

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0465052	(X3) Date Survey Completed 03/12/2018
Name of Provider or Supplier Sabine Medical Center Rural Health Clinic #1	Street Address, City, State 395 South Capital Street, Many, 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
D0000	A Recertification Survey was performed at Sabine Rural Health Center - CLIA # 19D0465052 on March 12, 2018. Sabine Rural Health Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1230 CONDITION: General Laboratory System 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director
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: Based on record review and interview with personnel, the laboratory failed to ensure that proficiency testing was performed by personnel who routinely perform laboratory testing. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2017 and 2018 revealed the following proficiency testing was performed by testing Personnel 3, qualified for waived testing only: 2017 Urine Drug Screen Event 1, sample UDS 03 2017 Hematology Event 2, Complete Blood Count samples 06 and 10 2. In interview on March 12, 2018, Personnel 2 confirmed that Personnel 3 was a testing personnel for waived testing only as should not have performed proficiency testing for moderate complexity testing.</p>
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7),</p>

that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on observation, record review and interview with laboratory personnel, the laboratory failed to monitor and evaluate the overall quality of the General Laboratory System. Findings: 1. The laboratory failed to successfully verify the accuracy of the performance of urine drug screening at least twice annually. Refer to D5217.

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 record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 1 serves as the Technical Consultant. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Consultant. 3. Review of personnel records revealed competency assessments for the duties of Technical Consultant were not documented. 4. In interview on March 12, 2018, Personnel 1 stated the laboratory director had a written delegation of duties to the Technical Consultant. Personnel 1 confirmed this document did not address competency assessment of the Technical Consultant.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory failed to successfully verify the accuracy of the performance of urine drug screening at least twice annually. Findings: 1. Review of American Proficiency Institute (API) proficiency testing records revealed the following scores for Pehncyclidine (PCP): a. 2017 Event 1: 67% b. 2017 Event 2: 67% 2. In interview on March 12, 2018 Personnel 1 & 2 confirmed the laboratory did not successfully participate in Proficiency Testing for PCP. Personnel 3 confirmed the laboratory ceased patient testing while further investigation was to be completed.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken

when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to document corrective actions performed when the refrigerator temperature was not maintained between 2 degrees and 8 degrees Celsius. Findings: 1. Review of the laboratory's temperature chart for refrigeration revealed the acceptable range to be 2 degrees to 8 degrees Celsius. 2. Further review of the temperature record revealed the temperature of Refrigerator 2 was documented at 0-1 degrees Celsius, outside of the acceptable limits, without corrective action for the following thirty eight (38) of one hundred and two (102) dates: December 1, 2017 December 4-8, 2017 December 11-13, 2017 December 26, 2017 December 28, 2017 January 2, 2018 January 3-5, 2018 January 15-18, 2018 January 26, 2018 January 29-31, 2018 February 5-8, 2018 February 12-13, 2018 February 19, 2018 February 22-23, 2018 March 1, 2018 March 2, 2018 March 5, 2018 March 6, 2018 March 12, 2018 3. Interview with Personnel 2 on March 12, 2018 confirmed that the temperatures documented were outside of the acceptable ranges. Personnel 2 stated that the temperatures were monitored, but corrective action was not documented.

D5805

TEST REPORT

CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on March 12, 2018 revealed the laboratory utilized the Alere iCassette for UDS testing which includes: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Marijuana (THC), Methylenedioxymethamphetamine (MDMA), Opiates, Oxycodone, Phencyclidine (PCP), Propoxyphene (PPX), and Tricyclic Antidepressants (TCA). 2. Review of the Alere iCassette Drug Screen package insert under the Intended Use section revealed "This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any

drug of abuse test result, particularly when preliminary positive results are indicated." 3. Review of random patient test reports for UDS revealed the laboratory included the following statements: "This test provides only a qualitative, preliminary, non-confirmed analytical result.." However, the comment did not include the complete comment of the manufacturer. 4. In further interview on March 12, 2018, Personnel 1 & 2 confirmed all UDS reports have the identified comment of a preliminary result; however, the full statement as listed in the manufacturer's package insert was not included. 5. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 120 UDS annually.

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 record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure proficiency samples are tested as required. 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 record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. 1. The laboratory failed to ensure that proficiency testing was performed by personnel who routinely perform laboratory testing. Refer to D2007. 2. The laboratory failed to successfully verify the accuracy of the performance of urine drug screening at least twice annually. Refer to D5217.

D6022

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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program identified temperatures out of acceptable range. Refer to D5781.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(8)

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.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D5805.