

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0693972	(X3) Date Survey Completed 07/24/2020
Name of Provider or Supplier Lowell F Clark Md Pa	Street Address, City, State 212 S Florida St, Bushnell, FL	
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	An announced CLIA recertification survey was conducted at Lowell F Clark MD PA on 07/24/20. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director
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 review of American Proficiency Institute (API) proficiency testing and</p>

	<p>interview with the Technical Consultant the laboratory did not have successful performance in proficiency testing in the Subspecialty of Routine Chemistry (See D2096).</p>
<p>D2096</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in 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 review of American Proficiency Institute (API) proficiency testing and interview with the Technical Consultant the laboratory did not have successful performance in proficiency testing in the Subspecialty of Routine Chemistry. Findings Included: Review of API proficiency testing revealed unsuccessful performance for the following analytes: Event #2 2019 Albumin 60% Event #1 2020 Albumin 0% Event #2 2019 Calcium 0% Event #1 2020 Calcium 0% Event #2 2019 Chlorine 40% Event #1 2020 Chlorine 60% Event #2 2019 Cholesterol 0% Event #1 2020 Cholesterol 0% Event #1 2019 Total Protein 0% Event #2 2019 Total Protein 20% Event #1 2020 Total Protein 0% Interview on 07/24/20 at 1:00 PM with the Technical Consultant confirmed the failures. The laboratory has ceased testing of these analytes until service comes and remedial proficiency testing is acceptable.</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 review of American Proficiency Institute (API) proficiency testing and interview with the Technical Consultant, the Laboratory Director failed to ensure that the laboratory performed successful proficiency testing in the Subspecialty of Routine Chemistry (See D6016).</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing scores and interview with the Technical Consultant, the Laboratory Director failed to ensure that the laboratory</p>

performed proficiency testing in such a manner as to achieve and maintain successful participation in proficiency testing in the subspecialty of routine chemistry. Findings Included: A review of the American Proficiency Institute (API) proficiency testing records revealed unsatisfactory proficiency testing scores for the following analytes: Event #2 2019 Albumin 60% Event #1 2020 Albumin 0% Event #2 2019 Calcium 0% Event #1 2020 Calcium 0% Event #2 2019 Chlorine 40% Event #1 2020 Chlorine 60% Event #2 2019 Cholesterol 0% Event #1 2020 Cholesterol 0% Event #1 2019 Total Protein 0% Event #2 2019 Total Protein 20% Event #1 2020 Total Protein 0% Interview on 07/24/20 at 1:00 PM with the Technical Consultant confirmed the failures. The laboratory has ceased testing of these analytes until service comes and remedial proficiency testing is acceptable.