

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0976471	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Integrus Bass Pavilion	Street Address, City, State 401 S Third, Enid, OK	
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
D0000	The recertification survey was performed on 11/05/19 The findings were reviewed with the laboratory director, laboratory manager/technical consultant #1, technical consultant #2, quality assessment specialist, director of total quality, chief nursing officer, director of pulmonary services, and the chief operating officer during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #2, the laboratory failed to ensure an analyzer and blood collection tubes were stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, technical consultant #2 stated the following to the surveyor: (a) CG8+ cartridge (blood gas panel plus electrolytes including glucose and ionized calcium measurement) testing was performed using the Abbott iSTAT analyzer (serial #387710); (b) Blood collection tubes were used for the following: (i) Patient testing on the iSTAT (ii) Collecting patient specimens to send to the reference laboratory (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for: (a) Abbot iSTAT analyzer - required a room temperature of 16-30 degrees C (Celsius) (b) Bood collection tubes - required a room</p>

temperature 4-25 degrees C (i) BD Vacutainer K2 EDTA (92 tubes of lot# 9126978) (ii) BD Vacutainer PST Gel and Lithium Heparin (92 tubes of lot# 9184981) (ii) BD Vacutainer Buff Na Citrate (95 tubes of lot#9126914) (3) The surveyor reviewed laboratory records from January 2018 through June 2019. There was no evidence that the room temperature, where the analyzer and blood collection tubes were maintained, had been monitored at an acceptable range of 16-25 degrees C to accommodate the analyzer and blood collection tubes; (4) The surveyor asked the technical consultant #2 if the room temperature, where the analyzer and blood collection tubes were maintained, was being monitored. Technical consultant #2 stated the room temperature was not being monitored.