

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0900618	(X3) Date Survey Completed 12/15/2022
Name of Provider or Supplier Advocate Medical Group - Beverly Center	Street Address, City, State 9831 S Western Avenue, Chicago, IL	
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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records confirmed the laboratory's initial unsuccessful PT performance for the hematology analyte hemoglobin for two of three PT events in 2022 (event 1 and 3 of 2022) and the subsequent unsuccessful PT performance for the hematology analyte hematocrit for three of five PT events from 2021 through 2022 (event 2 of 2021 and event 1 and 3 of 2022). See D2130.</p>

<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records the laboratory failed to achieve satisfactory performance for the hematology analyte hemoglobin for two of three PT events in 2022 (event 1 and 3 of 2022) and hematocrit for three of five PT events from 2021 through 2022 (event 2 of 2021 and event 1 and 3 of 2022). Findings include: 1. Review of the CASPER Report 0155D, generated on 12-01-2022, the laboratory received the following unsatisfactory analyte scores: Hematocrit EVENT 2, 2021 0% Unsatisfactory EVENT 1, 2022 60% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory Hemoglobin EVENT 1, 2022 60% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory 2. Review of WSLH PT records confirmed the laboratory received the following unsatisfactory analyte scores: Hematocrit EVENT 2, 2021 0% Unsatisfactory EVENT 1, 2022 60% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory Hemoglobin EVENT 1, 2022 60% Unsatisfactory EVENT 3, 2022 0% Unsatisfactory</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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialty of hematology (see D6016) resulting in the laboratory's subsequent unsuccessful PT performance for the hematology analyte hematocrit and the initial unsuccessful PT performance for hemoglobin.</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:</p>

Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records the laboratory director failed to ensure successful participation in an Health and Human Services (HHS) approved PT program for the specialty of hematology (see D2130) resulting in the laboratory's subsequent unsuccessful PT performance for the hematology analyte hematocrit and the initial unsuccessful PT performance for hemoglobin.