

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2004621	(X3) Date Survey Completed 11/22/2019
Name of Provider or Supplier Opans, Llc	Street Address, City, State 4134 Alston Avenue, Suite 100, Durham, NC	
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 CMS (Centers for Medicare and Medicaid Services) Casper reports 153 and 155 on 9/5/19 and desk review of 2018 and 2019 CAP (College of American Pathologists) proficiency testing records 11/20/19, the laboratory failed to successfully participate in proficiency testing for Total Bilirubin and Iron in two consecutive proficiency testing events. See the deficiency cited at D2096.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</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.

This STANDARD is not met as evidenced by:

Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153 and 155 on 9/5/19 and desk review of 2018 and 2019 CAP (College of American Pathologists) proficiency testing records 11/20/19, the laboratory failed to achieve satisfactory performance for Total Bilirubin and Iron in two consecutive proficiency testing events, resulting in unsuccessful performance. Findings: A. Total Bilirubin Desk review of CMS Casper 155D and 2018 and 2019 CAP proficiency testing results revealed: 1. The laboratory provided unacceptable responses for 2 of 5 samples and received a score of 60% for Total Bilirubin on the 2018 C-C event. 2. The laboratory provided unacceptable responses for 2 of 5 samples and received a score of 60% for Total Bilirubin on the 2019 C-A event. B. Iron Desk review of CMS Casper 155D and 2018 and 2019 CAP proficiency testing results revealed: 1. The laboratory provided unacceptable responses for 5 of 5 samples and received a score of 0% for Iron on the 2018 C-C event. 2. The laboratory provided unacceptable responses for 5 of 5 samples and received a score of 0% for Iron on the 2019 C-A event.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153 and 155 on 9/5/19 and desk review of 2018 and 2019 CAP (College of American Pathologists) proficiency testing records 11/20/19, the laboratory director failed to ensure successful participation in proficiency testing as required in Subpart H. See the deficiency cited at D6089.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on desk review of CMS (Centers for Medicare and Medicaid Services) Casper reports 153 and 155 on 9/5/19 and desk review of 2018 and 2019 CAP (College of American Pathologists) proficiency testing records 11/20/19, the laboratory director failed to ensure successful participation in proficiency testing as required in Subpart H. Findings: A. Total Bilirubin Desk review of CMS Casper 155D and 2018 and 2019 CAP proficiency testing results revealed: 1. The laboratory provided unacceptable responses for 2 of 5 samples and received a score of 60% for Total Bilirubin on the 2018 C-C event. 2. The laboratory provided unacceptable responses for 2 of 5 samples

and received a score of 60% for Total Bilirubin on the 2019 C-A event. B. Iron Desk review of CMS Casper 155D and 2018 and 2019 CAP proficiency testing results revealed: 1. The laboratory provided unacceptable responses for 5 of 5 samples and received a score of 0% for Iron on the 2018 C-C event. 2. The laboratory provided unacceptable responses for 5 of 5 samples and received a score of 0% for Iron on the 2019 C-A event.