Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0385140	07/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Orange City Municipal Hospital	1000 Lincoln Circle Se, Orange City, IA	

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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to successfully participate in two consecutive testing events in the subspecialty, toxicology, and for the analyte, digoxin. The laboratory had unsatisfactory scores for 2024 events 1 and 2. Refer to D2118 and D2119.
D2118	TOXICOLOGY CFR(s): 493.845(f)

	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 unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance (100% or greater) for two consecutive testing events for the analyte, digoxin. The findings include: 1. The laboratory received unsatisfactory performance scores of 40% for 2024 testing event 1 and 40% for 2024 testing event 2 for the analyte, digoxin. 2. The CASPER 155 report and graded results from API confirm the findings listed above.
D2119	TOXICOLOGY CFR(s): 493.845(g) Failure to achieve an overall testing event score of satisfactory performance 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 review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance (100% or greater) for two consecutive testing events in the subspecialty, toxicology. The findings include: 1. The laboratory received unsatisfactory performance scores of 70% for 2024 testing event 1 and 70% for 2024 testing event 2 for the subspecialty, toxicology. 2. The CASPER 155 report and graded results from API confirm the findings listed above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from API (2024 events 1 and 2), the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as

	required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report and graded results from the American Proficiency Institute (API), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2118 and D2119.