Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384994	04/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Adair County Health System	609 Se Kent Street, Greenfield, 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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and confirmed by interview with Technical Supervisor #1 (TS #1) at 9:20 am on 04/25/2025, the laboratory failed to take and document corrective action for three unacceptable PT scores from one out of four PT testing events from 01/01/2024- 04/25 /2025. The findings include: 1. For 2025 testing event 1, the laboratory received unacceptable PT test scores for the following: *2025 Core Chemistry 1st event: partial pressure of oxygen (PO2), blood gas (specimen BG-01); potassium, blood gas (specimen BG-02); and iron, total (specimen CH-05) 2. At the time of the survey, TS #1 confirmed the laboratory did not take and document corrective action for the PT scores listed above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must

	take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of Ortho Vitros chemistry quality control (QC) records, the laboratory's Quality Control policy, and confirmed by interview with Technical Supervisor #1 (TS #1)at 12:05 pm on 04/25/2025, the laboratory failed to take and document corrective action when chemistry QC fell outside the laboratory's established criteria for acceptability for 10 out of 31 days of patient testing reviewed from 12/01/2024- 12/31/2024 for the following analytes: amylase, blood urea nitrogen (BUN), chloride, blood alcohol, triglyceride, and total cholesterol. The findings include: 1. The laboratory performs chemistry testing on an Ortho Vitros instrument. 2. The laboratory's Quality Control policy stated that if one control measurement exceeds the mean, plus or minus two standard deviations (1-2 SD), the control run can be accepted. Control runs are unacceptable if the control measurement exceeds the mean, plus or minus three standard deviations (1-3s). 3. Review of chemistry QC records revealed "1-3s" QC rule failure flags on level 1 of control for the following dates and analytes: *12/02/2024- total cholesterol (5 patients reported) *12/04/2024- total cholesterol (5 patients reported) 4. Review of chemistry QC records revealed "1-3s" QC rule failure flags on level 3 of control for the following dates and analytes: *12/05/2024- triglyceride (11 patients reported) *12/13/2024- blood alcohol (2 patients reported) *12/15/2024- amylase (1 patient reported) *12/18/2024- chloride (11 patients reported) *12/24/2024- blood alcohol (1 patient reported) *12/27/2024- BUN (13 patients reported) *12/30/2024- BUN (18 patients reported and chloride (22 patients reported) *12/31/2024- chloride (9 patients reported) and blood alcohol (2 patients reported) 5. At the time of the survey, TS #1 confirmed that the laboratory did not have documented corrective action for the unacceptable QC results listed above. This is a repeat deficiency cited on 04/21/2023.