Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0888296	10/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
J Richard Lilly Md Abfp Chartered	5806 Baltimore Avenue, Hyattsville, 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
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 review of the standard operating procedures (SOP) and interview with the technical consultant (TC), the laboratory failed to ensure that rapid plasma reagin (RPR) analytic system records were maintained for at least two years. Findings: 1. According to the TC, a pending list is printed on Friday for RPR testing. Each patient is given a new identification number (ID#) that corresponds with one of the 10 circle positions on the RPR card where the testing is performed. The results are entered into the computer and the pending list with the new ID# is discarded. 2 During the survey on 10/11/2024 at 2:00 PM, the TC confirmed the laboratory did not maintain the original RPR pending list with the new specimen ID# that corresponds with the circle position on the RPR testing card for the required two years.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) program procedure, review of proficiency testing (PT) records, and interview with the technical consultant (TC), the laboratory failed to ensure that PT results evaluations were reviewed by the laboratory

	director (LD) in 14 of 14 PT modules. Findings: 1. The QA program procedure stated that "All proficiency testing results are reviewed by the laboratory director." 2. The laboratory received six different PT modules. Records for 2023 and 2024 were reviewed for a total of 17 PT events. Of the 17 PT events, 3 PT events did not have the results evaluations available yet. 3. Of the 14 remaining PT events, 2 PT events (Immunology 2024 1st and 2nd events) had no results evaluations printed for review and the remaining 12 PT events had the results evaluations printed, but they were not signed or dated by the LD indicating that the results had been reviewed. 4. During the exit interview on 10/11/2024 at 2:00 PM, the TC confirmed that 14 of 14 of the available PT results evaluations were not reviewed by the LD.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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) 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: I. Based on review of the standard operating procedures (SOP) and interview with the technical consultant (TC), the laboratory's written policies and procedures failed to include accurate instructions for how rapid plasma reagin (RPR) testing is performed. Findings: 1. The "Preparation of Patient Specimen" section of the RPR procedure states "Serum and plasma are both suitable specimens for the qualitative test ..." The TC was asked if the final report identified the specimen as serum or plasma and they stated that they do not accept plasma specimens for RPR testing. 2. The "Serum" section of the RPR procedure states "Keep serum specimen in the original collection tube if testing will be performed within a few hours. Remove serum from clot and store at a refrigerator temperature (2-8C [Celsius]) if testing is to be delayed." The TC stated that the RPR specimens are collected in a serum separator tiger top tube and are tested on Friday, they may or may not be poured into a second labeled tube per the SOP. 3. The "Plasma" section of the RPR procedure states "Testing must be performed on plasma within 24 hours of collection." The TC stated that the laboratory only accepts serum specimens. The RPR SOP and specimen collection procedure did not specify serum only. 4. According to the TC, a pending list is printed on Friday for RPR testing. Each patient is given a new identification number (ID#) that corresponds with one of the 10 circle positions on the RPR card where the testing is performed. The results are entered into the computer and the pending list with the new ID# is

	discarded. 5. During the survey on 10/11/2024 at 2:00 PM, the TC confirmed the laboratory only accepts RPR specimens for testing from a tiger top tube and this is not stated in the specimen collection procedure and the SOP does not include instruction for printing the pending RPR list and assigning a new ID# for the specimen that corresponds with the circle position on the RPR testing card. II. Based on review of the SOP and interview with the TC, the laboratory's written policies and procedures failed to include specific instructions for documentation of remedial actions when quality control (QC) materials are unacceptable. Findings: 1. The "Medonic QC Policy" states "If one QC level is out of range, do some troubleshooting, repeat that level. However, for some reasons, it is still out of range, then 2 QC levels within reference range are acceptable for testing patient samples." 2. During the survey on 10 /11/2024 at 2:00 PM, the TC confirmed the SOP failed to identify how many standard deviations would be acceptable for the QC level that is out of range. The SOP failed to provide instructions for documenting the troubleshooting actions taken to correct the problem.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the hematology operator's manual (OM) and interview with the technical consultant (TC), the laboratory failed to ensure that the complete white count testing (CBC) was performed within 24 hours of collection. Findings: 1. The OM states that the CBC specimens are to be tested within 24 hours of collection. 2. According to the TC, CBC specimens are received on Monday through Friday. The TC starts works Tuesday evening at 5:00 PM. The CBC specimens collected on Monday are being tested on Tuesday evening which is after the defined 24 hour limit of acceptability. 3. During the survey at on 10/11/2024 at 2:00 PM, the TC confirmed that the CBC specimens collected on Monday are not being testing within the required 24 hour limit.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) procedure, the manufacturer's operating manual, and maintenance forms, and interview with the technical consultant (TC), the laboratory failed to perform instrument maintenance with at least the frequency specified by the manufacturer for endocrinology testing. Findings: 1. The QA procedure stated "All instruments within the laboratory must have periodic maintenance checks which may be daily, monthly or according to the manufacturer's recommendations. Maintenance checks are to be recorded and corrective action

