

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2194890	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Tropical Texas Behavioral Health	Street Address, City, State 1901 S 24th Avenue, Edinburg, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D2000 - 42 C.F.R. 493.801 Condition: enrollment and testing of proficiency testing samples; D5400 - 42 C.F.R. 493.1250 Condition: analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: testing personnel. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of enrollment in proficiency testing for the regulated analyte percent (%) neutrophil. The findings include: 1. A review of the laboratory's test menu revealed the laboratory started performing % neutrophil testing in December 2022. 2. The laboratory was asked to provide documentation of enrollment in proficiency testing for the analyte. No documentation was provided. 3. The laboratory performed 189 tests from</p>

	<p>December 6, 2022 to April 18, 2023. 4. An interview with the Integrated Care RN representative on 06/21/2023 at 0915 hour in the conference room confirmed the facility had not enrolled in proficiency testing. This confirmed the findings.</p>
<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the facility failed to meet the requirements for analytic systems. The findings include: 1. The laboratory failed to have procedures or manufacturer instructions for the Athelas One analyzer (refer to D5401). 2. The laboratory failed to follow the manufacturer's instructions for use for the Athelas One analyzer (refer to D5411). 3. The laboratory failed to have documentation of performing verification studies on the Athelas One analyzer (refer to D5421). 4. The laboratory failed to have documentation of performing quality control testing each day of patient testing on the Athelas One analyzer (refer to D5447).</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of manufacturer's instructions, and staff interview, it was revealed the laboratory failed to have documentation of a procedure for the use of the Athelas One analyzer. The findings include: 1. A review of the laboratory's procedures revealed the facility failed to have documentation of a procedure for the use of the Athelas One analyzer for the analysis of the percentage of neutrophils. 2. A review of the manufacturer's instructions provided by the laboratory revealed the facility had the manufacturer's instructions for use for the Athelas Home analyzer (a waived methodology). 3. The laboratory was asked to provide documentation of a procedure or of manufacturer's instructions for the Athelas One analyzer. No documentation was provided. 4. An interview with the Integrated Care RN representative on 06/21/2023 at 1200 hours in the conference room revealed the facility did not have instructions for the Athelas One analyzer. This confirmed the findings.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p>

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.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions for the Athelas One analyzer, review of patient test records from December 6, 2022 to April 18, 2023, and staff interview, it was revealed the laboratory failed to ensure patients tested on the Athelas One analyzer were 21 years old or older. The findings include: 1. A review of the manufacturer's instructions for the Athelas One analyzer under the section titled "Specifications" revealed: "The Athelas One is indicated for use in adult populations (aged 21 and older)." 2. A review of patient test records from December 6, 2022 to April 18, 2023 identified 13 of 189 tests performed were on samples from someone under the age of 21 years (see patient alias list 1). Patient DOB: 09/23/2003 Age at testing: 19 years old Test Date: 02/08/2023 02/15/2023 02/22/2023 03/01/2023 03/08/2023 03/20/2023 03/27/2023 (two tests performed) 03/28/2023 04/03/2023 (two tests performed) 04/04/2023 (two tests performed) 3. An interview with the Integrated Care RN representative on 06/21/2023 at 1300 hours in the conference room 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 the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performed the required verification studies on the Athelas One analyzer. The findings include: 1. A review of the laboratory's test menu revealed the laboratory started performing percent (%) neutrophils testing on the Athelas One analyzer in December 2022. 2. A review of the laboratory's records revealed the facility failed to have documentation of performing verification studies (accuracy, precision, reportable range and verifying patient normal ranges). 3. The laboratory was asked to provide documentation of performing the required studies. No documentation was provided. 4. The laboratory reported performing 189 tests from December 6, 2022 to April 18, 2023. 5. An interview with the Integrated Care RN representative on 06/21/2023 at 1115 hours in the conference room revealed the studies had not been performed. This confirmed the findings.

