

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1013934	(X3) Date Survey Completed 09/21/2021
Name of Provider or Supplier Brownsville Pulmonary Center Pa	Street Address, City, State 510 Victoria Lane Suite 1, Harlingen, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Review of the laboratory's American Association of Bioanalysts (AAB) Proficiency Testing (PT) Attestation records for 2019, 2020 and 2021, review of personnel files and interview with the staff it was determined the laboratory failed to ensure all testing personnel participated in proficiency testing. The findings were: 1. Review of the laboratory's AAB PT Attestation records for 2019, 2020 and 2021 revealed the same person (Testing Person number 1) performed testing for 8 of 8 testing events. The reviewed events were: 2019 Events: Q1- Chemistry Q2- Chemistry Q3- Chemistry 2020 Events: Q1- Chemistry Q2- Chemistry Q3- Chemistry 2021 Events: Q1- Chemistry Q2- Chemistry 2. Review of personnel files revealed Testing Person</p>

number 2 performed testing since March of 2020. 3. In an interview on 09/21/2021 at 1000 hours in the office Testing Person number 2 (as described on CMS Form 209 signed by the laboratory director on 09/21/2021) stated that she did not remember performing PT testing for this facility in the past. This confirmed the findings.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel competency assessment records for 2019, 2020 and 2021, review of the laboratory's submitted Form CMS 209, review of the laboratory's policies and interview with the staff it was determined the laboratory failed to establish policies addressing competency assessment and its frequency for the laboratory's technical consultant. The findings were: 1. Review of the laboratory's competency assessment records revealed there were no competency assessments for Technical Consultant (TC) documented for 2019 and 2020. Further review revealed there were competency assessments documented for Technical Consultant each year from 2013 through 2018. 2. Review of the of the laboratory's submitted CMS Form 209 revealed the laboratory identified one technical consultant. 3. Review of the laboratory's policies revealed there was no policy in place defining the frequency of technical consultant's competency assessment. 4. In an interview on 09/21/2021 at 1015 hours in the office Testing Person number 2 (as described on CMS Form 209 signed by the laboratory director on 09/21/2021) stated that she was unaware of a policy addressing Technical Consultant's competency assessment. This confirmed the findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's quality control and calibration records for the OPTI CCA-TS2 instrument (used to perform blood gas analysis) for 2020 and 2021, and interview with the staff it was revealed the laboratory failed to perform calibration verification every 6 months for 1 of 2 intervals reviewed. The findings were: 1. Review of the quality control and calibration records for the OPTI CCA-TS2 instrument (Serial number 3717) for 2020 and 2021 revealed: a. Three levels of external liquid controls and a one-point cassette calibration verification was performed once each day of instrument use. Therefore, calibration verification is required every 6 months. b. Instrument calibration was performed 02/28/2020 at installation. Next instrument calibration verification was due 08/28/2020 but was performed on 11/30/2020. Elapsed time: 9 months 2. The laboratory was asked to provide documentation for calibration verification performed in August 2020 and no such documentation was provided. 3. In an interview on 09/21/2021 at 1100 hours in the office Testing Person number 2 (as described on CMS Form 209 signed by the laboratory director on 09/21/2021) stated calibration is performed every 6 months. This confirmed the findings.

D6018

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

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's American Association of Bioanalysts (AAB) Proficiency Testing (PT) records for 2019, 2020 and 2021 and interview with the staff it was determined the laboratory failed to have documentation of laboratory director review for 1 of 7 events. The findings were: 1. Review of the laboratory's PT records for 2019, 2020 and 2021 revealed no documentation of results' review for PT Event Q1 2020 - Chemistry. The reviewed events were: 2019 Events: Q1- Chemistry Q2- Chemistry Q3- Chemistry 2020 Events: Q1- Chemistry Q2- Chemistry Q3- Chemistry 2021 Events: Q1- Chemistry Q2- Chemistry 2. The laboratory was asked to provide documentation for PT Event Q1 2020 review of results and no such documentation was provided. 3. In an interview on 09/21/2021 at 09:30 hours in the office Testing Person number 2 (as described on CMS Form 209 signed by the laboratory director on 09/21/2021) confirmed the findings.

D6066

TESTING PERSONNEL QUALIFICATIONS
 CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of laboratory's personnel training records and interview with the staff it was determined the laboratory failed to ensure that 1 of 2 personnel documented receipt of the appropriate training for new instrumentation prior to testing patients' specimens. The findings were: 1. Review of the laboratory's personnel records revealed that Testing Person number one (TP1) (as described on CMS Form 209 signed by the laboratory director on 09/21/2021) did not have documentation of training on the new blood gases testing instrument OPTI CCA-TS2, Serial number 3717, placed in-service on 03/24/2020. 2. The laboratory was asked to provide documentation for training of TP1 on the OPTI CCA-TS2 instrument and no such documentation was provided. 3. In an interview on 09/21/2021 at 1100 hours in the office Testing Person number two (as described on CMS Form 209 signed by the laboratory director on 09/21/2021) stated that the laboratory was unable to locate documentation of training on OPTI CCA-TS2 instrument for TP1. This confirmed the findings.