

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2194849	(X3) Date Survey Completed 04/23/2024
Name of Provider or Supplier Post Oak Er Plc	Street Address, City, State 5018 A San Felipe, Houston, TX	
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	<p>An offsite revisit survey was conducted on 08/05/2024 for all previous deficiencies cited on 04/23/2024. All deficiencies have been corrected. The laboratory is in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). ----- An announced survey of the laboratory was conducted on 04/23/2024. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel</p>
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p>

This CONDITION is not met as evidenced by:
Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to achieve successful performance for 2 of 3 consecutive testing events in 2023 resulting in unsuccessful performance. The laboratory did not successfully participate in PT for the specialty of Chemistry, analyte Sodium. Refer to D2096.

D2093

ROUTINE CHEMISTRY
CFR(s): 493.841(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:
Based on review of laboratory's proficiency testing (PT) records for 2023 and staff interview, the laboratory failed to return proficiency testing results to the proficiency testing program within the time frame specified by the program for 1 of 3 2023 PT events, the 2023 Chemistry - Core - 3rd Event, resulting in an unsatisfactory performance for the event. Findings included: 1. Review of laboratory's American Proficiency Institute PT records for 2023 revealed the laboratory received a score of 0% for the following analytes for 2023 Chemistry - Core - 3rd Event: Albumin BNP (B-Type Natriuretic Peptide) Calcium, Total Chloride CO2 (Carbon Dioxide) Creatinine Kinase, Isoenzyme Creatinine D-Dimer Glucose Lactic Acid Magnesium Myoglobin Phosphorus Potassium Sodium Troponin 1 Urea Nitrogen 2. In an interview on 04/23/2024 at 1105 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) stated that the score was a result of non-submission of results prior to the programs deadline. This confirmed the findings.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on review of laboratory's proficiency testing (PT) records from 2022 and 2023, and staff interview, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for 2 of 3 consecutive proficiency testing (PT) events for the specialty Chemistry, analyte Sodium (Na). Two out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings included: 1. A review of the laboratory's American Proficiency Institute PT records from 2022 and 2023 revealed the following 2 out of 3 consecutive testing events with a score of less than 80% for the Sodium analyte: 2023 Chemistry - Core - 2nd Event: Analyte: Sodium Score: 60% 2023 Chemistry - Core - 3rd Event: Analyte: Sodium Score: 0% 2. In an interview on 04/23/2024 at 1105 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.

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 laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to document evaluation of "Not Graded" results for 4 of 4 analytes in 17 PT events reviewed from 2022 and 2023. Findings included: 1. Review of laboratory's PT records revealed the laboratory used American Proficiency Institute (API) as its PT provider. Review of API's instructions revealed: "Laboratories are responsible for documenting and performing corrective action for failures and must perform self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of the PT records from 2022 and 2023 revealed the following 4 of 4 analytes' "Not Graded" results did not have documentation of self-evaluation: 2022 Microbiology - 3rd Event: Sample: RSP-12 Analyte: BioFire FilmArray RP2,1/Influenza A Performance: Not Graded 2023 Chemistry - Core - 2nd Event: Sample: CM-06 Analyte: Troponin I Performance: Not Graded 2023 Microbiology - 1st Event: Sample: RSP-04 Analyte: BioFire FilmArray RP2,1/Influenza A Performance: Not Graded 2022 Microbiology - 2nd Event: Sample: RSP-10 Analyte: BioFire FilmArray RP2,1/Influenza A Performance: Not Graded 3. In an interview on 04/23/2024 at 1055 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of laboratory's quality control (QC) records, manufacturer package inserts, patient test orders and staff interview, the laboratory failed to ensure QC material for the Piccolo Met Lac 12 was not used for patient testing beyond the expiration date for 1 of 4 months reviewed (August through November 2023). Findings included: 1. Review of Piccolo MetLac 12 QC records from August through November 2023 revealed the laboratory used expired controls to perform October 2023 QC as follows: QC Control Level 1 (L1) Tested: 10/02/2023 at 08:10 AM Control ID: 2204012-1 QC Control Level 2 (L2) Tested: 10/02/2023 at 09:06 AM Control ID: 2204012-2 QC Control Level 1 (L1) Tested: 10/15/2023 at 03:58 AM Control ID: 2204012-1 QC Control Level 2 (L2) Tested: 10/15/2023 at 04:19 AM Control ID: 2204012-2 2. Review of manufacturer package inserts for the Bigresource Technology Inc. Chemistry Control Liquid Assayed (document #PI9010, REV 7/7 /2022) revealed: "Lot # 2204012 (Containing Vial Lots L1 #2204012-1 & L2 #2204012-2) Expiration date: 2023-09-30" 3. Review of laboratory's patient test orders from 09/30/2023 to 11/24/2024, the date of the next QC performed with unexpired control reagents, revealed there were 118 routine chemistry tests ordered

within the interval. The laboratory could not provide a list of Piccolo MetLac 12 tested patient samples prior to survey exit for the above interval. 4. In an interview on 04/23/2024 at 1420 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.

