Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0446429	04/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinnacle Regional Hospital	17651 B Highway, Boonville, MO	

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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of 2018 proficiency testing (PT) and interview with the general supervisor the laboratory failed to evaluate and document "not graded" analytes. Findings: 1. Review of 1st event 2018 PT for blood cell identification, BC1-01 was Not graded with no laboratory documentation. 2. Review of 2nd event 2018 PT for blood cell identification, BC1-10 was Not graded with no laboratory documentation. 3. Interview with the general supervisor on April 2, 2019 at 1:30 PM confirmed the laboratory failed to evaluate and document not graded analytes.
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 review of the procedure manual, manufacturer's inserts and interview with

	general supervisor, the laboratory failed to monitor and document the temperature of the room the GEM 4000 premier plus blood gas analyzer reagent cartridge. Findings: 1. Review of the manufacturer's product inserts revealed the GEM 4000 premier plus reagent cartridge must be stored at 15 degrees to 25 degrees Celsius. 2. Review of the room temperature documentation showed the laboratory failed to document room temperature for 2017, 2018 and to date 2019. 3. Interview with the general supervisor on April 2, 2019 at 1:30 PM confirmed the laboratory failed to document the room temperature in the laboratory where GEM 4000 premier plus reagent cartridges are stored and analyzed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the GEM 4000 blood gas analyzer and interview with the general supervisor, the laboratory failed to verify reference intervals(normal values). Findings: 1. Review of the verification procedures for the GEM 4000 blood gas analyzer for pH, pCO2, pO2, showed no verification of normal values. 2. Interview with the general supervisor on April 2, 2019 at 11:30 confirmed the laboratory failed to ensure the verification procedures for normal values for the GEM 4000 analyzer were appropriate for the laboratory's patient population.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of function check documentation, laboratory policy and interview with the general supervisor, the laboratory failed to perform and document function checks for five of five pipettors in use during 2018 and to date April 2, 2019. Findings: 1. Review of pipettor function check documentation revealed the MLA 1000 microliter pipettor dispense volume was last verified September 2017. The MLA 10 microliter pipettor dispense volume was last verified August 2017. The ID-Tipmaster multi-setting pipettor (12.5, 25 and 50 microliters) was last verified August 2017. The laboratory did not have function check documentation to verify accuracy of

	dispense volumes for the MLA 100 microliter pipettor and MLA 3 milliliter pipettor. 2. Laboratory policy" PM-15, Pipettes procedure" states, "Automatic pipettes and diluting devices of all types are checked for accuracy and reproducibility before being placed in service and yearly thereafter." 3. The laboratory did not have documentation to show the pipettors were checked for accuracy and reproducibilty during 2018 and to date April 2, 2019. 4. Interview with the general supervisor on April 2, 2019 at 1:30 PM confirmed the laboratory failed to perform and document pipettor function checks to verify accuracy and reproducibility as stated in the written policy.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of blood bank refrigerator alarm system documentation, blood bank procedure manual and interview with the general supervisor, the laboratory failed to perform three of four quarterly blood bank alarm inspections during 2018. Findings: 1. The laboratory did not have documentation to show inspection of the blood bank refrigerator alarm system for the second, third and fourth quarters of 2018. 2. The blood bank procedure manual states the blood bank refrigerator alarm system is inspected "quarterly." 3. Interview with the general supervisor on April 2, 2019 at 1: 30 PM confirmed the laboratory failed to perform and document blood bank alarm system inspections quarterly during 2018 as required by the procedure.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of approved reference ranges in the laboratory procedure manual, and interview with the general supervisor #1, the laboratory failed to ensure the test report included pertinent normal ranges as determined by the laboratory. Six of the seven blood gas parameters and three of six manual white blood cell differential parameters listed on the laboratory information system(LIS) report differed from those in the approved procedure manual. Findings: 1. Review of the patient report from the LIS system revealed six of the seven parameters for blood gas testing and three of the six manual white blood cell differential parameters did not correctly match those reference ranges in the procedure manual. LIS patient report Procedure manual pCO2 35-45 35-48 pO2 80- 83-108 sO2 90.0- 95.0-98.0 TCO2 23.0-27.0 22.0-28.0 BE -2.0-2.0 -2.0 - 3.0 HCO3 22.0-26.0 21-28 segmented neutrophils 39-79 50-66 lymphocytes