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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-- 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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's test menu, review of the laboratory's quality control records from December 2022 to April 2023, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing on 74 of 74 test days. The findings include: 1. A review of the laboratory's test menu revealed the laboratory started performing testing on the Athelas One analyzer in December 2022. 2. A review of the laboratory's quality control records from December 2022 to April 2023 revealed the laboratory failed to have documentation of performing quality control testing on 74 of 74 test days. 3. The laboratory was asked to provide documentation of performing quality control testing each day of patient testing. No documentation was provided. 4. The laboratory reported performing 189 tests from December 6, 2023 to April 18, 2023. 5. An interview with the Integrated Care RN representative on 06/21/2023 at 1100 hours in the conference room 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 records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. The findings include: 1. The laboratory director failed to ensure the facility had a qualified technical consultant (refer to D6004). 2. The laboratory director failed to ensure verification studies were performed (refer to D6013). 3. The laboratory director failed to ensure the facility was enrolled in proficiency testing (refer to D6015). 4. The laboratory director failed to ensure a quality control program was established (refer to D6020). 5. The laboratory director failed to ensure testing personnel had documentation of education and training (refer to D6029).

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	<p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, and staff interview, it was revealed the laboratory director failed to ensure the facility had a qualified technical consultant (refer to D6034).</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure verification studies were performed (refer to D5421).</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory was enrolled in proficiency testing for percent (%) neutrophils (refer to D2000).</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>Based on review of the laboratory's records and staff interview, the laboratory director failed to ensure a quality control program was established to ensure quality control testing was performed each day of patient testing (refer to D5447).</p>
<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure testing personnel had the appropriate education and training (refer to D6065 and D6066).</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209 and staff interview, it was revealed the laboratory failed to have a technical consultant (refer to D6034).</p>
<p>D6034</p>	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted Form CMS 209, personnel records, and confirmed in staff interview, the laboratory failed to employ an individual who met the qualifications of a Technical Consultant in 2023. Findings included: 1. Review of the laboratory's submitted Form CMS 209, the laboratory failed to designate a Technical Consultant. 2. The laboratory was asked to provide documentation of personnel meeting the qualifications of a technical consultant. No documentation was provided. 3. In an interview on 06/21/2023 at 0920 hours in the</p>

conference room, after review of the above records, the Integrated Care RN representative confirmed the findings. Word Key: CMS= Centers for Medicare and Medicaid Services RN = Registered Nurse

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(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 a review of laboratory records and confirmed in staff interview, the laboratory failed to perform competencies by a qualified Technical Consultant for 4 of 33 Testing Personnel (TP) in 2023. Findings included: 1. A review of laboratory records revealed the following competency records: a) TP#7 (as listed on the CMS Form 209): "6 Month Competency" completed on 06/16/2023 by TP#18 b) TP#17 (as listed on the CMS Form 209): "6 Month Competency" completed on 06/13/2023 by TP#18 c) TP#18 (as listed on the CMS Form 209): "6 Month Competency" completed on 06/07/2023 by TP#27 d) TP#27 (as listed on the CMS Form 209): "6 Month Competency" completed on 06/13/2023 by TP#18 Laboratory competencies were completed by personnel not meeting the qualifications of a Technical Consultant. 2. The laboratory was asked to provide documentation of a qualified Technical Consultant performing competency assessments. No documentation was provided. 3. In an interview on 06/21/2023 at 1005 hours in the conference room, after review of the above records, Quality Management representative confirmed the findings.

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 the laboratory's records and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 3 of 33 testing personnel (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 a review of the CMS Form 209 and confirmed in staff interview, the laboratory failed to provide education records for 3 of 33 Testing Personnel. Findings included: 1. A review of the CMS Form 209 (signed by the laboratory director on 06/14/2023) revealed the following patient testing personnel (TP): a) TP#2 b) TP#12 c) TP#16 2. The laboratory was asked to provide education records for the above personnel. No records were provided. 3. In an interview on 06/21/2023 at 0925 hours in the conference room, after review of the above results, the Lead Employment Specialist 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 a review of the laboratory's test menu, CMS Form 209, and confirmed in staff interview, the laboratory failed provide training records for 3 of 33 Testing Personnel. Findings included: 1. A review of the laboratory's test menu revealed Neutrophil Percentage was performed on the Athelas One test system. 2. A review of the CMS Form 209 (signed by the laboratory director on 06/14/2023) listed the following patient testing personnel (TP): a) TP#13 b) TP#15 c) TP#26 3. The laboratory was asked to provide Athelas One training records for the personnel above. No records were provided. 4. In an interview on 06/21/2023 at 1005 hours in the conference room, after review of the above records, the Quality Management representative confirmed the above findings.