

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0863413	(X3) Date Survey Completed 09/21/2023
Name of Provider or Supplier Sheo P Sharma Md Pa Facog	Street Address, City, State 1212 York Rd, Ste A101, Lutherville, 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
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 review of the "Patient Processing Logbook", proficiency testing (PT) records, interview with the laboratory director (LD), the laboratory failed to document the PT samples along with the regular patient workload. Findings: 1. The immunohematology PT records from the second event of 2022 through the second event of 2023 were reviewed for a total of four events. 2. Review of the "Patient Processing Logbook" worksheet showed that the PT samples for all four events were not documented on the in the same manner as the patients. The original test results were not documented and maintained in the same manner as the patients. 3. During the survey on 09/21/2023 at 10:30 AM, the LD confirmed that the PT results were not being documented in the same manner as the patients.</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 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)</p>

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 review of the "RH [Rhesus] testing using a finger stick" procedure and interview with the laboratory director (LD), the laboratory's procedure manual failed to include how much blood was to be collected from the finger stick to ensure an accurate and reliable test result. Findings: 1. The "RH testing using a finger stick" procedure states "The first drop of blood is to be wiped with a sterile gauze, and then the blood is collected in a labeled clean test tube." 2. The procedure does not identify how much blood is to be collected to ensure the reliability and accuracy of the test being performed. 3. During the survey on 09/21/2023 at 10:30 AM, the LD confirmed that the procedure manual failed to include the amount of blood to be collected to ensure the accuracy of the RH test results.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patients' final reports and interview with the laboratory director (LD), the laboratory failed to ensure that the final test reports listed the correct address of the laboratory where the testing was performed. Findings: 1. The laboratory moved to its new location on 11/20/2021. Review of the patients final reports showed that the previous address is still listed as the laboratory address. 2. During the survey on 09/21 /2023 at 10:30 AM, the LD confirmed that the final test reports failed to list the correct address of the laboratory where the testing was being performed.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are

reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the proficiency testing (PT) records and interview with the laboratory director (LD), the LD failed to ensure that corrective actions were taken when the results were unacceptable. Findings: 1. Review of the immunohematology PT results for the second event of 2023 show that the laboratory received an 80% for Rhesus (Rh) typing. The test result was reported a positive when it should have been negative. 2. The laboratory's investigation failed to determine the reason for the failure and review of patient results tested during that period to ensure that patients were not affected by the failure. 3. During the survey on 09/21/2023 at 10:30 AM, the LD confirmed that the investigation failed to include a review of the patients tested during that time period to ensure the accuracy and reliability of patient test results.