

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0508127	<b>(X3) Date Survey Completed</b>  02/15/2019
<b>Name of Provider or Supplier</b>  Mitchell County Hospital	<b>Street Address, City, State</b>  997 West I20, Colorado City, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.803 Condition: Successful participation 493.807 Condition: Reinstatement of laboratories performing nonwaived testing 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
<b>D2016</b>	<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> <p>This CONDITION is not met as evidenced by: Based on review of the CMS-155 proficiency testing report, the American Association</p>

of Bioanalysts (AAB)) proficiency testing records for 2017, 2018 and 2019 and interview of facility personnel the laboratory failed to successfully participate in a proficiency testing for Bacteriology. (See D 2020 and D 2021)

**D2017**

**REINSTATEMENT OF NONWAIVED LABORATORIES**

CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:

Based on review of the CMS-155 proficiency testing report, the American Association of Bioanalysts (AAB)) proficiency testing records for 2017, 2018 and 2019 and interview of facility personnel the laboratory failed to successfully participate in a proficiency testing for Bacteriology. (See D 2020 and D 2021)

**D2020**

**BACTERIOLOGY**

CFR(s): 493.823(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Review of the laboratory's CMS 155 report, the American Association of Bioanalysts (AAB) Non-Chemistry proficiency testing records from 2017, 2018 and 2019 and staff interview found the laboratory failed to attain an overall testing event score of 80% or higher in three of three consecutive testing events of 2018 for Bacteriology (Q1, Q2 and Q3). The findings included: 1. Review of the CMS report 155( printed February 4, 2019) found that the AAB proficiency testing agency reported a score of 0% for Bacteriology in the 2018 Q1 and Q2 Non Chemistry testing events. Review of the CMS report 155( printed February 15, 2019) found that the proficiency testing agency reported a score of 0% for Bacteriology in the 2018 Q1 and Q2 Non Chemistry testing events. 2. A review of the laboratory's American Proficiency Institute's bacteriology proficiency testing records from 2018 found: 2018 Q1 Cumulative scores - The laboratory was not given a score for Culture ID or Susceptibility testing. Code Dc ( Discontinued from reporting to CMS) was noted in each of the result fields. 2018 Q2 Cumulative Scores- The laboratory was not given a score for Culture ID or Susceptibility testing. The fields were blank. 2018 Q3 Cumulative scores - The specialty of Bacteriology does not appear on the report. 3. Interview of the General Supervisor conducted on February 12, 2019 at 11:16 AM

confirmed that the laboratory stopped testing Culture ID and Susceptibility testing at the end of 2017. She went on to say that she did not renew the proficiency testing for bacteriology in 2018 because she was no longer testing. She said she notified the state agency, but did not notify the Proficiency testing agency of discontinued testing in Culture ID and Susceptibility because she thought not renewing the order was enough. Further interview of the general supervisor conducted on February 15, 2019 at 10:30 AM found that she had communicated with the proficiency testing agency regarding the reported scores of 0% and was informed that they would look into the coding for discontinued testing and resubmit them to CMS. In this process, a score of 0% for the Q3 2018 Bacteriology testing event was generated.

**D2021**

**BACTERIOLOGY**  
CFR(s): 493.823(b)

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.

This STANDARD is not met as evidenced by:

Review of the laboratory's CMS 155 report, the American Association of Bioanalysts (AAB) bacteriology proficiency testing records from 2017, 2018 and 2019 and staff interview found the laboratory failed to successfully participate in three of three consecutive testing events of 2018 (Q1, Q2 and Q3). The findings included: 1. Review of the CMS report 155( printed February 4, 2019) found that the proficiency testing agency reported a score of 0% for Bacteriology in the 2018 Q1 and Q2 Non Chemistry testing events. Review of the CMS report 155( printed February 15, 2019) found that the proficiency testing agency reported a score of 0% for Bacteriology in the 2018 Q1 and Q2 Non Chemistry testing events. 2. A review of the laboratory's American Proficiency Institute's bacteriology proficiency testing records from 2018 found: 2018 Q1 Cumulative scores - The laboratory was not given a score for Culture ID or Susceptibility testing. Code Dc ( Discontinued from reporting to CMS) was noted in each of the result fields. 2018 Q2 Cumulative Scores- The laboratory was not given a score for Culture ID or Susceptibility testing. The fields were blank. 2018 Q3 Cumulative scores - The specialty of Bacteriology does not appear on the report. 3. Interview of the General Supervisor conducted on February 12, 2019 at 11:16 AM confirmed that the laboratory stopped testing Culture ID and Susceptibility testing at the end of 2017. She went on to say that she did not renew the proficiency testing for bacteriology in 2018 because she was no longer testing. She said she notified the state agency, but did not notify the Proficiency testing agency of discontinued testing in Culture ID and Susceptibility because she thought not renewing the order was enough. Further interview of the general supervisor conducted on February 15, 2019 at 10:30 AM found that she had communicated with the proficiency testing agency regarding the reported scores of 0% and was informed that they would look into the coding for discontinued testing and resubmit them to CMS. In this process, a score of 0% for the Q3 2018 Bacteriology testing event was generated.

