Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 24D0863151	**(X3) Date Survey Completed** 03/29/2023
Name of Provider or Supplier Warren Community Hospital	**Street Address, City, State** 300 West Good Samaritan Drive, Warren, MN	
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. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to retain Endocrinology quality control records for at least two years for one of four Endocrinology test results obtained between June and December 2022. Findings are as follows: 1. The laboratory performed Endocrinology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 03/29/23. 2. A Tosoh AIA 360 Automated Immunoassay analyzer was observed as present and available for use during the tour of the laboratory. The laboratory performed quantitative hCG testing using this analyzer. 3. Quality Control (QC) testing was required each day of patient testing as established in the Tosoh AIA 360 BHCG procedure found in the Procedure Manual - Chemistry, Coagulation, Hematology, Microscopy, Rapid tests, Urinalysis. 4. Manual documentation of quantitative hCG QC performance on 08/01/22 was not found on the HCG Total Beta Control Log for a quantitative hCG test result from 08/01/22. 5. The Tosoh Patient Test Result Log indicated four specimens received quantitative hCG testing between June and December 2022. Manual documentation of QC performance was found for three of the four testing dates. 6. In an interview at 3:05 p.m. on 03/29/23, the GS confirmed the above finding. The GS indicated records were no longer available in the Tosoh analyzer data to verify quantitative hCG QC performance on 08/01/22. .
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Technical Consultant failed to ensure comprehensive semi-annual and annual competency assessments were performed for six of six testing personnel in 2021 and 2022. Findings are as follows: 1. The laboratory performed Endocrinology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 03/29/23. 2. Quidel Corporation QuickVue hCG Combo test kits were observed as present and available for use during the tour. 3. Personnel competency evaluations encompassing all duties performed were required as established in the Competence Testing procedure found in the Procedure Manual - General, Safety, Phlebotomy. 4. The QuickVue serum hCG test was not included on the Annual Competency Checklist forms completed between April 2021 and December 2022. Testing personnel (TP) were not assessed for competency on this test. See below. 2021 - 5 of 5 tenured TP were not assessed annually 2021 - 1 of 1 new TP was not assessed semi-annually 2022 - 6 of 6 TP were not assessed initially 5. The laboratory was unable to provide documentation of serum hCG competency assessments upon request. 6. In an interview at 11:20 a.m. on 03/29/23, the GS confirmed the above finding. .
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 review of personnel documents and interview with laboratory personnel, the laboratory failed to ensure staff performing high complexity testing meet the qualification requirements of 493.1489 to perform the functions specified in 493.1495 for the complexity of testing performed. Findings are as follows: The laboratory failed to obtain an equivalency evaluation of foreign credentials for one testing personnel performing high complexity testing in 2021 and 2022. 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 document review and interview with laboratory personnel, the laboratory failed to obtain a foreign credential equivalency evaluation for one of three testing personnel with foreign credentials who were performing high complexity testing between April 2021 and March 2023. Findings are as follows: 1. The laboratory performed testing under the following Specialties - Subspecialties as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:10 a.m. on 03/29/23: Microbiology - Bacteriology, Mycology, Parasitology Diagnostic Immunology - General Immunology Chemistry - Routine, Urinalysis, Endocrinology, Toxicology Hematology Immunohematology - ABO/Rh, Antibody Detection, Compatibility 2. Testing Personnel 3 (TP3) was listed on the Laboratory Personnel Report (CLIA)

	Form CMS-209 as an employee performing high complexity testing. Competency Assessment records from 2021 and 2022 indicated TP3 was trained and competent to perform testing in all areas of the laboratory. 3. TP3 completed education in the Philippines as indicated in education credentials provided by the laboratory. 4. Appropriate education was required for all testing personnel as established in the Competence Testing procedure found in the Procedure Manual - General, Safety, Phlebotomy 5. An equivalency evaluation of TP3's foreign credentials was not found in personnel records. The laboratory was unable to provide the equivalency evaluation upon request. 6. In an interview at 11:15 a.m. on 03/29/23, the GS confirmed the above finding. 7. The laboratory was given an opportunity to provide the missing documentation within five days of the survey date. 8. In an email received at 4:20 p. m. on 03/30/23, the GS indicated a foreign credential evaluation had not been completed for TP3. .