02/03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included monitoring the recording and reporting of test results in the evaluation of the competency of TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, did not conduct and document competency assessments for the TP, therefore did not include the review of intermediate test results or worksheets, quality control records, test accuracy verification results and preventive maintenance records in the evaluation of the TP competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:25 AM.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to include the review of intermediate test results or worksheets, quality control records, test accuracy verification results and preventive maintenance records in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02/03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included the review of intermediate test results or worksheets, quality control records, test accuracy

	verification results and preventive maintenance records in the evaluation of the competency of TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, did not conduct and document competency assessments for the TP, therefore did not include the review of intermediate test results or worksheets, quality control records, test accuracy verification results and preventive maintenance records in the evaluation of the TP competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:25 AM.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to include direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11 /2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02/03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, did not conduct and document competency assessments for the TP, therefore did not include direct observation of performance of instrument maintenance and function checks in the evaluation of the TP competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:25 AM.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or

	external proficiency testing samples in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02 /06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02/03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, did not conduct and document competency assessments for the TP, therefore did not include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the TP competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:25 AM.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to include the assessment of problem solving skills in the evaluation of the competency of four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02/06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02 /03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and documentation that included the assessment of problem solving skills in the evaluation of the competency of TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, did not conduct and document competency assessments for the TP, therefore did not include the assessment of problem solving skills in the evaluation of the TP competency and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 10:25 AM.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for 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 record review and an interview with the Clinical Director (CD), the Technical Supervisor (TS) failed to evaluate and document the six month competency assessment during the first year of testing patients for four out of four testing personnel (TP) who conducted high complexity tissue biopsy grossing and slide interpretation testing procedures for frozen sections in the subspecialty of Histopathology. This deficient practice had the potential to affect 41 out of 41 frozen section cases performed since the implementation of testing on 08/11/2022 through 02 /06/2023. Findings Include: 1. Review of the laboratory's Form CMS-209, approved by the Laboratory Director on 02/03/2023, revealed four out of four individuals listed as TP to perform high complexity frozen section tissue biopsy grossing and slide interpretation testing procedures. 2. Review of the laboratory's "Pathology Policies" manual provided on the date of the inspection did not find any mention of competency assessment procedures. 3. The Inspector requested the laboratory's competency assessment policy and procedure and the six month (first semi-annual) frozen section tissue biopsy grossing and slide interpretation competency assessment documentation for TP#1, TP#2, TP#3 and TP#4 from the CD. The CD confirmed the laboratory did not establish a competency assessment policy and procedure, the TS did not conduct and document a six month competency assessment for frozen section tissue biopsy grossing and slide interpretation testing procedures for TP#1, TP#2, TP#3 and TP#4, as required and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 02/06/2023 at 8:15 AM.