Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0430815	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Morrison Community Hospital	303 N Jackson, Morrison, 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
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 review of laboratory documents, lack of documentation, and interviews with the general supervisor (GS) and the laboratory director (LD); the laboratory failed to ensure patient testing records and activities were documented and retained in the subspecialty of histopathology from the beginning of 2024 through the date of survey, 04/09/2025, affecting 25 patients. Findings include: 1. Review of laboratory records revealed the document titled, "Pathologist Visit Log", which indicated, on the following dates, that Frozen Section Tissue Biopsies were performed: Date: "On-Site Activity or Items Addressed": 01/30/2024 "Frozen Section" 02/27/2024 "Frozen Sections x2" 03/26/2024 "Frozen x3" 05/28/2024 "Frozen x4" 07/23/2024 "Frozen x4" 08/27/2024 "Frozen x3" 09/24/2024 "Frozen x2" 11/26/2024 "Frozen Section" 02 /11/2025 "Frozen Section x1" 03/25/2025 "4 frozens" 2. Interview with LD via telephone on 04/09/2024, at 1:10 pm, revealed that the laboratory did not document which patients had Frozen Section Tissue Biopsies performed on each day of patient testing. 3. Interview with the GS on 04/09/2025, at 12:24 pm, confirmed the laboratory failed to ensure patient testing records and activities were documented and retained in the subspecialty of histopathology from the beginning of 2024 through the date of survey, 04/09/2025, affecting 25 patients.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210

	If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory records, lack of documentation, and interviews with the general supervisor and testing personnel #3; the laboratory failed to ensure accuracy of five of five analytes not evaluated by the PT provider (See D5213), failed to test one sample of control material each eight hours of testing using a combination of control materials that include both low and high values on each day of patient testing for four of four blood gas testing patients reviewed (See D5537), and failed to have a system in place that twice annually evaluates the relationship between testing on two of two Siemens Epoc analyzers and one of one Siemens Atellica analyzer (See D5775).
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, laboratory test reports, the CMS-209 (Laboratory Personnel Report), lack of documentation, and interviews with the laboratory director, general supervisor, and testing personnel #3; the laboratory failed to perform bi-annual method accuracy verifications (proficiency testing/peer reviewed histopathology interpretations) twice a year for frozen section biopsy testing (See D5217), failed to outline all components of the test procedures for Frozen Section Tissue Biopsy testing (See D5403), failed to have one of one procedure reviewed, approved, signed, and dated by the current laboratory director (See D5407), failed to ensure 22 of 22 provided histopathology reports were signed by a qualified individual (See D5607), and failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system by ensuring the Cryostat temperature was recorded for two of ten days of patient testing reviewed (See D5791) in the subspecialty of histopathology.
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 review of the CMS-209 (Laboratory Personnel Form), laboratory policies and procedures, lack of documentation, and interview with the general supervisor (GS); the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one general supervisor. Findings

	include: 1. Review of the CMS-209 (Laboratory Personnel Form) revealed one general supervisor. 2. Review of the laboratory policies and procedures revealed the laboratory lacked a competency assessment policy and procedure to assess the competency of one of one GS. 3. Interview with GS #1 on 04/08/2025, at 12:18 pm, confirmed the laboratory failed to have a competency policy and procedure in place to assess competency for one of one GS.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, lack of documentation, and interviews with the general supervisor (GS) and testing personnel (TP) #3; the laboratory failed to ensure accuracy of five of five analytes not evaluated by the PT provider in the specialties of chemistry and immunohematology in 2023 and 2024. Findings include: 1. Review of API comparative evaluation summaries for the following PT events of 2023 and 2024 revealed the following un-graded PT samples: PT Event: Analyte: Sample: 2023 Event 1 - Chemistry ALT* CH-01 2023 Event 3 - Immunohematology Compatibility SER-12 2024 Event 1 - Chemistry Total Bilirubin CH-02 2024 Event 1 - Chemistry Total Bilirubin CH-03 2024 Event 1 - Chemistry Total Bilirubin CH-05 *ALT = alanine aminotransferase 2. Review of laboratory records found no documented review of the ungraded PT analytes in the specialties of chemistry and immunohematology in 2023 and 2024. 3. Interviews with the GS and TP #3 on 04/09 /2025, at 2:22 pm, confirmed the laboratory failed to ensure accuracy of five of five analytes not evaluated by the PT provider in the specialties of chemistry and immunohematology in 2023 and 2024.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy verifications (proficiency testing/peer reviewed histopathology interpretations) twice a year for frozen section biopsy testing in the subspecialty of histopathology from the beginning of 2024 through the date of survey, 04/09/2025, affecting 25 patient test results. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Frozen Sections", which stated, under "7. Competency: Each of the pathologists will review one frozen section per year which has been performed at [this laboratory] ...." 2. Review of laboratory records revealed no documentation of bi-annual method accuracy verifications for histopathology frozen section biopsies tested from the beginning of 2024 through the date of survey, 04/09/2025, affecting 25 patients. Date: # of frozen section biopsies