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 laboratory's test verification records and staff interview, the laboratory failed to document verification of patient normal ranges for 2 of 2 new test platforms implemented in 2023, the Piccolo MetLac 12 panel and the iStat Troponin cartridge. Findings included: 1. Review of laboratory's new test verification records revealed the following new test platforms were implemented in 2023: Piccolo MetLac 12 panel implemented 03/29/2023. iStat Troponin cartridge implemented 08/01/2023. 2. Further review of the new test platform verification records revealed neither the Piccolo MetLac 12 panel's nor the iStat Troponin cartridge's verification studies included verification of manufacturer established patient normal ranges with representative samples from the laboratory's patient normal population. 3. In an interview on 04/23/2024 at 1300 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) stated that the laboratory adopted the manufacturer established normal ranges, but that the laboratory did not verify that its normal patient population falls within those ranges for the above test platforms. This confirmed the findings.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
Based on review of laboratory's temperature records, corrective action records and staff interview, the laboratory failed to document corrective action for 22 of 22 out-of-range and/or unrecorded temperatures out of 4 months reviewed in 2023, January, February, November, and December. Findings included: 1. Review of laboratory's temperature records revealed the laboratory defined acceptable temperature ranges as follows: Ambient Temperature: 20-24C (Degrees Celsius) Laboratory Refrigerator: 2.0-8.0C 2. Review of laboratory's temperature records for January, February, November, and December 2023 revealed: a. The laboratory documented the following temperatures outside the acceptable range: Ambient Temperature Date Temperature (C) 01/01/2023 25.0 01/02/2023 24.7 01/05/2023 24.2 01/07/2023 24.5 01/08/2023

24.5 01/11/2023 24.3 01/12/2023 24.6 01/22/2023 24.1 01/28/2023 24.1 01/29/2023
 25.3 02/05/2023 24.4 02/06/2023 24.5 02/07/2023 24.7 02/08/2023 24.3 02/09/2023
 24.1 Refrigerator Temperature: Date: Temperature (C) 11/07/2023 1.9 11/19/2023
 1.8 11/20/2023 1.1 11/21/2023 1.8 11/22/2023 1.6 b. The laboratory did not record
 temperatures as follows: Refrigerator Temperature: Date: Temperature (C) 12/25
 /2023 No temperature recorded. 12/26/2023 No temperature recorded. 3. Review of
 laboratory's corrective action records revealed there was no corrective action
 documented for any of the above out-of-range temperatures, or days where laboratory
 refrigerator temperature was not recorded. 4. In an interview on 04/23/2024 at 1530
 hours in the breakroom, the laboratory's Technical Consultant (as indicated on
 submitted Form CMS 209) confirmed the findings.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
 CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
 Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and staff interview, the Laboratory Director failed to provide overall management of the laboratory for one of two laboratory's 2022 and 2023 test specialties, Chemistry. Findings included: 1. Laboratory Director failed to ensure successful participation in a HHS approved proficiency testing program for the specialty Chemistry, analyte Sodium. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for the analyte Sodium for 2 of 3 consecutive events from 2023. Refer to D2096.

D6063

LABORATORY TESTING PERSONNEL
 CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of laboratory's personnel records, patient test volumes and staff interview, the laboratory failed to have documentation of education to qualify 3 of 25 testing personnel who perform moderate complexity testing in 2022 and 2023. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on review of laboratory's personnel records and staff interview, the laboratory failed to have documentation of education to qualify 3 of 25 testing personnel performing moderate complexity testing in 2022 and 2023. Findings included: 1. Review of laboratory records revealed the following three of twenty-five testing personnel (TP) employed by the facility did not meet qualification requirements for moderate complexity testing: TP number 11: Record contained associate degree in science did not specify the degree's discipline. There was no transcript or High School diploma available for review. TP number 20: Record contained associate degree in radiography. There was no transcript or High School diploma available for review. TP number 22: Record contained associate degree in radiologic technology. There was no transcript or High School diploma available for review. 2. In an interview on 04/23 /2024 at 1030 hours in the breakroom, the laboratory's Technical Consultant (as indicated on submitted Form CMS 209) confirmed the findings.