

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2161100	(X3) Date Survey Completed 05/25/2021
Name of Provider or Supplier Center For Digestive Disease	Street Address, City, State 129 Vision Park Blvd, Suite 307, Shenandoah, 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	
D2016	<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 a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API), it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified</p>

	<p>under CLIA. The laboratory did not successfully participate in the specialties of: a) Bacteriology for the analyte Molecular Bacti- GI b) Virology for the analyte Molecular Virology- GI. Refer to D2028 and D2064.</p>
<p>D2020</p>	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed the laboratory failed to attain an overall testing score of at least 80% in the specialty of Bacteriology. Findings include: 1. 2020 Microbiology- 3rd Event unacceptable score of 0% 2. 2021 Microbiology- 1st Event unacceptable score of 0%</p>
<p>D2021</p>	<p>BACTERIOLOGY CFR(s): 493.823(b)</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: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed that the laboratory failed to participate in the API- Microbiology 3rd event 2020 and API- Microbiology 1st event 2021, resulting in unsatisfactory performance for the specialty Bacteriology. Findings include: 1. API- Microbiology 3rd event 2020 the laboratory failed to participate, resulting in a score of 0% 2. API- Microbiology 1st event 2021 the laboratory failed to participate, resulting in a score of 0%.</p>
<p>D2028</p>	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>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> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center</p>

	<p>for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed the laboratory failed to achieve satisfactory performance of at least 80% for the same analyte in 2 out of 3 consecutive testing events in the specialty Bacteriology for the analyte Molecular Bacti- GI. Findings include: Molecular Bacti- GI: 1. 2020 Microbiology- 3rd Event unacceptable score of 0% 2. 2021 Microbiology- 1st Event unacceptable score of 0%</p>
<p>D2056</p>	<p>VIROLOGY CFR(s): 493.831(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed the laboratory failed to attain an overall testing score of at least 80% for the specialty of Virology. Findings include: 1. 2020 Microbiology- 3rd Event unacceptable score of 0% 2. 2021 Microbiology- 1st Event unacceptable score of 0%</p>
<p>D2057</p>	<p>VIROLOGY CFR(s): 493.831(b)</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: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed that the laboratory failed to participate in the API- Microbiology 3rd event 2020 and API- Microbiology 1st event 2021, resulting in unsatisfactory performance for the specialty Virology. Findings include: 1. API- Microbiology 3rd event 2020 the laboratory failed to participate, resulting in a score of 0% 2. API- Microbiology 1st event 2021 the laboratory failed to participate, resulting in a score of 0%</p>
<p>D2064</p>	<p>VIROLOGY CFR(s): 493.831(e)</p> <p>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>

	<p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed the laboratory failed to achieve satisfactory performance of at least 80% for the same analyte in 2 out of 3 consecutive testing events in the specialty Virology for the analyte Molecular Virology- GI. Findings include: Molecular Virology- GI: 1. 2020 Microbiology- 3rd Event unacceptable score of 0%- failure to participate. 2. 2021 Microbiology- 1st Event unacceptable score of 0%- failure to participate.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <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.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6018.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(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;</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the laboratory's American Proficiency Institute (API) proficiency test results, it was revealed the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2020, D2021, D2028, D2056, D2057, D2064.</p>