

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0980753	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Columbiana Clinic Llc	Street Address, City, State 22266 Highway 25 Bypass, Columbiana, AL	
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	This is the laboratory's second unsuccessful proficiency testing participation for Sodium (NA), resulting in non-initial proficiency testing participation.
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 review of the Casper Reports (#153/#155) and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to successfully participate in proficiency testing (PT) for Sodium (Na) for Event #2, 2017, Event #3, 2017 and Event #2, 2018. These failures resulted in non-initial proficiency testing participation for the laboratory. The findings include: 1. Previously cited, the initial unsuccessful participation: The laboratory scored 40 %</p>

	<p>(percent) for Na for testing Event #2 of 2017, and 0 % for Na for Event #3, 2017. The zero score was due to the laboratory's untimely submission of the testing results to the proficiency testing provider. 2. A review of the Casper Reports and API proficiency testing evaluations revealed the laboratory scored 40 % for Na for Event #2, 2018, resulting in two unsuccessful performances, a non-initial PT participation.</p>
<p>D2087</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Casper Reports (#153/#155) and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to perform satisfactorily in proficiency testing for Sodium (Na) for Events #2 and #3 of 2017 and Event #2 of 2018. These failures resulted in non-initial proficiency testing participation for the laboratory. The findings include: 1. Previously cited, the initial unsuccessful participation: The laboratory scored 40 % (percent) for Na for testing Event #2 of 2017, and 0 % for Na for Event #3, 2017. The zero score was due to the laboratory's untimely submission of the testing results to the proficiency testing provider. 2. A review of the Casper Reports and API proficiency testing evaluations revealed the laboratory scored 40 % for Na for Event #2, 2018, resulting in two unsuccessful performances, a non-initial PT participation.</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 review of the Casper Reports (#153/#155) and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory director failed to ensure the laboratory successfully participated in proficiency testing (PT) for Sodium (Na), as evidenced by the laboratory's failures of Na for Events #2 and #3, 2017 and Event #3, 2018. These failures resulted in non-initial proficiency testing participation for the laboratory. The findings include: 1. Refer to D2016.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p>

This STANDARD is not met as evidenced by:
Based on a review of the Casper Reports (#153/#155) and a review of API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory director failed to ensure the laboratory's quality assessment program was maintained in a manner to identify possible errors within the laboratory systems that resulted in the laboratory's non-initial performance of proficiency testing for Sodium. The findings include: 1. Refer to D2016. Patricia Watson, BS, MT (ASCP)Licensure and Certification Supervisor