

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0968213	(X3) Date Survey Completed 04/02/2020
Name of Provider or Supplier Associated Specialists Inc	Street Address, City, State 527 Medical Park Drive, Suite 204, Bridgeport, WV	
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
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 proficiency testing (PT) records of American Proficiency Institute (API) and CASPER reports 155D and 153D, the laboratory failed to successfully participate in PT for each analyte on the CLIA test menu. Findings: 1. Review of the CLIA database, via CASPER report 153D for unsuccessful PT participation, identified a PT failure of the laboratory for analyte 0355 (Chloride). 2. Review of the individual laboratory PT scores, via CASPER report 155D and API, identified the following unsatisfactory scores for analyte 0355 Chloride: a. 20% for Chloride in API 2nd event 2019 b. 40% for Chloride in API 1st event 2020</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 a review of CASPER report 155D and the proficiency testing (PT) records from the American Proficiency Institute (API), the laboratory produced unsatisfactory results for the same analyte (0355 Chloride) in Chemistry for 2 out of 3 testing events. Findings; 1. Review of the individual laboratory PT report scores (CASPER report 155D) and comparative evaluation scores from API, identified the following unsatisfactory scores for analyte 0355 Chloride: a. 20% for Chloride API 2nd testing event 2019 b. 40% for Chloride API 1st testing event 2020</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 proficiency testing (PT) records from the CLIA database (CASPER reports 153D and 155D) and comparative evaluation records from the American Proficiency Institute (API), the laboratory director failed to provide overall anagement and direction in accordance with CLIA regulations. Findings: 1. Review of CASPER reports 153D and 155D, and API evaluation scores identified unsatisfactory analyte scores for 0355 Chloride in 2 of 3 testing events. a. 20% for Chloride API 2nd testing event of 2019 b. 40% for Chloride API 1st testing event 2020</p>
<p>D6004</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) scores and CASPER reports 153D and 155D, the laboratory director failed to ensure satisfactory performance form the laboratory in proficiency testing. Findings: 1. Review of API PT evaluation scores, CASPER reports 153D and 155D, identified</p>

unsatisfactory scores for analyte 0355 Chloride in 2 of 3 testing events. a. 20% for Chloride API 2nd testing event 2019 b. 40% for Chloride API 1st testing event 2020