

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0690142	(X3) Date Survey Completed 05/29/2018
Name of Provider or Supplier Jose J Chavez Md	Street Address, City, State 17 Surrey Court, Columbia, SC	
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: During a PT desk review performed on 5/29/2018, based on review of CASPER report 155D and graded reports from American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for platelets (Plt) for three consecutive proficiency testing events reviewed (2017, Events 1, 2, and 3). See D2130, D6000, and D6016.</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:

During a PT desk review performed on 5/29/2018, based on review of CASPER report 155D and graded reports from API, the laboratory failed to achieve satisfactory performance for Plt in three consecutive testing events (2017, Events 1, 2, and 3) resulting in unsuccessful proficiency testing performance. Findings include: 1. Review of the CASPER report 155D revealed of the following proficiency testing scores for hematology analytes: a. 2017, Event 1: Plt--0% b. 2017, Event 2: Plt--0% c. 2017, Event 3: Plt--40% 2. The above scores were confirmed upon review of the graded proficiency reports from API. Scores less than 80% for these analytes indicate unsatisfactory performance. A failure of the analytes for two consecutive or two out of three testing events is scored as unsuccessful. A failure of the analyte for three consecutive or three out of four/five events is scored as a repeat unsuccessful.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

During the proficiency testing desk review performed on 5/29/2018, based on review of CASPER report 155D and graded reports from API, the laboratory director failed to ensure proficiency testing for platelet was performed as required by 42 CFR, Part 493.801 (see D2016, D2130, and D6016).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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;

This STANDARD is not met as evidenced by:

During the desk review on 5/29/2018, based on CASPER report 155D review and API graded report review, the laboratory director failed to ensure the laboratory attained a result of 80% for platelet, specialty of hematology. The laboratory failed three consecutive proficiency testing events for platelet (2017, Events 1, 2, and 3).