Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0384022	03/26/2025
Name of Provider or Supplier	**Street Address, City, State**	
Iowa Specialty Hospital Belmond	403 First Street Southeast, Belmond, 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, blood gas quality control (QC) and calibration records and confirmed by interview with general supervisor identifier #1 (GS #1) at 9:37 am on 3/26/2025, the laboratory failed to retain blood gas QC records for 51 out of 177 days and calibration records for 149 out of 177 days from 10/1/2024 - 3/26/2025. 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 QC and calibrations daily. 3. GS #1 also confirmed the blood gas analyzer would internally store the QC and calibration data and the laboratory would periodically download the information as a way to retain the data. The laboratory learned the day of the survey, the blood gas analyzer would only store a set number of data points for QC and calibration. 4. Review of pH, pO2, pCO2, oxyhemoglobin, carboxyhemoglobin, and methemoglobin QC records revealed that the laboratory did not retain the QC records on 11/4/2024 - 12/4/2024 and 1/16/2025 - 2/6/2025. 5. Review of pH, pO2, pCO2, oxyhemoglobin, carboxyhemoglobin, and methemoglobin calibration records revealed that the laboratory did not retain the calibration records on 10/1/2024 - 10/29/2024, 11/5/2024 - 1/8/2025 and 1/16/2025 - 3/11/2025. 6. GS #1 confirmed the lack of QC and calibration records.
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 (GS #1) at 11:05 am on 03/26/2025, the laboratory failed to perform comparison testing twice annually for four out of four time periods from 3/26/2023 - 3/26/2025 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 3/26/2023 - 3/26/2025.