Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0681162	(X3) Date Survey Completed 03/25/2025
Name of Provider or Supplier Iowa Specialty Hospital - Clarion	**Street Address, City, State** 1316 South Main Street, Clarion, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory test menu, lack of blood gas calibration records and confirmed by interview with general supervisor identifier #1 (GS #1) at 12:44 pm on 3/25/2025, the laboratory failed to retain blood gas calibration records for two out of two years from 3/25/2023 - 3/25/2025. The findings include: 1. The laboratory test list indicated the laboratory performed pH, partial pressure oxygen (pO2), partial pressure carbon dioxide (pCO2), oxyhemoglobin, carboxyhemoglobin, and methemoglobin using the RAPIDPoint 500e blood gas analyzer. 2. GS #1 confirmed that the RAPIDPoint 500e blood gas analyzer automatically performed calibrations daily. 3. GS #1 also confirmed the blood gas analyzer would internally store the calibration data. The laboratory intended to periodically download the calibration data as a way to retain the data. 4. Lack of pH, pO2, pCO2, oxyhemoglobin, carboxyhemoglobin, and methemoglobin revealed that the laboratory did not retain blood gas calibration records from 3/25/2023 - 3/25/2025. 5. GS #1 confirmed the lack of calibration records. The GS #1 did not realize the laboratory failed to download the calibration data from the blood gas analyzer.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) records and confirmed by the general supervisor identifier #1 (GS #1) at 11:18 am on 3/25/2025, the laboratory failed to take and document correct action when the laboratory received unaccepable PT results for four out of six testing events from 1/1/2023 - 12/31/2024. The findings include: 1. For 2023 event 1, the laboratory received an unacceptable score of 80% for the analyte, hematocrit (specimen XE-3). 2. For 2023 event 2, the laboratory received an unacceptable score of 80% for the analyte, partial oxygen pressure (pO2) (specimen BG-10). 3. For 2024 event 1, the laboratory received an unacceptable score of 80% for the analyte, parathyroid hormone (specimen IAS-02). 4. For 2024 event 2, the laboratory received an unacceptable score of 80% for the analyte, Enterococcus faecium (Biofire, specimen BCP-07). 5. GS #1 confirmed the laboratory did not take and document corrective action for the above unacceptable PT scores.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of the laboratory test list and confirmed by interview with general supervisor identifier #1 (GS #1) at 2:52 pm on 03/25/2025, the laboratory failed to perform comparison testing twice annually for four out of four time periods from 3/25 /2023 - 3/25/2025 for Clostridium difficile testing. The findings include: 1. The laboratory test list indicated the laboratory performed Clostridium difficile testing using the Alere C. Diff Quik Check, Cepheid GeneXpert, and BioFire Torch test systems. 2. At the time of the survey, GS #1 confirmed the laboratory did not perform comparison testing for Clostridium difficile testing between the three different test system from 3/25/2024 - 3/25/2025.