

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1056115	(X3) Date Survey Completed 08/30/2018
Name of Provider or Supplier Vitrologic, Inc	Street Address, City, State 1704 Old Towne Road, Charleston, 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 proficiency testing desk review performed on 8/30/2018, based on review of CASPER report 155D and graded reports from American Association of Bioanalysts (AAB), the laboratory failed to successfully participate in proficiency testing for the sub-specialty of routine chemistry, the analyte total protein, for three consecutive events (2017, events 2 and 3; 2018, event 1). See D2087 and D2096.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</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.

This STANDARD is not met as evidenced by:

During the proficiency testing desk review performed on 8/30/2018, based on review of CASPER report 155D and graded proficiency reports from AAB, the laboratory failed to attain a satisfactory score of at least 80% for total protein on three consecutive proficiency testing events. Findings include: 1. The CASPER 155D report revealed the following scores for your laboratory's total creatinine: a. 2017, Event 2: 40% b. 2017, Event 3: 0% c. 2018, Event 1: 20% 2. The scores were confirmed by review of the graded AAB results. Scores less than 80% for these analytes indicate failure or unsatisfactory performance.

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 8/30/2018, based on review of CASPER report 155D and graded AAB reports, the laboratory director failed to ensure proficiency testing for total protein was performed as required by 42 CFR, Part 493.801 (see D2016, D2087, 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 8/30/2018, based on CASPER report 155D review and AAB graded report review, the laboratory director failed to ensure the laboratory attained a result of 80% for total protein, specialty of routine chemistry. The laboratory failed three consecutive proficiency testing events for the total protein (2017, Events 2 and 3; 2018, Event 1).