

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0456357	(X3) Date Survey Completed 10/30/2020
Name of Provider or Supplier Cozad Community Hospital	Street Address, City, State 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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of 2020 proficiency testing (PT) results and proficiency testing desk review, the laboratory failed to successfully participate in proficiency testing for the analyte bilirubin, total. Refer to D2096</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is</p>

unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of 2020 proficiency testing (PT) results and interview with the general supervisor the laboratory failed to achieve successful performance for the analyte, bilirubin, total, in two out of three testing events. Findings are: 1. 2020 second event, score 40% 2. 2020 third event, score 40% 3. Interview with the general supervisor on 10/28/2020 at 2:00 PM confirmed the laboratory was unsuccessful in the PT events listed above.

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 2020 proficiency testing (PT) results, lack of documentation, and interview with the general supervisor the laboratory failed to document corrective action for unsatisfactory proficiency testing scores. Findings are: 1. Surveyor review of routine chemistry 2020 proficiency testing results revealed unsatisfactory performance for lactic acid. Review revealed 40% for the first event and 20% for the second event. 2. Surveyor review of routine chemistry 2020 proficiency testing results revealed unsatisfactory performance for troponin. Review revealed 60% for the first event, 20% for the second event, and 40% for the third event. 3. No documentation of corrective action could be presented at the time of survey for these unsatisfactory scores. 4. Interview with the general supervisor at 2:00 PM on 10/28/2020 confirmed no corrective action was performed for unsatisfactory proficiency testing scores.

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 review of testing personnel listed on the CMS-209, review of list of tests performed, review of 2018 and 2019 testing personnel competencies, and interview with technical consultant the laboratory failed to have technical consultant perform competencies on personnel performing moderate complexity testing. Findings are: 1. Review of the CMS-209 personnel form presented by the laboratory, revealed six testing personnel performing moderate complexity testing. 2. Review of list of tests performed revealed moderate complexity testing for erythrocyte sedimentation rate and moderate complexity for insulin-like growth factor bind protein1 (IGFBP-1). 3. Review of 2018 and 2019 annual competencies for the six testing personnel revealed

no annual competencies performed for moderate complexity erythrocyte sedimentation rate and moderate complexity insulin-like growth factor bind protein1 (IGFBP-1). 4. Interview with the technical consultant on 10/28/2020 at 2:00 PM revealed the technical consultant did not perform competencies on the six testing personnel performing moderate complexity testing for erythrocyte sedimentation rate and moderate complexity for insulin-like growth factor bind protein1 (IGFBP-1).

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 2019 and 2020 proficiency testing results (see D2096 and D5293) and competency records (see D6046) the laboratory director failed to fulfill the laboratory director responsibilities.