

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0143291	(X3) Date Survey Completed 05/18/2022
Name of Provider or Supplier Great Neck Pediatric Associates Pc	Street Address, City, State 173 East Shore Road, Great Neck, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on the review of the American Proficiency Institute (API) Proficiency Test (PT) records, the laboratory failed to rotate proficiency testing for hematology between the three testing persons in calendar year 2020. Findings: 1. API attestation form for hematology PT for calendar year 2020 had same testing person signature. 2. Confirmed on an interview with technical consultant on 5/18/2022 about 11am.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on the review of November 2020 Quality Control (QC) records of hematology analyzer Coulter AcT Diff, the laboratory failed to maintain expiration dates of QC materials. Finding 1. Lot# 068300 Expiration date 11/23/2020 was used between 11/12/2020-11/30/2020. 2. Approximately 50 patients were tested. 3. Confirmed on an interview with technical consultant on 5/18/2022 about 10:45am. PLEASE NOTE: THIS IS RECITED FROM THE SURVEY CONDUCTED ON 1/4/2017 AND 6/13/2018</p>

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on the review of calibration record, the laboratory failed to perform calibration at least every six months. Findings: 1. Calibration performed only once for calendar year 2021 on 2/15/2021. 2. Confirmed on an interview with technical consultant on 5 /18/2022 about 11:30am PLEASE NOTE: THIS IS RECITED FROM THE SURVEY CONDUCTED ON 6/13/2018

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 quarterly Quality Assurance (QA) records, the laboratory director failed to maintain overall QA program to maintain quality service provided. Refer to D5439, D2007

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are

maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on the review of November 2020 QC records of hematology analyzer, the technical consultant failed to maintain Quality Control program appropriate for hematology testing. Refer to D5417