

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0872283	(X3) Date Survey Completed 09/11/2019
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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
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 record review and staff interview the laboratory failed to enroll in proficiency testing (PT) for the specialty of chemistry and failed to test PT samples in the same manner it tests patient samples. Refer to 2006. Findings include: 1. Record review of the Clinical Laboratory Improvement Amendments (CLIA) CMS116 application test menu on 9/11/19 revealed the laboratory performs microscopic urinalysis testing 2. Record review of the laboratory's PT enrollment forms on 9/11/19 revealed the laboratory failed to provide evidence or documentation of PT enrollment for microscopic urinalysis in 2017, 2018 and 2019. 3. Staff interview with the laboratory director on 9/11/19 at 12:30 PM confirmed the above findings. 4. The laboratory performs 160 chemistry tests annually.</p>
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of</p>

this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to ensure proficiency testing (PT) samples were processed in the same manner as patient samples for microbiology PT testing. Findings include: 1. Record review of the laboratory's patient log book on 9/11/19 at 10:00 AM revealed PT samples were not being recorded in the laboratory's patient log, which resulted in the laboratory being unable to identify the mix up of PT samples for the American Proficiency Institute PT events 3 in 2018 and event 2 in 2019. 2. Interview with Technical Consultant#1 on 9/11/19 at 10:00 AM confirmed that PT samples were not being logged into the patient log book like patient samples in 2017, 2018 and 2019. 3. The laboratory performs 235 throat culture tests annually.

D2016

SUCCESSFUL PARTICIPATION

CFR(s): 493.803(a)(b)(c)

(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.

This CONDITION is not met as evidenced by:
Based on proficiency testing (PT) record review, the laboratory failed to successfully achieve a score of 80 percent (%) in two of three testing events for 2018 and 2019 for the subspecialty of bacteriology, specifically event 3: 40% and event 2: 40%. Refer to D2028.

D2028

BACTERIOLOGY

CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

	<p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) data summary reports the laboratory failed to successfully achieve a score of 80 percent (%) in two of three testing events for 2018 and 2019 for the subspecialty of bacteriology. Findings include: 1. Record review of the Center for Medicare & Medicaid Services (CMS) PT Data Report on 9/11/19 revealed the laboratory obtained unsatisfactory scores for two of three PT events for analyte #005 Bacteriology as follows: Year/Event # PT Score 2018 - Event - 3 40% 2019 - Event - 1 100% 2019 - Event - 2 40% 2. Record review of the American Proficiency Institute PT program results for the Microbiology survey on 9/11/19 revealed the laboratory obtained unsatisfactory scores in two of three PT events as evidenced below. Year/Event # PT Score 2018 - Event -3 40% 2019- Event -1 100% 2019 - Event- 2 40% 3. The laboratory performs 235 throat cultures annually in the subspecialty of bacteriology.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's personnel competency records on 9/11/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the technical consultant and clinical consultant. b. Competency documentation for the above laboratory personnel was not available. 2. Staff interview with the technical consultant on 9/11/19 at 11:15 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed in 2017 and 2018.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy bi-annually for microscopic KOH testing in the specialty of microbiology. Findings include: 1. Record review of the laboratory's Proficiency testing on 9/11/19 revealed that biannual verification for accuracy was not performed in 2017 and 2018 for 4 of 4 testing personnel. 2. Staff interview with laboratory director on 9/11/19 at 12:30 PM confirmed the above findings. 3. The laboratory performs 6 microscopic KOH tests annually.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

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 documentation and interview with the technical consultant, the laboratory director failed to enroll in proficiency testing (PT), process PT samples in the same manner as patient samples, ensure remedial actions taken for unsuccessful PT failures, investigate or document unsuccessful PT scores and ensure training and competency of all testing personnel. Findings include: 1. The laboratory director failed to enroll in PT testing for microscopic urinalysis testing (See D6015) 2. The laboratory director failed to ensure PT samples were processed in the same manner as patient samples (See D6016) 3. The laboratory director failed to ensure remedial actions were taken for unsuccessful PT failures for bacteriology (See D6018) 4. The laboratory director failed to investigate or document unsuccessful PT scores (See D6019) 5. The laboratory director failed to ensure training/competency for new testing personnel. (See D6029)

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to enroll in proficiency testing (PT) for the specialty of chemistry. Findings include: 1. Record review of the Clinical Laboratory Improvement Amendments (CLIA) CMS116 application test menu on 9/11/19 revealed the laboratory performs microscopic urinalysis testing. 2. Record review of the laboratory's PT enrollment forms on 9/11/19 revealed the laboratory failed to provide evidence or documentation of PT enrollment for microscopic urinalysis in 2017, 2018 and 2019. 3. Staff interview with the laboratory director on 9/11/19 at 12:30 PM confirmed the above findings. 4. The laboratory performs 160 microscopic urinalysis tests annually.

