| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>19D0860228 | (X3) Date Survey Completed<br><br>12/09/2021 |
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| **Name of Provider or Supplier**<br><br>Pam Health Specialty Hospital Of New Orleans | **Street Address, City, State**<br><br>3801 Bienville St, 1st Floor, New Orleans, 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 |
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| **D0000** | An Initial survey was performed on December 9, 2021 at Curahealth New Orleans, CLIA ID # 19D0860228. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of policies and procedures, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include frequency of performance and the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on December 9, 2021 at 11:30 am, the health system personnel confirmed the laboratory did not have personnel competency policy that included the identified information. |
| **D5401** | PROCEDURE MANUAL |

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| | CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's polices revealed the laboratory did not have written policies and procedures that included the following: a) Retention of records requirements b) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria 2. In interview on December 9, 2021 at 12:16 pm, the CEO stated the laboratory did not have the identified policies. II. Based on review of the laboratory's policies, quality control records, and interview with personnel, the laboratory failed to follow their established control procedure for blood gas testing. Findings: 1. Review of the laboratory's "Blood Gas Quality Control" policy revealed "External Controls (Tri-Controls Levels 1, 2, 3) are used to verify reactivity of each new lot and each new shipment and at least monthly and after major system maintenance or software upgrades of hand held devices. Controls to be performed the first of each month (+/- 4 days)." 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) under "Quality Control Plan" section revealed "Three levels of Abbott Tri-controls must be analyzed on each iSTAT analyzer with each new shipment/lot of cartridges before use and every 30 days thereafter." 3. Review of the laboratory's quality control records revealed the laboratory runs two levels (Tri-Control Level 1 and Level 3), not three (3), monthly, new lot, new shipment. 4. In interview on December 9, 2021 at 1:45 pm, the health system personnel confirmed the laboratory runs two (2) levels of external controls, not three (3) levels for blood gas testing. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to document visual inspections of blood culture bottles before use per manufacturer's requirements. Findings: 1. Observation by surveyor during laboratory tour on December 9, 2021 revealed the laboratory utilizes the following BacT/ALERT blood culture bottles for collection: BacT/ALERT FA Plus BacT /ALERT FN Plus 2. Review of the BacT/ALERT package insert revealed "Prior to use, visually inspect all BacT/ALERT bottles for evidence of damage or contamination. A bottle should not be used if any evidence of leakage is notes. Do not use a bottle which contains media exhibiting turbidity, excess gas pressure, or a |

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| | yellow sensor; these are signs of possible contamination." 3. Review of the laboratory's policies revealed the laboratory did not have a policy related to blood culture bottle inspections. 4. In interview on December 9, 2021 at 9:57 am, Testing Personnel l and the health system personnel stated the laboratory receives blood culture bottles from a local hospital and does not document visual inspections of blood culture bottles. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of laboratory records, test menu, and interview with personnel, the laboratory failed to perform performance verification studies for the i-Stat 1 blood gas analyzer. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2021 at 9:43 am revealed the laboratory utilizes the i-Stat 1 for blood gas testing (pH, PCO2, and PO2). 2. Review of the laboratory's records revealed the laboratory did not have documentation of performance of verification studies that included the following: a) Accuracy studies to include raw data and acceptability criteria b) Precision studies to include run-to run, day to day, within-run, operator variance studies and acceptability criteria c) Reference Range d) Reportable Range to include acceptability criteria e) Laboratory Director approval/signature 3. In interview on December 9, 2021 at 1:16 pm, the health system personnel stated she could not find the laboratory's validation studies for the i-Stat. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of policies, quality control documents, test menu, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Findings: 1. In interview on December 9, 2021 at 9:02 am, Testing Personnel 1 stated external QC for the i-Stat is run every |

