

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0432460	(X3) Date Survey Completed 10/04/2018
Name of Provider or Supplier Hopedale Medical Complex	Street Address, City, State 107 S Tremont St, Hopedale, IL	
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 surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and communications with the American Proficiency Institute (API) program personnel; this laboratory failed to successfully participate in the testing of PT samples for Compatibility Testing under the specialty of Immunohematology during event 3, of 2017 and event 2, of 2018. Findings include: 1. Review of the CASPER 155 report on October 03, 2018 and communication with the PT provider API on 10 /03/18 at 2:51 PM, confirmed the initial unsuccessful PT performance under the specialty of Immunohematology for Compatibility Testing. See D-2181.</p>

D2181

COMPATIBILITY TESTING

CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory for 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 surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and communications with the American Proficiency Institute (API) program personnel; this laboratory failed to successfully participate in the testing of PT samples for Compatibility Testing under the specialty of Immunohematology during event 3, of 2017 and event 2, of 2018. Findings include: 1. Review of CASPER Report 155 on October 03, 2018, revealed that the initial unsuccessful PT performance was under the specialty of Immunohematology for Compatibility Testing as listed below. COMPATIBILITY TESTING EVENT-3, 2017 (0% Unsatisfactory) EVENT-2, 2018 (80% Unsatisfactory) 2. During phone communication with the PT provider API on October 03, 2018 at 2:51 PM, confirmed the failing scores for the initial unsuccessful PT performance for Compatibility Testing for events 3 of 2017 and event 2, of 2018.