	documented on the appropriate log sheet." 2. The manufacturer's operator's manual for the Tosoh AIA-900 immunoassay analyzer included daily, weekly, monthly, and every three months maintenance activities. 3. Maintenance records for the Tosoh AIA-900 analyzer were reviewed from 06/2024-09/2024. 4. Monthly maintenance activities were not documented for 06/2024 and 09/2024. 5. Every three months maintenance was not documented for any of the four months reviewed. 6. The maintenance form for 08/2024 was blank even though quality control was tested on 08 /04/2024, 08/09/2024, 08/20/2024, 08/28/2024, & 08/31/2024. 7. During the exit interview on 10/11/2024 at 2:00 PM, the TC confirmed that monthly maintenance for the Tosoh AIA-900 was not documented in 06/2024 and 09/2024, that every three month maintenance was not documented between 06/2024-09/2024, and that all maintenance activities were not documented for 08/2024.
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 calibration records, and interview with the technical consultant (TC), the laboratory failed to ensure that calibration verification was performed and documented once every six month for the Medonic hematology analyzer. Findings: 1. The calibration records that were reviewed showed that calibration verification had been performed on 05/17/2024. The previous recertification survey was concluded on 03/30/2023. 2. The records show that the calibration verification had not been performed between 03/30/2023 and 05/17/2024. There was a 13 month gap between the performance of each calibration verification. 3. During the exit interview on 10/11 /2024 at 2:00 PM, the TC confirmed that the calibration verification procedures were not performed once every six months as required.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)

	(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the media quality control log sheets for Selective Strep Agar (SSA) and Uricult and interview with the technical consultant (TC), the laboratory did not maintain documentation of the quality control (QC) for media purchased from outside vendors prior to using for patient testing. Findings: 1. The media quality control log sheets that were reviewed for 2023 and 2024 did not include documentation from the manufacturer showing that the media had been tested for sterility and the ability to support growth and inhibit growth of specific organisms prior to being used for patient and proficiency testing. The sticker or packaging of the media should include documentation showing that the media purchased meets with Clinical & Laboratory Standards Institute (CLSI) standards performed by the manufacturer. 2. During the survey on 10/11/2024 at 2:00 PM, the TC confirmed that the laboratory did not have documentation showing that the media purchased met the defined CLSI standards as required. II. Based on review of the hematology and chemistry QC Levy-Jennings (L-J) graphs and interview with the technical consultant (TC), the laboratory did not document remedial actions when QC results had to be repeated. Findings: 1. Review of hematology L-J graphs for the month of November 2023 show that the QC was repeated on 11/18 and chemistry QC was repeated on 11 /8, 11/18, and 11/28. 2. Review of hematology L-J graphs for the month of May 2024 show that the QC was repeated on 05/02, 05/15, 05/17, and 05/31 and chemistry QC was repeated on 05/15, 05/24, and 05/31. 3. During the survey on 10/11/2024 at 2:00 PM, the TC confirmed that the laboratory records failed to include documented remedial actions when the hematology and chemistry QC results were unacceptable.
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 review of the quality assurance (QA) program procedure, review of proficiency testing (PT) records, and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the root cause was investigated, corrective actions were taken, and risk to patient results was assessed when PT results were unacceptable. Findings: 1. The QA program procedure stated "All proficiency testing results are reviewed by the lab director. Failed results will be investigated to determine the cause of the failure and what corrective action needs to be taken to prevent the recurrence. This action will be documented on a proficiency testing failure form." 2. The laboratory received a score of 60% for total bilirubin in the 2024 1st

	chemistry event. a. The PT corrective action form stated "Although the results (CET 2 & CET 5) were not within acceptable range but they were still within 2 SD [standard deviations]. These results were acceptable." b. The SD index showed that PT sample CET 2 had a SD of -2.00 and PT sample CET 5 had a SD of -2.90 c. There was no investigation into the root cause of the unacceptable PT scores and, therefore, no corrective action taken. d. There was no assessment of whether the root cause of the unacceptable PT scores had the potential to affect patient results. 3. The laboratory received a score of 33% for folate in the 2024 1st special chemistry event. a. The PT corrective action form stated that the result for PT sample CS 3 was unacceptable due to a clerical error and for PT sample CS 1, "the result was out of acceptable range but it was within 2 SD." b. The SD index showed that PT sample CS 1 had a SD of -2.16. c. There was no investigation into the root cause of the unacceptable PT scores and, therefore, no corrective action taken. d. There was no assessment of whether the root cause of the unacceptable PT scores had the potential to affect patient results. 4. During the exit interview on 10/11/2024 at 2:00 PM, the TC confirmed that the root causes of the PT failures from the 2024 1st event were not investigated, corrective actions were not taken, and potential risk to patient results was not assessed.
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 review of the quality assessment (QA) records, and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that monthly QA evaluations were performed and documented accurately. Findings: 1. The QA records for April 2023 through September 2024 were reviewed. 2. The laboratory was closed from February 12, 2023 through May 14, 2023. The monthly evaluations for May and June 2023 were not available at the time of the survey. 3. The monthly evaluation for the month of October 2023 was approved on 10/02/23, November 2023 was approved on 11/3/23, and December 2023 was approved on 12/04/23. 4. During the survey on 10/11/2024 at 2:00 PM, the TC confirmed that the monthly evaluations for May and June 2023 were missing and could not explain why the monthly evaluation for October through December 2023 were completed at the beginning of the month and not the end.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on review of the procedure manuals and interview with the technical consultant (TC), the laboratory director (LD) did not ensure that all policies and procedures followed in the laboratory were approved (signed and dated). Findings: 1. Review of the laboratory procedure manuals showed that the manual labeled "Laboratory Procedure Manual", and the manual that included the updated rapid plasma reagin (RPR), Uricult, Taxo A (sensitivity discs), and throat culture procedures were not approved by the LD who took over the position in March 2023. 2. During the survey at on 10/11/2024 at 2:00 PM, the TC confirmed that the old and updated procedures had not been approved by the LD.