

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235176	(X3) Date Survey Completed 04/01/2019
Name of Provider or Supplier St Mary's Medical Center Himg Campus	Street Address, City, State 5170 U S Route 60 East, Huntington, 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 review of the proficiency testing records from the American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for each analyte on the CLIA test menu. Findings: 1. Review of the CLIA database, via CASPER report 153D for failed proficiency testing results, found a PT failure for the laboratory for analyte #0265 (albumin). 2. Review of the individual laboratory PT report scores (CASPER report 155D) and comparative evaluation scores from API demonstrated the following unsatisfactory scores for albumin: a. 20% for 3rd event 2018 b. 60% for 1st event 2019</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 review of the proficiency testing records from the American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for each analyte on the CLIA test menu. Findings: 1. Review of the CLIA database, via CASPER report 153D for failed proficiency testing results, found a PT failure for the laboratory for analyte #0265 (albumin). 2. Review of the individual laboratory PT report scores (CASPER report 155D) and comparative evaluation scores from API demonstrated the following unsatisfactory scores for albumin: a. 20% for 3rd event 2018 b. 60% for 1st event 2019</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 the proficiency testing records, the laboratory director failed to provide overall management and direction in accordance with the regulations. Findings: 1. Refer to citation at D6004 for details.</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 reappoints 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 the proficiency testing records, the laboratory director failed to ensure satisfactory performance of proficiency testing for each analyte. Findings: 1. Review of the individual laboratory PT report scores (CASPER report 155D) and comparative evaluation scores from API demonstrated the following unsatisfactory scores for albumin: a. 20% for 3rd event 2018 b. 60% for 1st event 2019</p>