

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2151696	(X3) Date Survey Completed 10/04/2021
Name of Provider or Supplier Omni Laboratory Services	Street Address, City, State 5862 N Lincoln Ave, 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 review of CASPER Report 0155D and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for the specialty of Hematology (See D2031) and the analytes red blood cells (RBC) and hematocrit (HCT) during PT event 3 of 2020 and event 2 of 2021 (See D2030).</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</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.

This STANDARD is not met as evidenced by:

Based on review of CASPER Report 0155D and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for the analytes red blood cells (RBC) and hematocrit (HCT) in event 3 of 2020 and 2 of 2021, for the specialty of hematology. Findings include: 1. Review of the CASPER 0155D report revealed that the initial unsuccessful PT performance occurred during API PT event 3 of 2020 and event 2 of 2021, as listed below. HEMATOLOGY EVENT -3, 2020 RBC, 0% Unsatisfactory EVENT -2, 2021 RBC, 20% Unsatisfactory EVENT -3, 2020 HCT, 0% Unsatisfactory EVENT -2, 2021 HCT, 0% Unsatisfactory 2. Interview with the API representative on 10-04-2021 at 9:32 AM confirmed the initial unsuccessful PT performance for the analytes RBC and HCT in event 3 of 2020 and event 2 of 2021.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of CASPER Report 0155D and interview with an American Proficiency Institute (API) representative the laboratory failed to successfully participate in proficiency testing (PT) for the specialty of Hematology in event 3 of 2020 and 2 of 2021. Findings include: 1. Review of the CASPER 0155D report revealed that the initial unsuccessful PT performance occurred during API PT event 3 of 2020 and event 2 of 2021, as listed below. HEMATOLOGY EVENT -3, 2020 Hematology, 48% Unsatisfactory EVENT -2, 2021 Hematology, 67% Unsatisfactory 2. Interview with the API representative on 10-04-2021 at 9:32 AM confirmed the initial unsuccessful PT performance for the specialty of Hematology for event 3 of 2020 and event 2 of 2021.