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| | month. 2. Observation by surveyor during the laboratory tour on December 9, 2021 at 9:43 am revealed the laboratory utilizes the i-Stat 1 for blood gas testing (pH, PCO2, and PO2). 3. Review of the laboratory's "Blood Gas Quality Control" revealed "External Controls (Tri-Controls Levels 1, 2, 3) are used to verify reactivity of each new lot and each new shipment and at least monthly and after major system maintenance or software upgrades of hand held devices. Tri-Controls to be performed the first of each month (+/- 4 days)." 4. Review of the laboratory's IQCP documents revealed the laboratory did not include in-house quality control data to support the reduction of external controls to monthly. 5. In interview on December 9, 2021 at 11: 22 am, the health system personnel confirmed the laboratory did not have QC data to support the reduction of external controls to monthly. 6. Review of the laboratory's test menu revealed 360 blood gas tests are performed annually. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of policies, quality control records, patient test records, and interview with personnel, the laboratory failed to perform quality control as required by laboratory policy on the i-Stat analyzer for one (1) of twenty three (23) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 9, 2021 at 9:43 am revealed the laboratory utilizes the i-Stat 1 for blood gas testing (pH, PCO2, and PO2). 2. Review of the laboratory's "Blood Gas Quality Control" policy revealed "External Controls (Tri-Controls Levels 1, 2, 3) are used to verify reactivity of each new lot and each new shipment and at least monthly and after major system maintenance or software upgrades of hand held devices. Controls to be performed the first of each month (+/- 4 days)." 3. Review of the laboratory's Individualized Quality Control Plan (IQCP) under "Quality Control Plan" section revealed "Three levels of Abbott Tri-controls must be analyzed on each iSTAT analyzer with each new shipment/lot of cartridges before use and every 30 days thereafter." 4. Review of QC records revealed the laboratory did not perform at least two (2) levels of external controls in February 2021. 5. Further review of the laboratory's QC records revealed the laboratory tested Tri-Control Level 1 on March 1, 2021 with the following note: "Level 1 passed Note: 3 level expired and not delivered due to Inclement weather 2/14 til 2/23 3/1-still not delivered." 6. In interview on December 9, 2021 at 12:12 pm, Testing Personnel 1 stated no external controls for blood gas testing were run in February 2021 because their control was expired and inclement weather delayed delivery. 7. Review of patient test records revealed the following patients were reported for blood gas analytes without external QC performed: February 8, 2021: Patient EU0000901686 February 17, 2021: Patient EU0000901959 February 24, 2021: Patient EU0000902114 |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness |

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| | of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the anlaytic system. Findings: 1. Review of the laboratory's "Maintenance, Calibration, And Quality Control-QA Tracking Sheet" revealed the following monitors: General, Maintenance, Calibration, Proficiency Testing, Problems areas, and Corrective action. 2. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 I. b) The laboratory failed to follow their established control procedure for blood gas testing. Refer to D5401 II. c) The laboratory failed to document visual inspections of blood culture bottles before use per manufacturer's requirements. Refer to D5411. d) The laboratory failed to perform performance verification studies for the i-Stat 1 blood gas analyzer. Refer to D5421. e) The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445. f) The laboratory failed to perform quality control as required by laboratory policy on the i-Stat analyzer for one (1) of twenty three (23) months reviewed. Refer to D5447. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of random selection of patient final reports, test menu, and interview with personnel, the laboratory failed to include the laboratory's address on patient final reports. Findings: 1. Review of the following random selection of patient final test reports revealed the address of the laboratory performing the testing was not included: Patient EU0000902114 Patient EU0000901959 Patient EU0000901686 2. In interview on December 9, 2021 at 1:45 pm, the health system personnel confirmed the laboratory did not include the address on patient final reports. 3. Review of the laboratory's test menu revealed 360 blood gas tests are performed annually. |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(ii)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform |

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| | 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;<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5411. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to follow their established control procedure for blood gas testing. Refer to D5401 II. 2. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control (QC) for blood gas testing. Refer to D5445. 3. The laboratory failed to perform quality control as required by laboratory policy on the i-Stat analyzer for one (1) of twenty three (23) months reviewed. Refer to D5447. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5) |

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| | 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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793. |
| **D6026** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(8)<br><br>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)(8) Ensure that reports of test results include pertinent information required for interpretation.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's test menu, patient final test reports, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Refer to D5209. |
| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>The laboratory director is responsible for the overall operation and administration of |

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| | 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;<br><br>This STANDARD is not met as evidenced by:<br>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. Refer to D5401 I. |