Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	19D0971268	02/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Medical Center	218 Corporate Drive, Houma, LA	
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	A Certification Survey was conducted on February 15, 2018 at Physicians Medical Center, CLIA ID # 19D0971268. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not establish complete policies for the following: a) Record Retention requirements b) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance) studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on February 15, 2018 at 12:39 pm, Personnel 3 confirmed the laboratory's policies did not include the identified information.
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 observation, record review, and interview with personnel, the laboratory failed to have complete performance specification verification studies for the i-STAT 1 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on February 15, 2018 revealed the laboratory utilizes the i-STAT 1 for testing of the following analytes: a) Chem 8+ Cartridge: Sodium, Potassium, Chloride, Ionized Calcium, Glucose, BUN, Creatinine b) PT/INR c) CG4 + Cartridge: pH, pCO2, and pO2. 2. In interview on February 15, 2018 at 12:39 pm, Personnel 3 stated the laboratory received a new i-STAT 1 analyzer in September 2016 to replace their old i-STAT. Personnel 3 further stated the new i-STAT was the same model as their previous analyzer. 3. Review of the laboratory's Policy and Procedure Manual revealed the laboratory did not have a policy/procedure for performance specification verification studies. 4. Review of the laboratory's validation records revealed the following data: a) One (1) comparative patient sample on old i-STAT and new i-STAT for Chem 8 + panel (performed October 3, 2016) with Laboratory Director's signature on data page b) Calibration verification (performed September 29, 2016), with Laboratory Director's signature on data page c) Comparative QC on old i-STAT and new i-STAT for two (2) days 5. Further review of the laboratory's validation records revealed the laboratory did not include the following information: a) How the data records apply to accuracy, precision (to include day-to-day, run-to-run, within-run, and operator variance), reportable range, and reference range studies b) Summary and Acceptability criteria c) Laboratory Director's approval/signature 6. In interview on February 15, 2018 at 12:39 pm, Personnel 3 stated the performance studies were performed prior to her hire date(June 2017). Personnel 3 further stated she was told that a previous employee was advised that the laboratory only needed to perform a comparative patient sample, comparative QC, and calibration verification for their new i-STAT. 7. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following test volumes annually: Chemistry (to include: Sodium, Potassium, Chloride, Ionized Calcium, Glucose, BUN, Creatinine): 1,106 Blood Gases (to include: pH, pCO2, PO2): fifteen (15) PT/INR: twenty six (26)
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory

	failed to include in-house quality control (QC) data to support reduction of the frequency of QC in their Individualized Quality Control Plan (IQCP). Findings: 1. Observation by surveyor during the laboratory tour on February 15, 2018 revealed the laboratory utilizes the i-STAT 1 for testing of the following analytes: Sodium, Potassium, Chloride, Ionized Calcium, Glucose, BUN, Creatinine, PT/INR, pH, pCO2, and pO2. 2. Review of the laboratory's IQCP documents revealed the following "Conduct Liquid Quality Control (Integrity Testing) for acceptance of newly received cartridge lots, monthly, and for troubleshooting purposes." 3. Further review of the laboratory's IQCP documents revealed the laboratory did not include in-house QC data to support the reduction of performing external (liquid) controls to monthly. 4. In interview on February 15, 2018 at 10:30 am, Personnel 3 stated liquid controls for the i-STAT are run every month. Personnel 3 confirmed the laboratory did not have in-house QC data for the liquid controls to support the reduction. Personnel 3 further stated the IQCP was performed prior to her hire date (June 2017). 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs the following tests volumes annually: Chemistry (to include: Sodium, Potassium, Chloride, Ionized Calcium, Glucose, BUN, Creatinine): 1,106 Blood Gases (to include: pH, pCO2, PO2): fifteen (15) PT/INR: twenty six (26)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with laboratory personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D5445.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6051.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the following testing personnel: Personnel 3 Personnel 4 Personnel 5 Personnel 6 Personnel 7 Personnel 8 Personnel 9 Personnel 10 Personnel 11 Personnel 12 Personnel 13 Personnel 14 Personnel 15 Personnel 16 Personnel 17 Personnel 18 Personnel 19 Personnel 20 Personnel 21 Personnel 22 Personnel 23 Personnel 24

	Personnel 25 Personnel 26 Personnel 27 Personnel 28 Personnel 29 Personnel 30 Personnel 31 Personnel 32 Personnel 33 Personnel 34 Personnel 35 Personnel 36 2. Review of the laboratory's "Staff i-STAT Education" policy revealed competency assessment would include "Assessment of test performance through testing external proficiency testing samples." 3. Review of the laboratory's 2017 College of American Pathologists (CAP) Proficiency Testing (PT) records revealed the following testing personnel performed PT testing: Personnel 3 Personnel 4 Personnel 6 Personnel 34 4. In interview on February 15, 2018 at 11:00 am, Personnel 3 stated she thought rotating staff who performed PT was sufficient. Personnel 3 further stated she was unaware that all testing personnel had to perform blind or PT samples annually as part of competency assessment. Personnel 3 confirmed that not all testing personnel performed external PT, previously analyzed specimens, or internal blind samples annually.