	16-50 21-37 monocytes 0-11 3-7 2. Interview with the general supervisor #1 on April 2, 2019 at 11:00 AM confirmed the laboratory failed to ensure correct reference ranges approved in the procedure manual were included on the LIS patient report.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratories individualized quality control plans (IQCP) , quality control (QC) records for 2018 and 2019 and interview with the general supervisor, the laboratory director failed to maintain the the QC program. Findings: 1. The " Individualized Quality Control Plan (IQCP): Stratus CS STAT Flourometric Analyzer" signed by the laboratory director states, " Quality Control will be done each 30 days for the Troponin I, CKMB, ProBNP and D-Dimer." 2. Review of Troponin I QC records (logs) for 2018 and 2019 showed the laboratory performed two levels of QC on December 10, 2018 and not again until February 3, 2019. No QC was documented to show the laboratory performed two levels of QC during January 2019. No documentation was available to show the laboratory identified/narrated/corrected the problems with Troponin QC during January 2019. 3. Review of CKMB record (log) for 2019 showed the laboratory performed two levels of QC on January 10, 2019 and not again until March 4-5 2019. No CKMB QC was documented to show the laboratory performed two levels of QC during February 2019. The log indicated CKMB "QC not working"on March 5, 2019. No acceptable CKMB QC was documented on the log March 4 or March 5, 2019. No documentation was available to show the laboratory identified/narrated/corrected problems with CKMB QC during February and March 2019. No acceptable QC was documented after January 10, 2019 and to date April 2, 2019. 4. Review of D-Dimer QC records (log) for 2019 showed the laboratory performed two levels of QC on January 10, 2019 and not again until March 5, 2019. No QC was documented to show the laboratory performed two levels of QC during February 2019. No documentation was available to show the laboratory identified/narrated/corrected problems with D-Dimer QC during February 2019. 5. The "Individualized Quality Control Plan (IQCP): Sure-Vue Serum/Urine hCG STAT", signed by the director states,"For quality control, the laboratory follows the manufacturer's recommended quality control procedure by testing external quality control material for each shipment of a new lot number. The laboratory in addition performs external controls for serum each month." Review of hCG records (log) for 2019 showed the laboratory performed a positive and negative control on January 18, 2019 and not again until March 4, 2019. No QC was documented to show the laboratory performed two levels of QC during February 2019. No documentation was available to show the laboratory identified/narrated/corrected problems with hCG QC during February 2019. 6. On April 2, 2019 the laboratory could not provide records to show whether patients were tested for Troponin I, CKMB, D-Dimer and serum hCG during time frames identified. 7. Interview on April 2, 2019 at 1:30 PM, the general supervisor could not explain the causes of the QC problems that occurred with Stratus analyzer and serum hCG testing. Interview confirmed the director failed to maintain the IQCP and identify QC problems as they occur.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of arterial blood gas (ABG) quality control (QC) records and interview with the general supervisor #2 confirmed the technical supervisor failed to review QC for blood gas testing on the GEM 4000 analyzer. Findings: 1. Review of the QC records for the GEM 4000 analyzer for pH, pCO2, pO2, revealed the technical supervisor failed to review the records to verify instrument accuracy. 2. Interview with the general supervisor #2 on April 2, 2019 at 11:00AM confirmed the technical supervisor failed to review quality control records to ensure acceptable levels of analytic performance.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 initial competencies and interview with the general supervisor on April 2, 2019 at 1:30 PM confirmed , the technical supervisor failed to ensure 5 of 5 initial competencies were evaluated and documented.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Review of the personnel records for competency evaluations for 2017 and 2018 and interview with the general supervisor, the technical supervisor failed to ensure that 3 of 3 new testing personnel were evaluated semiannually the first year of employment. Findings: 1. Review of personnel records for competency evaluations showed testing personnel #4, #5 and #9 semiannual competencies were not documented. 2. Interview with the general supervisor on April 2, 2019 at 1:30 PM confirmed the technical supervisor failed to ensure that 3 new testing personnel were evaluated and documented semiannually the first year of employment.