Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1101671	06/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Now Llc	15215 Shady Grove Road Ste 100, Rockville, MD	

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	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 review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program, the laboratory failed to successfully participate in the API PT program for hematology testing, in which the laboratory is certified under CLIA. (Refer to D2130) Findings: Repeat Deficiency
D2017	REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)

	(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate. This CONDITION is not met as evidenced by: Based on review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program, the laboratory failed to successfully participate in the API PT program for hematology testing, the following analyte was noted as failed in the first event of 2020, 2019 2nd and 3rd event. The technical consultant (TC) was contacted by telephone on June 5, 2020 to cease testing the CELL I.D. OR WBC DIFF analyte and submit notification of when testing was ceased. As of June 19, 2020 the notification has not been received from the TC. Findings: 1. American Proficiency Institute 2020 1st event hematology CELL I.D. OR WBC DIFF 40% 2. American Proficiency Institute 2019 3rd event hematology CELL I.D. OR WBC DIFF 0% 3. American Proficiency Institute 2019 2nd event hematology CELL I.D. OR WBC DIFF 33%
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 review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program, the laboratory failed to successfully participate in the API PT program for hematology testing, the following analyte was noted as failed in the first event of 2020, 2019 2nd and 3rd event. Findings: Repeat Deficiency 1. American Proficiency Institute 2020 1st event hematology CELL I.D. OR WBC DIFF 40% 2. American Proficiency Institute 2019 3rd event hematology CELL I.D. OR WBC DIFF 0% 3. American Proficiency Institute 2019 2nd event hematology CELL I. D. OR WBC DIFF 33%
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 review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program , the laboratory director failed to ensure the laboratory successfully participate in the API PT program for hematology testing, in which the laboratory is certified under CLIA. (Refer to 2130) Findings: Repeat Deficiency
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the federal proficiency testing data report and review of the comparative evaluation summery from American Proficiency Institute (API) proficiency testing (PT) program, the laboratory director failed to ensure that an approved corrective action plan was followed when the laboratory failed to successfully attain a score of 80% in the API PT program for hematology testing. Findings: Repeat Deficiency 1. American Proficiency Institute 2020 1st event hematology CELL I.D. OR WBC DIFF 40% 2. American Proficiency Institute 2019 3rd event hematology CELL I.D. OR WBC DIFF 0% 3. American Proficiency Institute 2019 2nd event hematology CELL I.D. OR WBC DIFF 33%