	performed: 01/30/2024 "Frozen Section" 02/27/2024 "Frozen Sections x2" 03/26 /2024 "Frozen x3" 05/28/2024 "Frozen x4" 07/23/2024 "Frozen x4" 08/27/2024 "Frozen x3" 09/24/2024 "Frozen x2" 11/26/2024 "Frozen Section" 02/11/2025 "Frozen Section x1" 03/25/2025 "4 frozens" 3. Interview with the LD via telephone on 04/09/2025, at 2:25 pm, confirmed the laboratory failed to perform bi-annual method accuracy verifications (proficiency testing/peer reviewed histopathology interpretations) twice a year for frozen section biopsy testing in the subspecialty of histopathology from the beginning of 2024 through the date of survey, 04/09/2025.
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 the general supervisor (GS); the laboratory failed to outline all components of the test procedures for Frozen Section Tissue Biopsy testing in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Frozen Sections", which failed to outline the following components: a. Microscopic examination, including the detection of inadequately prepared slides. b. Control procedures. c. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. d. Limitations in the test methodology, including interfering substances. e. Pertinent literature references. f. The laboratory's system for entering results in the patient record and reporting patient results. g. Description of the course of action to take if a test system becomes inoperable. 2. Interview with the GS on 04/09/2025, at 1:39 pm, confirmed the laboratory failed to outline all components of the test procedures for Frozen Section Tissue Biopsy testing in the subspecialty of histopathology.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 review of laboratory policies and procedures, lack of documentation, and interview with the general supervisor; the laboratory failed to have one of one procedure reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Report) in the subspecialty of histopathology. Findings include: 1. Review of laboratory policy and procedure manuals revealed no laboratory director approval, including signature and date, by the current laboratory director on the histopathology procedure titled, "Frozen Sections". 2. Interview with the GS on 04/09/2025, at 1:39 pm, confirmed the laboratory failed to have the histopathology procedure reviewed, approved, signed, and dated by the current laboratory director.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interviews with the general supervisor (GS) and testing personnel (TP) #3; the laboratory failed to test one sample of control material each eight hours of testing using a combination of control materials that include both low and high values on each day of patient testing for four of four blood gas testing patients reviewed in the subspecialty of routine chemistry. Findings include: 1. Blood gas testing reports were reviewed from 2023 through the date of survey, 04/09/2025. 2. Review of four of four patient test reports for blood gas testing in the subspecialty of routine chemistry found that no quality control testing was documented for the dates performed. Date: Patient #: 05/20/2023 188874 11/22 /2023 39391 04/09/2024 3919 09/19/2024 15599 3. Interview with the GS and TP #3 on 04/09/2025, at 2:25 pm, confirmed the laboratory failed to test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of patient testing in the subspecialty of routine chemistry.
D5607	HISTOPATHOLOGY CFR(s): 493.1273(d)(f) (d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, patient test reports, and interview with the general supervisor (GS); the laboratory failed to ensure 22 of 22 provided histopathology reports were signed by a qualified individual (histopathology testing personnel A) from 2024 through the date of survey, 04/09/2025. Findings include: 1. Review of the CMS-209, Laboratory Personnel Report, revealed the same qualified individual functioned as the laboratory

