Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D1028178	02/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Physicians Of The North Shore	27 Centennial Dr, Peabody, MA	

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	A CLIA paper desk review of proficiency testing was conducted on 2/9/18 for the Apex Health, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of an occurrence of unsuccessful proficiency testing performance for the subspecialty of Hematology, the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on proficiency testing review for calendar year 2017 (three testing events), of

	American Proficiency Institute proficiency testing results, the laboratory failed to successfully participate (achieve a score of 80 percent or more) in a proficiency testing program for the Cell Identification analyte as evidenced by the following: The laboratory achieved a score for Cell Identification of zero (0) percent for the second and third testing events of 2017 resulting in unsuccessful performance for the analyte. Refer to D2121 and D2130. .
D2121	HEMATOLOGY CFR(s): 493.851(a) 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: Based on proficiency testing review for calendar years 2017 (three testing events) of American Proficiency Institute proficiency testing results, the laboratory failed to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event resulting in unsatisfactory analyte performance for the Cell Identification analyte as evidenced by the following: Cell Identification: The laboratory achieved a score for Cell Identification of zero (0) percent for the second and third testing events of 2017 resulting in unsatisfactory performance for the analyte for each of the testing events.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or 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 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 calendar year 2017 proficiency testing review (three testing events), of American Proficiency Institute proficiency testing program results the laboratory failed to undertake remedial action in response to unsatisfactory proficiency testing events as evidenced by the following: Cell Identification analyte: The laboratory achieved a score for Cell Identification of zero (0) percent for the second and third testing events of 2017 resulting in unsatisfactory performance for each of the testing events and overall unsuccessful performance for the analyte (refer to D2130). Based on the second unsatisfactory testing event score there was no assurance that appropriate training had been undertaken, and technical assistance employed, to correct the problems associated with proficiency testing failures.
D2130	HEMATOLOGY CFR(s): 493.851(f) 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: Based on proficiency testing review for calendar year 2017 (three testing events), of American Proficiency Institute proficiency testing results, the laboratory failed to achieve satisfactory performance for the same analyte for two consecutive proficiency testing events as evidenced by the following: The laboratory achieved a score for Cell Identification of zero (0) percent for the second and third testing events of 2017 resulting in unsuccessful performance for the analyte. Refer to D2016.