Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0681081	07/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
St Joseph Berea/Respiratory Therapy	305 Estill Street, Berea, KY	

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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on staff interview and record review on July 19, 2019, the laboratory failed to attain a satisfactory score of at least eighty percent (80%) on the hemoglobin certified analyte. Findings include: Record review on July 19, 2019 at 2:00 PM, of the Blood Gas Proficiency Testing Results for the hemoglobin certified analyte, revealed the laboratory scored zero percent (0 %) in the first event of 2019. There was no documentation to identify the cause of the failure. Interview with testing personnel, on July 19, 2019 at 4:00 PM, revealed the Laboratory Director did not identify a source of error that would explain the failure, and the laboratory did not have a resource to investigate the problem any further.
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. This STANDARD is not met as evidenced by: Based on staff interview and record review on July 19, 2019, the laboratory failed to retain the quality control results for three (3) of six (6) days of patient testing. Findings include: Record review on July 19, 2019 at 4:00 PM, revealed three (3) days of control results for patient testing were missing from the quality control records

	between September 19, 2018 through December 10, 2018. Interview with testing staff, on July 19, 2019 at 4:00 PM, revealed the laboratory did not have a system in place to ensure laboratory Quality Control results were retained for a minimum of two (2) years before discarding.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on staff interview and record review on July 19, 2019, the laboratory failed to monitor and document the barometric pressure and humidity in the laboratory using the correct reference range where the testing was performed. Findings include: 1. The Manufacturer's Operations Manual for the ABL-90 blood gas analyzer lists an operating range for humidity for the analyzer between twenty percent (20%) to eighty percent (80 %). Review of the facility Worksheet revealed the reference range was documented as zero percent (0 %) to one hundred percent (100%) between 01/21/19 and 04/02/19. There were seventeen (17) days between January 21, 2019 through April 2, 2019, that the humidity was out of range based on the manufacturer's recommended range for the ABL-90 analyzer. 2. The Manufacturer's Operation Manual listed a range of barometric pressures for the ABL-90 blood gas analyzer between 525 and 800 millimeters of mercury (mmhg). Record review of the maintenance logs revealed the laboratory did not record barometric pressure from November 15, 2018 through July 18, 2019. 3. Testing personnel acknowledged in an interview July 19, 2019 at 2:25 PM, the Laboratory Director failed to have a system in place between November 15, 2018 though July 18, 2019, to ensure temperature, humidity and barometric pressure was monitored and recorded daily using the manufacturer's recommended ranges.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on staff interview with the Technical Consultant and record review on July 19, 2019, there was no documented evidence Quality Assurance was completed and reviewed by the Laboratory Director from January 1, 2017 through July 18, 2019. Findings include: 1. Record review revealed there was no documented evidence of Quality Assurance completed and reviewed by the Laboratory Director from January 1, 2017 through July 18, 2019. The Technical Consultant acknowledged in an

	interview on July 19, 2019 at 4:00 PM, the Laboratory Director did not have a system in place to document quality assurance from January 1, 2017 through July 18, 2019.