

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2097934	(X3) Date Survey Completed 01/10/2023
Name of Provider or Supplier Goncharov Medical Pc	Street Address, City, State 151 W 30th Street Suite 403, New York, 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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) procedure, 2020, 2021 & 2022 QA records and an interview with the testing person, the laboratory failed to identify the problems and take corrective action to resolve the problems and prevent reoccurrence. FINDINGS: 1. The monthly QA performed in 2020, 2021 and 2022 failed to identify the following failures: a. Failure to perform Lot to lot QC for Micros 60, Pentra 400 and TOSOH AIA 900 2020, 2021, 2022 b. Pentra 400 requires a humidity of 40-80% lab range does not comply with the manufacturer's requirement. c. No procedure for specimen rejection and acceptability d. No calibration verification for the Pentra 400 for 2020, 2021, 2022 2. The testing person confirmed on January 10, 2023, at approximately 1:30 that the laboratory failed to identify the problems and take corrective action to resolve the problems and prevent reoccurrence.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on the review of laboratory policy and procedure manual and an interview with the testing person, the laboratory failed to establish policy and procedure of criteria for specimen acceptability and rejection. Confirmed in an interview with testing person on 1/10/2023 about 1:00 PM.

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 laboratory humidity log, the laboratory failed to follow manufacturer requirement of Horiba Pentra C400 humidity range of 40-80%. The laboratory humidity was out of range from 1/2020 through survey date. Confirmed in an interview with testing person on 1/10/2023 about 1:30 PM

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 review of the manufacturer's ABX Horiba Pentra 400 chemistry analyzer operational & laboratory manual, calibration, and quality control (QC) records for the calendar years 2020, 2021 and 2022 and an interview with the testing person, the laboratory failed to perform & document calibration verification, as required by the laboratory's QC & calibration procedures for the calendar years 2020, 2021 and 2022. FINDINGS: 1. The laboratory performs the manufacturer's QC requirements for the Pentra 400 analyzer using a 2 level P & N control each day of testing and 1B multi-calibrator run in triplicate with each new lot of control and/or reagent lot. 2. The calibration/verification procedure requires that calibration verification is performed every six months when the laboratory is using a 2 level controls and 1 point calibrator. 3. The laboratory failed to perform & document calibration verification for the calendar years 2020, 2021 and 2022. 4. Approximately 1658 patient specimens were tested and reported in 2020 , 2581 patient samples were tested & reported in 2021, 3,058 patient samples were tested and reported for 2022. 5. The testing person confirmed on January 10, 2023, at approximately 2:30 PM that the laboratory failed the laboratory failed to perform & document calibration verification, as required by the laboratory's QC & calibration procedures for the calendar years 2020, 2021 and 2022

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Control (QC) records and an interview with the testing person, the laboratory failed to perform a verification of current lot number to new lot number for the analyzers Horiba Micros 60, Horiba Pentra C400, and TOSOH AIA 900, from 1/ 2020 through survey date. FINDINGS: 1. The new QC lot to lot validation documentation's for the analyzers Horiba Micros 60, Horiba Pentra C400, and TOSOH AIA 900 were not available for review from 1/2020

	<p>through survey date. 2. The testing person confirmed in an interview on 1/10/2023 about 12: 00 PM.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory manual, QC & calibration records and an interview with testing person, the director failed to provide overall management for all phases of moderate complexity testing. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. maintained their written QA policy for all phases of laboratory testing, Refer to D6021;</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's QA policy, QA documentation and an interview the testing person, the laboratory director failed to follow the establish QA procedure for having an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory system. Refer to D5293, D5403, D5413, D5439 and D5469</p>