Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0863413	(X3) Date Survey Completed 02/15/2022
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the testing personnel (TP), the laboratory failed to attest to the routine integration of Rhesus (Rh) factor PT samples into the patient workload using the laboratory ' s routine methods for the 2020 3rd PT event. Findings: 1. Records from Rh factor PT events for 2020 and 2021 were reviewed. 2. Documentation from the 2020 3rd event was missing the signed forms of TP attesting that the PT samples were integrated into the laboratory ' s regular patient workload using routine methods. 3. During the survey on 02/15/2022 at 12:45 pm, the TP confirmed that the laboratory was missing the signed attestation forms for the 2020 3rd PT event for Rh factor testing.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by:

	Based on procedure review and interview with the testing personnel (TP), the laboratory failed to establish procedures for blood collection via finger stick for Rhesus (Rh) factor testing. Findings: 1. The laboratory performed Rh factor testing to detect and identify RhD blood group status in patient samples. 2. The TP stated that patient blood was collected either intravenously or via finger stick. 3. The laboratory ' s procedure manual did not include instructions for when and how to collect and process blood for Rh factor testing via finger stick. 4. During the survey on 02/15 /2022 at 2:45 pm, the TP confirmed that the laboratory did not have a procedure for collecting and processing patient samples via finger stick for Rh factor testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on review of the procedure manual and quality control (QC) records and interview with the testing personnel (TP), the laboratory failed to ensure that QC reagents were used within their expiration date for Rhesus (Rh) factor testing. Findings: 1. The procedure titled "Reagent rH Testing: Quality Assuance/Control Procedure" stated "The reagents to be tested should be clear, free of particulate material and should be within their expiration date. The cells used in testing of the reagents should be known to be positive and negative for the D antigen and within their expiration date." 2. The laboratory recorded the lot numbers and expiration dates for reagents on the "Daily Reagent Quality Control Sheet" (QC log). 3. The QC logs were reviewed from 09/01/2021 through 02/12/2022. 4. The QC logs showed that on 19 days between 11/20/2021 and 12/31/2021, the laboratory either did not record the lot number and expiration date of the Rh positive and negative cells or recorded use with expired cells (Rh positive cells lot number 148505 and Rh negative cells lot number 398505 both expired on 11/19/2021). The QC logs showed that a total of 70 patients were tested for Rh factor during these 19 days. 5. During the survey on 02/15 /2022 at 2:45 pm, the TP confirmed that the laboratory used QC reagents beyond their expiration date.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure manual and quality control (QC) records and interview with the testing personnel (TP), the laboratory failed to record QC results for Rhesus (Rh) factor testing on 41 of 82 days reviewed. Findings: 1. The procedure titled "Reagent rH Testing: Quality Assurance/Control Procedure" stated "When performing immunohematology testing it is vital that the results are 100% accurate. This means that the reagents used MUST be analyzed for their reactivity PRIOR to any patient testing. For each day of testing the following must be performed and the

	results recorded and initialed by the technician in the Daily Reagent Quality Control Log Sheet." 2. The Daily Reagent Quality Control Sheets were reviewed from 09/01 /2021 through 02/12/2022 for a total of 82 days when patient testing was performed. 3. Daily QC results were not recorded for 4 of 17 days of testing in 09/2021, for 9 of 17 days of testing in 10/2021, for 8 of 12 days of testing in 11/2021, for 6 of 15 days of testing in 12/2021, for 10 of 14 days of testing in 01/2022, and for 4 of 7 days of testing reviewed in 02/2022. 4. Records showed a total number of 231 patients tested on days when QC results were not recorded: 26 patients in 09/2021, 59 patients in 10 /2021, 37 patients in 11/2021, 32 patients in 12/2021, 56 patients in 01/2022, and 21 patients in 02/2022. 5. During the survey on 02/15/2022 at 2:45 pm, the TP confirmed that QC results were not recorded each day patients were tested for Rh factor.