

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0900079 | (X3) Date Survey Completed 09/03/2019 |
| Name of Provider or Supplier Abilene-Taylor County Public Health | Street Address, City, State 850 N 6th, Abilene, 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 surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1403 Condition: Laboratories Performing Moderate Complexity Testing; Laboratory Director 493. 1409 Condition: Laboratories Performing Moderate Complexity Testing; Technical Consultant 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Review of package inserts, policy and procedures, observations, quality control records and interview of facility personnel found that the laboratory failed to follow the manufacturer's instructions when using the Siemens 10 SG Urinalysis Reagent strips. The laboratory failed to test external quality control materials as defined by the manufacturer when using the Siemens 10 SG Urinalysis Reagent strips lot 804050 expiration 2019-10-31. THIS IS A REPEAT DEFICIENCY CITED IN THE AUGUST 2015 INSPECTION. Findings included: 1. Review of the package insert for the Siemens 10 SG urinalysis reagent strips found under the heading QUALITY CONTROL - "Test known negative and positive specimens or controls whenever a new bottle is first opened." 2. Quality control records for for urinalysis testing using the Siemens 10 SG urinalysis reagent strips were requested but not provided. 3. Observations made during the tour the laboratory found that the laboratory was currently using Siemens 10 SG Urinalysis Reagent Strips lot 803022 expiration 2019-08-31. There was no documentation of the date opened on the bottle. 4. Review of patient test records found two patient specimens had been tested on September 3,</p> |

| | |
|---------------------|---|
| | <p>2019 using the expired urinalysis reagent strips. 653 patient urine specimens were tested in 2019 . 5. Interview of testing person one conducted on September 3, 2019 at 4:00 PM found that external quality control materials were not tested when each new bottle of urinalysis reagent strips is first opened.</p> |
| <p>D2100</p> | <p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Review of the CMS 155, proficiency testing records, and interview of facility personnel found that the laboratory failed to participate in one of three testing events of 2019. The laboratory failed to test proficiency specimens for the second Chemistry testing event of 2019 for the analyte hCG. Findings included: 1. Review of the CMS 155 found the laboratory received a score of 0% for hCG in the 2019 Chemistry second testing event. 2. Review of the American Association of Bioanalysts (AAD) proficiency testing records found no results were submitted to the proficiency testing agency for grading for the analyte hCG in the first testing event of 2015. 3. Interview of testing person one listed on the CMS report 209 Laboratory Personnel Report conducted on September 3, 2019 at 3:33 PM confirmed that the laboratory failed to test and submit results for the Q2 2019 chemistry testing event.</p> |
| <p>D3037</p> | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Review of proficiency testing records and interview of facility personnel found that the laboratory failed to retain all proficiency testing records for serum hCG testing for at least two years. The findings included: 1. Review of the American Association of Bioanalysts (AAB) proficiency testing records for Chemistry found that the laboratory failed to retain results for five of six testing events between the 2017 Q3 Chemistry testing event and the 2019 2nd testing event. The laboratory failed to retain any original test records, attestation statements were reviewed results. 2. Proficiency testing records were requested but not provided. 3. Interview of testing person one on the CMS report 209 Laboratory Personnel Report conducted on September 3, 2019 at 2:46 PM confirmed that proficiency testing records were not retained. She went on to say she "could get the results online." Further explained that she did not know she had to retain proficiency testing records.</p> |
| <p>D6000</p> | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR</p> |

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:

Review laboratory records, personnel records and interview facility personnel found the laboratory director failed to provide overall management and direction of the laboratory. THIS IS A REPEAT DEFICIENCY FROM THE AUGUST 2015 INSPECTION 1. The laboratory director failed to ensure that proficiency testing materials were tested and returned to the proficiency testing program for grading before the end of the submission period. (See D6017) 2. The laboratory director failed to ensure the quality assessment program had been established and maintained. (See D6021) 3. The laboratory director failed to ensure that all testing personnel performing moderate complexity testing met the minimum education requirements. (See D6028)

D6017

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records from 2018 and 2019 and staff interview the laboratory director failed to ensure proficiency test results were returned prior to the submission deadline in one of five Chemistry testing events. (refer to D2100).

