

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0677670	(X3) Date Survey Completed 06/13/2019
Name of Provider or Supplier Shalom Press Md	Street Address, City, State 2550 Sweethome Rd, Amherst, NY	
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 a proficiency testing (PT) desk review of Center for Medicare Medicaid Service (CMS) PT reports and PT records from the Wisconsin State Lab of Hygiene (WSLH) PT program, the laboratory failed to participate and perform successfully in a PT program approved by CMS, for the Immunohematology sub-specialty ABO group and Rh (D) typing. The following scores were assigned: 2018 second event = 0% 2019 first event = 80% This is considered unsuccessful PT performance. Refer to D2160.</p>
D2160	ABO GROUP AND D(RHO) TYPING

CFR(s): 493.859(e)

(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on a PT desk review of CMS PT reports and PT records from the WSLH PT program, the laboratory failed to participate and perform successfully in a PT program approved by CMS, for the Immunohematology sub-specialty ABO group and Rh (D) typing. The following scores were assigned: 2018 second event = 0% 2019 first event = 80% This is considered unsuccessful PT 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:

Based on PT desk review of the PT CMS data reports and WSLH PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, for the Immunohematology sub-specialty ABO group and Rh (D) typing. Refer to 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:

Based on a PT desk review of CMS PT reports and PT records from the WSLH PT program, the laboratory failed to participate and perform successfully in a PT program approved by CMS, for the Immunohematology sub-specialty ABO group and Rh (D) typing. The following scores were assigned: 2018 second event = 0% 2019 first event = 80% This is considered unsuccessful PT performance.