Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 33D0999729	**(X3) Date Survey Completed** 02/18/2022
Name of Provider or Supplier Prine Health Medical Group Pllc	**Street Address, City, State** 1129 Northern Boulevard, Suite 101, Manhasset, 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**
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of Abbott Cell Dyn Emerald systems startup records and an interview with the technical consultant, the laboratory failed to retain background records for the year of 2020. Findings: 1. The laboratory was not able to retrieve the startups from a backup file for the year of 2020. 2. The technical consultant and testing person confirmed on 2/18/2022 about 10:30am, The laboratory was not able to retrieve the startups from a backup file for the year of 2020.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the review of training and competency procedure, training, and competency records 2019, 2020 and 2021, the laboratory failed to perform and document the six-month competency evaluation for the #2 testing person, as required by the laboratory's competency procedure. Findings: 1. The #2 testing person hired on 10/22/2019, training was completed on 12/17/2019, however, the laboratory director failed to perform and document the six-month evaluation which was due on 6/2020. 2. The

	technical consultant and testing person #2 confirmed on 2/18/2022 at approximately 10am, that the laboratory director failed to perform and document the six-month evaluation which was due on 6/2020.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on the review of the laboratory's Quality Assessment (QA) procedure, the QA documentation for 2020 and 2021 and an interview with the technical consultant and #2 testing person, the laboratory failed to maintain the written QA policy, to identify the failure to include a monthly review for the refrigerator temperatures and take remedial action when the temperatures fall outside the establish refrigerator temperatures. Refer to D5413 Findings: 1. The laboratory failed to ensure that the refrigerator temperatures were within the establish ranges. 2. The technical consultant and #2 testing person confirmed on 2/18/2022 about 10:45am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of the laboratory's, refrigerator temperature logs for 2020 and 2021 and an interview with the technical consultant and #2 testing person, the laboratory failed to maintain the laboratory's temperature procedure for the calendar years 2020 and 2021. Findings: 1.The laboratory failed to ensure that the refrigerator temperatures were within the establish range 35-46F for the following days: a. 2020 March - 2 days April - 18 days May - 16 days June - 20 days July - 12 days August - 1 day September - 1 day December - 1 day b. 2021 April - 2 days May - 1 day July - 1 day October - 1 day
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 the review of the API Proficiency Testing Program records for the year 2020, the laboratory director failed to provide a plan of correction for the score less than 100%. 1. Proficiency testing score of year 2020 first event: a. Hematology 96% b. Platelets 80%
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the quarterly QA documentation, and confirmed in an interview with the technical consultant, the laboratory director failed ensure that the laboratory's QA program was maintained for all phases of laboratory testing. Refer to D5209, D3031, D5219, D5413, D6019
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of training and competency evaluation records for the testing personal and confirmed in an interview with the technical consultant, the laboratory director and technical consultant, failed to perform the six-month competency evaluation for testing person #2 on first year of testing. Refer to D5209.