Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0430815	12/22/2021
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review, manuals, and interview, the laboratory failed to ensure the laboratory director (LD) attested to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods for nine out of nine Pt events in 2021 during the year of 2021. Findings include: 1. The laboratory procedures manual and American Proficiency Institute (API) PT documents for 2019 through 2021 were reviewed. 2. The PT policy and procedure and API-PT program instructions required the signature of the LD or technical supervisor (TS) to attest to the treatment and testing of PT samples when submitting any PT results to the PT program, as a condition of participation, for each PT event. 3. The PT documents of 2021 revealed nine out of nine attestation statements were not signed by the LD or TS for tests performed in the specialties of Hematology, Chemistry and Immunochemistry. 4. On a Recertification survey conducted on 12/22/2021 at 2:30 PM, the TS confirmed the above findings.
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 interview, the laboratory director (LD) failed to ensure prior to testing patients' specimens, all personnel had the appropriate education to perform all testing operations reliably to provide and report accurate results, affecting three out of five testing personnel (TP). Findings include: 1. The laboratory personnel documents, the Laboratory Personnel Report (CMS 209), and patients' test logs were reviewed. 2. The LD failed to ensure three new laboratory employees met education requirements to perform high complexity testing. See D6168 and D6171. 3. The personnel training and competency records and test logs revealed all three employees were performing patient testing in laboratory 4. On a Recertification survey conducted on 12/22/2021 at 2:30 PM, the TS confirmed the above findings.
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: Based on record review, the Laboratory Personnel Report (CMS 209), and interview, the laboratory failed to employ individuals who meet the qualification requirements of 493.1489 to perform the functions of highly complex testing in the laboratory for three out of five testing personnel (TP), prior to testing patients. Findings: 1. The laboratory failed to ensure new laboratory staff meet the education criteria specified in 493.1489(b) (1-3) for highly complex 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 have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could

	have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (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; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS-209), and interview, the laboratory failed to ensure laboratory employees meet the qualification requirements for performing highly complex testing for three out of five testing personnel (TP). Findings: 1. The CMS 209 list three new hires (TP1, TP2, and TP3) to performing moderately and highly complex testing in the laboratory. 2. Review of the employee files revealed the three new TP failed to include education credentials. 3. On a Recertification survey conducted on 12/22/2021 at 2:30 PM, the TS confirmed the above findings.