Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D0456357	10/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cozad Community Hospital	300 East 12th Street, Cozad, NE	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of 2020 and 2021 proficiency testing (PT) results and interview with the general supervisor, the laboratory failed to successfully participate in proficiency testing for the analytes D(Rho) and compatibility testing (Refer to D2162 and D2181).
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f) Failure to achieve satisfactory performance for the same analyte in two consecutive

	testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of 2021 proficiency testing (PT) results and interview with the general supervisor, the laboratory failed to achieve successful performance for the analyte, D(Rho), in two out of three testing events. Findings: 1. 2021 first event, score 80% 2. 2021 second event, score 80% 3. Interview with the general supervisor on 10 /28/2021 at 1:40 PM confirmed the laboratory was unsuccessful in two out of three PT testing events.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of 2020 and 2021 proficiency testing (PT) results and interview with the general supervisor, the laboratory failed to achieve successful performance for the analyte, compatibility testing, in two out of three testing events. Findings: 1. 2020 third event, score 80% 2. 2021 second event, score 60% 3. Interview with the general supervisor on 10/28/2021 at 1:20 PM confirmed the laboratory was unsuccessful in two out of three PT testing events.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of core chemistry 2021 proficiency testing (PT) results, chemistry quality control logs, chemistry calibration data, PT investigation documentation, and interview with the general supervisor, the laboratory failed to identify and correct problems. Findings: 1. Review of core chemistry, first event 2021 PT results revealed unsatisfactory performance for the analyte, Creatinine Kinase (CK-MB), with a score of 60%. 2. PT investigation documentation, performed on 2/24 /2021, of unsatisfactory performance presented by the laboratory revealed "Upon review of QC & re-calibration it was noted that CKMB QC was running on the low side of ranges. CKMB was re-calibrated because this shift was noted." 3. Review of quality control review documentation for January 2021 and February 2021 revealed "QC reviewed for shifts & trends none noted." 4. Review of chemistry calibration log for CK-MB revealed calibration was performed on 2/8/2021. Interview with general supervisor on 10/28/2021 at 1:37 PM confirmed the laboratory calibrated on 2/8/2021 due to a change in lot numbers not due to a shift in quality control. 5. PT investigation

	documentation, performed on 2/24/2021, revealed "QC will be reveiwed weekly by lead tech and bi-monthly to catch any shifts or trends." Interview with general supervisor on 10/28/2021 at 1:37 PM revealed the laboratory had not performed the action stated.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of reagents in use found in the blood bank refrigerator, record review of blood bank quality control logs, and interview with the general supervisor, the laboratory failed to ensure testing personnel did not use outdated reagents to perform immunohematology testing. Findings: 1. Observation of reagents in the laboratory's blood bank refrigerator revealed MTS Diluent 2 (Lot # MD142) with an expiration date of 8/3/2021 and MTS Diluent 2 plus (Lot # MDP191) with an expiration date of 8/11/2021. 2. Review of quality control documentation indicates quality control performed from 8/14/2021 - 10/16/2021 was done with expired MTS Diluent 2 and expired MTS Diluent 2 plus. 3. Interview with the general supervisor on 10/28/2021 at 12:54 PM confirmed the laboratory had expired reagents in use. The general supervisor also confirmed nine blood bank patients were tested using expired reagents.
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 review of 2020 and 2021 proficiency testing records, the laboratory director failed to fulfill the laboratory director responsibilities (Refer to D6091 and D6092).
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on surveyor review of immunohematology 2020 proficiency testing (PT) results and investigation, blood bank logs, and interview with the general supervisor revealed the laboratory failed to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Surveyor review of immunohematology, third event 2020 proficiency testing results revealed

	unsatisfactory performance for the analyte, compatibility testing, with a score of 80%. 2. PT investigation documentation, performed on 1/6/2021, of unsatisfactory performance presented by the laboratory revealed "clerical error occurred see attached result sheet." 3. Surveyor review of result sheet for sample SER-13 revealed compatibility reactions and interpretation as incompatible. Review of result submitted for sample SER-13 to proficiency testing revealed result as incompatible. Expected result for sample SER-13 was compatible. 4. Interview with the general supervisor on 10/28/2021 at 1:20 PM confirmed the laboratory had not had a clerical error therefore the laboratory failed to evaluate the laboratory's performance and to identify any problems that require corrective action.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: The laboratory director failed to ensure a corrective action plan was followed when proficiency testing result was found to be unacceptable (Refer to D5293).