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Assurance Plan, review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assurance plan was followed. The findings included: 1. A review of the laboratory's Quality Assurance Plan (revision 3.1, December 18, 2017) found on page 6 under records: "records will be maintained and stored as per CLR

regulation 42 CFR 493.1105; retention requirements." 2. Review of proficiency testing records found that the laboratory failed to retain the original submission forms, attestation statements and copies of reviewed proficiency testing results. 3. Interview of testing person one conducted on September 3, 2019 at 2:46 PM confirmed that the laboratory had not retained copies of proficiency testing records for a minimum of two years.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Review of personnel files, laboratory test records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that seven of seven testing personnel performing serum hCG testing had the appropriate education and training for performing non waived procedures. (see D 6065 and D6066)

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

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.

This CONDITION is not met as evidenced by:

Based on observations, review of quality control records, review of calibration records, review patient test records, review of corrective action logs, review of package inserts and interview of facility personnel found that the technical consultant failed to provide technical and scientific oversight of the laboratory. (See D6054 and D6055)

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of personnel records and interview of facility personnel, the laboratory failed to have documentation of competency assessment for two of 10 testing personnel performing

moderate complexity testing . The findings included: 1. A review of the laboratory's submitted Form CMS 209 found the laboratory identified 10 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of competency assessment is for two of 10 testing personnel performing serum hCG testing. They were (as listed on Form CMS 209): testing person seven (hire date September 3, 2018) - no annual competency assessments were available for review testing person 10 (hire date April 2017) - no annual competency assessments were available for review. 3. The laboratory was asked to provide documentation of education for the employees listed above. Documentation of a vocational nursing certificate was provided for testing person 5. 4. Interview of testing person one conducted on September 3, 2019 at 2:19 PM confirmed that no competency assessments were available for review

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 submitted Form CMS 209, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory failed to ensure all testing personnel met the requirements to perform moderate complexity testing (refer to D6065 and D6066). THIS IS A REPEAT DEFICIENCY FROM THE AUGUST 2015 INSPECTION

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 the laboratory's submitted Form CMS 209, review of personnel records and interview of facility personnel, the laboratory failed to have documentation of education for three of 10 testing personnel performing moderate complexity testing. THIS IS A REPEAT DEFICIENCY FROM THE AUGUST 2015 INSPECTION The findings included: 1. A review of the laboratory's submitted Form CMS 209 found the laboratory identified 10 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records

revealed the laboratory failed to have documentation of education for three of 10 testing personnel to qualify them to perform moderate complexity testing. They were (as listed on Form CMS 209): testing person five (hire date January 2019) testing person 6 (hire date September 3, 2018) testing person 10 (hire date April 2017) 3. The laboratory was asked to provide documentation of education for the employees listed above. Testing person five offered a vocational nursing certificate. 4. Interview of testing person one conducted on September 3, 2019 at 2:19 PM confirmed that no documentation of initial training was available for review. Interview of testing person five conducted on September 3, 2019 at 2:15 PM confirmed that she had a GED but did not have a copy of and cannot get a copy of it before the end of the survey.

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 the laboratory's submitted Form CMS 209, review of personnel records and interview a facility personnel, families the laboratory failed to have documentation of initial training for three of 10 testing personnel performing moderate complexity testing. THIS IS A REPEAT DEFICIENCY FROM THE AUGUST 2015 INSPECTION The findings included: 1. A review of the laboratory's submitted Form CMS 209 found the laboratory identified 10 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for three of 10 testing personnel to qualify them to perform moderate complexity testing. They were (as listed on Form CMS 209): testing person five (hire date January 2019) testing person 6 (hire date September 3, 2018) testing person 10 (hire date April 2017) 3. The laboratory was asked to provide documentation of training for the employees listed above. No documentation was provided. 4. Interview of testing person one conducted on September 3, 2019 at 2:19 PM confirmed that no documentation of initial training was available for review.