**D2173**

**COMPATIBILITY TESTING**

CFR(s): 493.863(a)

Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing records (3 testing events per year) from 2017 and 2018, and interview facility personnel the laboratory failed to attain an overall compatibility testing event score of at least 100% which constitutes unsatisfactory performance. Findings included: 1. Review of proficiency testing records found that the laboratory attained a score of 0% in the American Association of Bioanalysts (AAB) 2018 Q1 testing event for compatibility testing. The laboratory submitted unacceptable responses for five of five specimens, resulting in a score of 0% for Compatibility testing. 2. Interview of the general supervisor conducted on February 12, 2019 at 11:44 AM confirmed that the laboratory results submitted were the same as on their original worksheet and that no further action was taken other than review of recorded results and Quality control results. She stated that the agglutination was "1+ to 2+" (reactivity) for specimens 1-5, so they reported the result as Immediate Spin only, incompatible.

**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 a review of the laboratory testing records, patient test records, and interview of facility personnel it was revealed that the laboratory failed to enroll in a proficiency testing program for each of the each of the specialties and subspecialties for which it seeks certification, or have another means to verify the accuracy of results for Serum Ketones . The findings included: 1. A review of facility records found no documentation of the laboratory participating in a CMS approved proficiency testing program, or have another means to verify the accuracy of results at least twice each year in 2017, 2018 or 2019 for serum Ketones and White Blood Cell (WBC) and Red Blood Cell (RBC)counts for body fluids. 2. Review of patient test records found that the laboratory tested: 20 patient specimens for serum Ketones in 2018 2 patient specimens in 2019 and 0 patient specimens in 2018 for body fluid cell count procedures. 3. Interview of the General Supervisor listed on the CMS report 209 Laboratory Personnel Report conducted on February 13, 2019 at 9:51 AM confirmed that the laboratory did enroll but failed to test specimens and submit responses for serum ketones to the proficiency testing program for serum ketones, and the laboratory did not enroll in, or participate in a proficiency testing program for body fluids or have another method to verify the accuracy of results..

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the quality control records, patient testing records, and confirmed in interview with the General Supervisor, the laboratory failed to include a negative and positive control each day of patient testing for the serum Acetest procedure. The findings included: 1. Review of quality control records found no documentation of quality control testing for Acetest reagent tablets. 2. Review of patient test records found that the laboratory tested 20 patient specimens in 2018 without testing a negative and positive quality control each day of testing. 3. Interview of the general supervisor conducted on February 13, 2019 at 09:41 AM confirmed the above findings.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Review of proficiency testing records and interview of facility personnel found that the laboratory director failed to ensure that corrective actions were taken when proficiency testing failures occurred in Bacteriology. (see D 6092)

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure 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:

The laboratory director failed to ensure that proficiency testing reports received were evaluated to identify problems requiring corrective action when failures in Bacteriology were reported to the Center for Medicare and Medicaid Services (CMS) for three of three testing events in 2018. The findings included: 1. Review of the CMS report 155 ( printed February 4, 2019) found that the proficiency testing agency reported a score of 0% for Bacteriology in the 2018 Q1 and Q2 Non Chemistry testing events. Review of the CMS report 155( printed February 15, 2019) found that the proficiency testing agency reported a score of 0% for Bacteriology in the 2018 Q1 and Q2 Non Chemistry testing events. 2. A review of the laboratory's American Proficiency Institute's bacteriology proficiency testing records from 2018 found: 2018 Q1 Cumulative scores - The laboratory was not given a score for Culture ID or Susceptibility testing. Code Dc ( Discontinued from reporting to CMS) was noted in each of the result fields. 2018 Q2 Cumulative Scores- The laboratory was not given a score for Culture ID or Susceptibility testing. The fields were blank. 2018 Q3 Cumulative scores - The specialty of Bacteriology does not appear on the report. 3.

Interview of the General Supervisor conducted on February 12, 2019 at 11:16 AM confirmed that the laboratory stopped testing Culture ID and Susceptibility testing at the end of 2017. She went on to say that she did not renew the proficiency testing for bacteriology in 2018 because she was no longer testing. She said she notified the state agency, but did not notify the Proficiency testing agency of discontinued testing in Culture ID and Susceptibility because she thought not renewing the order was enough. Further interview of the general supervisor conducted on February 15, 2019 at 10:30 AM found that she had communicated with the proficiency testing agency regarding the reported scores of 0% and was informed that they would look into the coding for discontinued testing and resubmit them to CMS. In this process, a score of 0% for the Q3 2018 Bacteriology testing event was generated.