Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0037201	01/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Caro Community Hospital	401 N Hooper St, Caro, MI	

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 interview with General Supervisor (GS) #1, the laboratory failed to establish and implement policies and procedures to assess the competency of personnel serving the roles of Clinical Consultant (CC), Technical Consultant (TC), Technical Supervisor (TS), General Supervisor (GS), and Testing Personnel (TP) job responsibilities for 22 (April 2022 to January 2024) of 23 months reviewed. Findings include: 1. A review of the laboratory's personnel records revealed a lack of documentation for the competency assessments for the CC, TC, TS, GS, and TP job responsibilities. 2. A review of the "Competency Policy" revealed a lack for assessing federal regulatory responsibilities for the CC, TC, TS, GS, and TP. 3. An interview on 1/08/24 at 1:54 pm, GS#1 confirmed the laboratory had not established or implemented a policy or procedure for assessing competency for job responsibilities for the roles listed above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a

	minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #1, the laboratory failed to perform calibration verification at least every 6 months for Aspartate Aminotransferase (AST) for 1 (July 2022) of 4 calibration verification testing events reviewed. Findings include: 1. A review of the laboratory's "Dimension EXL Verification/Linearity" policy revealed a section stating, "Each level demonstrates a linear relationship to each other for their respective analytes. It is intended to simulate human patient serum samples for the purpose of determining linearity, calibration verification and verification of reportable range for the following analytes: Chloride, Sodium, Potassium, Calcium, and AST." 2. A review of the laboratory's calibration verification data from 2022 and 2023 revealed a lack of calibration verification data for AST during the July 2022 event. 3. An interview on 1/8/24 at 1:47 pm with General Supervisor #1 confirmed the laboratory did not have calibration verification data for AST from the July 2022 event.
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 interview with the General Supervisor (GS) #2, the laboratory failed to establish a procedure and test its peripheral blood smear staining materials for predictable staining characteristics at least each day of patient testing for 22 (April 2022 to January 2024) of 23 months reviewed. Findings include: 1. A record review revealed a lack of a procedure to perform and document the peripheral blood smear staining material for quality. 2. When queried, GS#2 was unable to provide the surveyor the documentation requested. 3. An interview on 1/08/2024 at 11:57 am, GS#2 confirmed the laboratory had not established a procedure or practice of documenting its peripheral blood smear intended staining characteristics each day of patient testing.
D5503	BACTERIOLOGY

	CFR(s): 493.1261(a)(2) (a) The laboratory must check the following for positive and negative reactivity using control organisms: (a)(2) Each week of use for gram stains. This STANDARD is not met as evidenced by: . Based on record review and interview with General Supervisor #1, the laboratory failed to perform control procedures for its gram stains for 2 (week of 3/9/22 and 7/6 /22) of 2 weeks the laboratory had performed patient testing. Findings include: 1. A review of patient test records revealed the laboratory performed 2 patient Cerebrospinal Fluid (CSF) gram stains total between 2022 and 2023: a. Patient #1 performed on 3/9/22. b. Patient #2 performed on 7/6/22. 2. A review of the laboratory's "Gram Stain Policy" revealed a section titled "Quality Control" stating, "Weekly and with each new lot number prepare a smear of E. coli (ATCC 25922) and Staph epidermidis or Staph aureus (ATCC 25923)." 3. The surveyor requested documentation of control procedures performed using gram staining materials for the patients listed above on 1/8/24 at 12:49 pm. 4. An interview on 1/18/24 at 12:49 pm with General Supervisor #1 confirmed the laboratory had not performed and documented gram stain control procedures at least weekly for the patients listed above.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 interview, the Technical Consultant (TC) #1 as listed on the CMS-209 failed to ensure the 6-month (semi-annual) competency assessment for 1 (#6) of 8 Testing Personnel (TP) were performed and documented for the moderately complex hematology coagulation testing. Findings include: 1. Record review of the TP competency assessments revealed a lack of documentation for the 6-month assessment for 1 (TP#6) of 8 TP performing coagulation. 2. An interview on 1 /08/2024 at 9:53 am, TC#1 confirmed there was no documentation for the semi-annual coagulation competency assessment for TP#6.
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 interview with General Supervisor (GS) #1, the Technical Supervisor (TS) failed to perform the semiannual immunohematology competency assessment for 1 (Testing Personnel # 6) of 8 personnel listed on the CMS-209. Findings include: 1. A record review of the testing personnel competency

	assessments revealed the 6-month immunohematology assessment was performed by Testing Personnel #1 for 1 (Testing personnel #6) of 8 assessments reviewed. 2. An interview on 1/08/2024 at 1:54 pm, GS1 confirmed the immunohematology 6-month assessment for Testing Personnel #6 was not performed by a qualified Technical Supervisor.
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 and interview with General Supervisor #1, the laboratory failed to ensure personnel performing highly complex testing met the testing personnel qualification requirements of 493.1489. Findings include: 1. The laboratory failed to ensure personnel performing high complexity testing were qualified as testing personnel. Refer to 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 and interview with the General Supervisor (GS) #1, the laboratory failed to ensure testing personnel performing high complexity hematology, chemistry, and immunohematology testing were qualified for 2 (Testing Personnel (TP) #6 and #7) of 8 TP listed on Form CMS-209. Findings include: 1. A review of testing personnel credentials revealed a lack of documentation showing TP #6 and #7 was qualified to perform high complexity hematology, chemistry, and immunohematology testing. 2. An interview on 1/08/2024 9:53 am, General Supervisor #1 confirmed TP #6 and #7 were lacking documentation to show they were qualified to perform high complexity testing. 3. The laboratory was given 7 days to provide the documents and they were not made available.