	director, the technical supervisor, and testing personnel A. 2. Review of laboratory policies and procedures revealed the procedure titled, "Frozen Sections", which stated, under "6. Reporting Results: The pathologist will report the frozen section diagnosis verbally to the ordering physician. This will be documented on both the requisition and the final pathology report." 3. Review of 22 of 22 provided patient test reports for histopathology failed to be signed by a qualified individual. Specimen #: Date of Service: S24-00746 01/30/2024 S24-01526 02/27/2024 S24-01529 02/27/2024 S24-02332 03/26/2024 S24-02333 03/26/2024 S24-02334 03/26/2024 S24-04068 05/28 /2024 S24-04069 05/28/2024 S24-04070 05/28/2024 S24-05554 07/23/2024 S24-05556 07/23/2024 S24-05557 07/23/2024 S24-06464 08/27/2024 S24-06494 08/27 /2024 S24-06497 08/27/2024 S24-07244 09/24/2024 S24-07245 09/24/2024 S24-09142 11/26/2024 S25-01107 02/11/2025 S25-02306 03/25/2025 S25-02311 03/25 /2025 S25-02314 03/25/2025 4. Interview with the GS via electronic communication on 04/16/2025, at 9:58 am, confirmed the laboratory failed to ensure 22 of 22 provided histopathology reports were signed by a qualified individual (histopathology testing personnel A) from 2024 through the date of survey, 04/09/2025.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: a) Based on direct observation, review of laboratory records, lack of documentation, and interviews with the general supervisor (GS) and testing personnel (TP) #3; the laboratory failed to have a system in place that twice annually evaluates the relationship between testing on two of two Siemens Epoc analyzers (Serial Numbers: 47483 and 48458) and one of one Siemens Atellica analyzer (Serial Number: SNIRC006762331) utilized for sodium (Na), potassium (K), chloride (Cl), glucose, blood urea nitrogen (BUN), creatinine, and lactic acid analytes in the subspecialty of routine chemistry from the beginning of testing in November, 2023 through the date of survey, 04/09/2025. Findings include: 1. Upon a tour of the laboratory on 04/08 /2025, at 3:04 pm, direct observation identified two Siemens Epoc analyzers (Serial Numbers: 47483 and 48458) and one Siemens Atellica analyzer (Serial Number: SNIRC006762331) utilized for sodium (Na), potassium (K), chloride (Cl), glucose, blood urea nitrogen (BUN), creatinine, and lactic acid analytes in routine chemistry testing. 2. Review of laboratory procedures for Atellica and Epoc analyte testing identified that the procedures failed to address how the relationship between the three analyzers will be evaluated twice annually. 3. Review of laboratory records revealed one instrument-to-instrument comparisons performed using one Epoc analyzer (with no indication of which Epoc analyzer) and the Atellica analyzer from the beginning of testing in November, 2023 through the date of survey, 04/09/2025. Date of "Atellica Epoc Comparison Study": October, 2024 4. Interviews with the GS and TP #3 on 04 /09/2025, at 1:10 pm, confirmed the laboratory failed to have a system in place that twice annually evaluates the relationship between testing on two of two Siemens Epoc analyzers and one of one Siemens Atellica analyzer utilized for routine chemistry testing. b) Based on direct observation, review of laboratory records, lack of documentation, and interviews with the general supervisor (GS) and testing personnel (TP) #3; the laboratory failed to have a system in place that twice annually evaluates

