

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0991111	(X3) Date Survey Completed 07/31/2018
Name of Provider or Supplier Legend Health Shenandoah Clinic	Street Address, City, State 909 W Maple Road, Clawson, MI	
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
D0000	The Shenandoah Clinic PC laboratory was found to be in substantial compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003). No deficiencies were cited.
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 the CMS database and review of the American Proficiency Institute (API) proficiency testing reports, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the chemistry analyte: cholesterol, high density lipoprotein (HDL). Findings include: Review of the CMS database and the API proficiency testing reports showed</p>

unsatisfactory performance for three of five proficiency testing events for the chemistry analyte: cholesterol, HDL. Refer to D2096.

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

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 review of the CMS database and the American Proficiency Institute (API) proficiency testing reports, the laboratory failed to achieve satisfactory performance for the chemistry analyte cholesterol, high density lipoprotein (HDL) in three of five consecutive testing events. Findings include: Unsatisfactory performance for three of five consecutive proficiency testing events constituting subsequent unsuccessful performance for cholesterol, HDL: cholesterol, HDL PT event Score 1st event 2017 60% 3rd event 2017 60% 2nd event 2018 60%