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 staff interview, the laboratory failed to ensure proficiency testing (PT) samples were processed in the same manner as patient samples for microbiology PT testing. Findings include: 1. Record review of the laboratory's patient log book on 9/11/19 at 10:00 AM revealed PT samples were not being recorded in the laboratory's patient log, which resulted in the laboratory being unable to identify the mix up of PT samples for the American Proficiency Institute PT events 3 in 2018 and event 2 in 2019. 2. Interview with Technical Consultant#1 on 9/11/19 at 10:00 AM confirmed that PT samples were not being logged into the patient log book like patient samples in 2017, 2018 and 2019. 3. The laboratory performs 235 throat culture tests annually.

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 record review and staff interview the laboratory director failed to evaluate and review laboratory's performance and identify problems that required corrective action for unacceptable Proficiency Testing (PT) results in the subspecialty of bacteriology. Findings include: 1. Record review of American Proficiency Institute (API) PT Performance Summary report on 9/11/19 revealed the laboratory obtained an unacceptable score for the following events. a. 2018 Event-3 Throat culture score of 40% b. 2019 Event-2: Throat culture score of 40% Investigation or remedial action was not documented for the above unacceptable results. 2. Record review of the 2018 and 2019 API Performance Summary reports and Attestation sheets on 9/11/19 revealed the PT Events were not signed that they were reviewed by the laboratory director. 3. Staff interview with the laboratory director on 9/11/19 at 12:45 PM confirmed the above findings. 4. The laboratory performs 235 throat culture tests annually.

D6019

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

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory director failed to investigate or take corrective action when unsuccessful Proficiency Testing (PT) scores are received in the subspecialty of bacteriology. Findings include: 1. Record review on 9

/11/19 of the laboratory's American Proficiency Institute PT records revealed: a. Unacceptable test scores of 40% for Events 3 in 2018 and Event 2 in 2019. b. Investigation or remedial action was not documented for the above unacceptable results. c. The PT events were not signed as reviewed by the laboratory director. 2. Staff interview with Technical Consultant #1 on 9/11/19 at 11:00 AM confirmed the laboratory did not investigate the unacceptable PT results. 3. The laboratory performs 235 throat culture tests annually.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory director failed to ensure new testing personnel (TP) received appropriate training to perform moderate complexity testing prior to reporting patient test results in the subspecialty of bacteriology. Findings include: 1. Record review of 2017 and 2019 new TP files on 9/11/19 revealed the training documentation for 2 of 2 new TP did not indicate preanalytical, analytical and post analytical training documentation. 2. Record review of the laboratory's procedure manual on 9/11/19 revealed no policy was available for the training/competency of new TP. 3. Staff interview with the technical consultant #1 on 9/11/19 at 10:00 AM confirmed the above findings. 4. The laboratory performs 235 throat culture tests annually.

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 record review and staff interview, the laboratory failed to document annual competency of testing personnel (TP) to assess their knowledge and skills necessary to perform moderate complexity microscopic urinalysis and KOH analysis testing in the subspecialty of bacteriology. Findings include: 1. Record review of TP competency records on 9/11/19 revealed the laboratory did not have annual competency documentation for 4 of 4 TP performing microscopic urinalysis and KOH testing in 2017 and 2018. 2. Staff interview with the laboratory director on 9/11/19 at 12:45 PM confirmed the laboratory failed to assess and document annual competency for the above TP for microscopic urinalysis and KOH testing. 3. The laboratory performs 160 microscopic urinalysis and 6 KOH tests annually.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, testing personnel did not test unknown samples to assess their knowledge and skills to maintain their competency in the subspecialty of bacteriology. Findings include: 1. Record review of the American proficiency Institute throat culture attestation sheets on 9/11/19 revealed 2 of 6 testing personnel (TP) did not examine unknown samples including proficiency testing (PT) material to accurately assess their knowledge and skills in 2018. 2. Record review of the above TP competency documentation on 9/11/19 revealed PT was checked off that the above TP examined PT testing material in 2018. 3. Staff interview with the technical consultant#1 on 9/11/19 at 1:00 PM confirmed 2 of 6 TP did not examine unknown samples including proficiency testing material to accurately assess their skills for throat culture testing in 2018. TC#1 stated he/she thought the PT box on the competency form meant that TP was proficient in testing moderate complexity testing. 4. Laboratory performs approximately 235 throat culture tests annually.