	the relationship between testing on two of two Siemens Epoc analyzers (Serial Numbers: 47483 and 48458) utilized for blood gas testing including pH, carbon dioxide pressure (pCO2), oxygen pressure (pO2), bicarbonate, base excess, oxygen saturation, and total carbon dioxide (T.CO2), from the beginning of testing in November, 2023 through the date of survey, 04/09/2025, in the subspecialty of routine chemistry. Findings include: 1. Upon a tour of the laboratory on 04/08/2025, at 3:04 pm, direct observation identified two Siemens Epoc analyzers (Serial Numbers: 47483 and 48458) utilized for blood gas testing in the subspecialty of routine chemistry. 2. Review of the laboratory's procedure for Epoc blood gas testing identified that the procedure failed to address how the relationship between the two Epoc analyzers will be evaluated twice annually. 3. Review of laboratory records revealed no instrument-to-instrument comparisons for blood gas analytes performed on two of two Siemens Epoc analyzers from the beginning of testing in November, 2023 through the date of survey, 04/09/2025. 4. Interviews with the GS and TP #3 on 04/09/2025, at 1:10 pm, confirmed the laboratory failed to have a system in place that twice annually evaluates the relationship between testing on two of two Siemens Epoc analyzers utilized for blood gas testing from the beginning of testing in November, 2023 through the date of survey, 04/09/2025, in the subspecialty of routine chemistry.
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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director (LD) and the general supervisor (GS); the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system by ensuring the Cryostat temperature was recorded for two of ten days of patient testing reviewed in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Frozen Sections", which stated, under "2. Operation of Cryostat: ... Each time of use, the temperature and quality of stain are recorded." 2. Review of laboratory records revealed a lack of documentation on the following dates of patient testing: i) 03/26/2024 No Cryostat temperature documentation ii) 11/26/2024 No Cryostat temperature documentation 3. Interview with the LD, via telephone, and the GS on 04/09/2025, at 2:22 pm, confirmed the laboratory failed to record the Cryostat temperature for two of ten days of patient testing reviewed in the subspecialty 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 laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director, the general supervisor, and testing personnel #3; the laboratory director failed to perform bi-annual method accuracy verifications (proficiency testing/peer reviewed histopathology interpretations) twice a year for frozen section biopsy testing in the subspecialty of histopathology (See D6079), failed to ensure a system was in place that twice annually evaluates the relationship between testing on two of two Siemens Epoc analyzers and one of one Siemens Atellica analyzer (See D6086), failed to ensure accuracy of five of five analytes not evaluated by the PT provider in the specialties of chemistry and immunohematology in 2023 and 2024 (See D6091), failed to ensure one sample of control material was tested each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of patient testing for four of four blood gas testing patients reviewed (See D6093), failed to ensure one of one procedure was reviewed, approved, signed, and dated in the subspecialty of histopathology (See D6106), and failed to establish and maintain competency records for the duties of one of one general supervisors (See D6103).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory director (LD); the LD failed to perform bi-annual method accuracy verifications (proficiency testing/peer reviewed histopathology interpretations) twice a year for frozen section biopsy testing in the subspecialty of histopathology from the beginning of 2024 through the date of survey, 04/09/2025, affecting 25 patient test results (See D5217).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, lack of documentation, and interviews with the general supervisor (GS) and testing personnel (TP) #3; the laboratory director failed to ensure a system was in place that twice annually evaluates the relationship between testing on two of two Siemens Epoc analyzers (Serial

	Numbers: 47483 and 48458) and one of one Siemens Atellica analyzer (Serial Number: SNIRC006762331) (See D5775).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute proficiency testing (PT) records, laboratory records, lack of documentation, and interviews with the general supervisor and testing personnel #3; the laboratory director failed to ensure accuracy of five of five analytes not evaluated by the PT provider in the specialties of chemistry and immunohematology in 2023 and 2024 (See D5213).
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 records, lack of documentation, and interviews with the general supervisor (GS) and testing personnel (TP) #3; the laboratory director failed to ensure one sample of control material was tested each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of patient testing for four of four blood gas testing patients reviewed in the subspecialty of routine chemistry (See D5537).
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 laboratory competency records, laboratory policy and procedure, lack of documentation, the CMS-209 (Laboratory Personnel Report) and interview with the general supervisor (GS); the laboratory director failed to establish and maintain competency records for the duties of one of one general supervisors. Findings Include: 1. Review of CMS-209 Laboratory Personnel Report revealed the laboratory had one general supervisor. 2. Review of laboratory competency records revealed that the GS failed to have competency evaluations documented for the GS

	position in 2023 and 2024. 3. Review of laboratory policy and procedure titled "Employee Training and competency assessment" revealed that no procedure was in place to assess general supervisor competency (See D5209). 4. On survey date 04-08-25, at 12:18 pm, the GS confirmed that the laboratory did not have a procedure in place to assess GS competency and had not completed competency assessment records for the GS in 2023 or 2024.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, and interview with the general supervisor; the laboratory director failed to ensure one of one procedure was reviewed, approved, signed, and dated in the subspecialty of histopathology (See D5407).
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (b)(3) Providing orientation to all testing personnel; and (b)(4) Evaluating and documenting the competency of all testing personnel. This STANDARD is not met as evidenced by: Based on review of laboratory competency records, laboratory policy and procedure, and interview with the general supervisor (GS); the general supervisor failed to ensure competency for 3 of 27 testing personnel (TP) that performed high complexity testing for hematology, coagulation, urinalysis, immunohematology, and serology. Findings Include: 1. The laboratory's competency assessment records were reviewed for 2023 through 2025. 2. Review of laboratory policy and procedure revealed a document titled "Employee Training and Competency assessment", which stated, "Annually, all technical staff will have a competency assessment, performed by the laboratory manager, for each test system." 3. Review of competency assessment records revealed that the laboratory failed to have competency assessment records for Hematology, Coagulation, Urinalysis, Blood Banking, and Serology for: TP #1 for 2023 and 2024 TP #12 for 2025 TP #22 for 2024 4. On survey date 04-08-2025, at 12:18 pm, GS confirmed that the laboratory did not have competency assessment records for TP #1, TP #12, and TP #22.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Repeat Deficiency Based on review of laboratory personnel records and interview

	with general supervisor; the laboratory failed to ensure 5 of 27 testing personnel (TP) were qualified for laboratory testing (See D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Repeat Deficiency Based on review of laboratory personnel records and interview with general supervisor (GS); the laboratory failed to ensure 5 of 27 testing personnel (TP) were qualified for high complexity laboratory testing. Findings include: 1. Laboratory was cited for this during previous survey on 12-22-2021. 2. Review of personnel educational documentation revealed 5 of 27 TP (TP #12, TP #14, TP #18, TP #19, and TP #24) failed to meet the education requirements to qualify as a high complexity TP. TP #12 - No educational documentation (degree and/or transcripts) provided, lab provided ASCP certification. TP #14 - No educational documentation (degree and/or transcripts) provided, lab provided medical technologist certificate. TP #18 - No foreign equivalency documentation provided for a foreign Bachelor of Science degree. TP #19 - No educational documentation (degree and/or transcripts)

	provided, lab provided an undergraduate certificate in health science Lab. Technology. TP #24 - No educational documentation (degree and/or transcripts) provided, lab provided an undergraduate certificate in health science Lab. Technology. 3. On survey date 04-09-2025, at 2:26 pm, the GS confirmed the laboratory failed to ensure TP #12, TP #14, TP #18, TP #19, and TP #24 were qualified for high complexity laboratory testing.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on surveyor requests for documentation, lack of documentation/materials provided, and interviews with the general supervisor (GS) and testing personnel (TP) #3; the laboratory failed to ensure retrieval of all laboratory records, slides, and necessary documentation upon surveyor request for documents from the past 24 months of patient testing. Findings include: 1. The laboratory failed to provide an individualized quality control plan for blood gas testing in the subspecialty of routine chemistry. 2. The laboratory failed to provide educational documentation for 5 of 27 surveyor requested TP. 3. The laboratory failed to provide 3 of 25 histopathology patients' records requested from the frozen section patients recorded on the "Pathologist Visit Log". Date: Pathology Visit Log: # of cases provided: 05/28/2024 "Frozen x4" 3 cases provided. 07/23/2024 "Frozen x4" 3 cases provided. 03/25/2025 "4 frozens" 3 cases provided. 4. The laboratory failed to provide 18 of 22 reviewed histopathology patient test reports requested. 5. The laboratory failed to provide histopathology slides for 25 of 25 histopathology cases. 6. Interviews with the GS and TP #3 on 04/09/2025, at 2:25 pm, confirmed the laboratory failed to ensure retrieval of all laboratory records, slides, and necessary documentation upon surveyor request.