Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0067532	04/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
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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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on record review and interview with the technical Consultant (TC) and Laboratory Director (LD) the laboratory failed to ensure proficiency testing (PT) was rotated amongst all testing personnel (TP) in the specialty of Hematology. Findings include: 1. Record review on 4/11/2024 of the laboratory's 2022 and 2023 American Proficiency Institute (API) Hematology/Coagulation PT records revealed, one of three TP (TP3) did not run PT samples in 2022 or 2023. 2. Record review on 4/11/2024 of the laboratory's 2022 and 2023 competency assessment records for TP3, revealed: a. The section referring to PT performance was checked off as completed. b. The form was signed as complete by the TC. 3. Staff interview on 4/11/2024 at 3:00 PM with the TC and LD confirmed TP3 did not participate in PT in 2022 and 2023, yet it was marked as completed on TP3's 2022 and 2023 competency form. TC also confirmed TP3 did not run an internal blind or previously analyzed specimen in 2022 and 2023. 4. The laboratory performs 6,534 tests annually in the specialty of Hematology.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be

	maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) Chemistry Core Proficiency Testing (PT) records and interview with the technical consultant (TC) and Laboratory Director (LD) the laboratory failed to attain an overall testing event score of at least 80 percent leading to unsatisfactory performance in the specialty of Chemistry. Findings include: 1. Record review on 4/11/2024 of the laboratory's 2022, 2023 and 2024 to date API Chemistry Core PT records revealed: a. 2022 Event 3 - The laboratory received a score of 20% for the regulated analyte Cholesterol Total. The laboratory only repeated results and did not investigate or employ corrective action or retraining. b. 2023 Event 1 - The laboratory received a score of 60% for the regulated analyte Chloride. The laboratory only repeated results and did not investigate or employ corrective action or retraining. c. 2024 Event 1 - The laboratory received a score of 60% for the regulated analyte Calcium. The laboratory only repeated results and did not investigate or employ corrective action or retraining. 2. Staff interview on 4/11/2024 at 3:00 PM with the TC confirmed the above findings. The TC stated, "I thought repeating the testing was enough of an investigation."
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with the technical consultant (TC) and Laboratory Director (LD) , the laboratory did not have an ongoing mechanism to evaluate the TC based on their CLIA responsibilities. Findings Include: 1. Record review on 4/11/2024 of the laboratory's 2022, 2023 and 2024 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the TC based on their CLIA responsibilities. 2. Staff Interview on 4/11/2024 at 3:00 PM with the TC and LD confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on American Proficiency Institute (API) proficiency testing (PT) record review and staff interview with the technical consultant (TC) and Laboratory Director (LD) the laboratory failed to verify at least twice annually the accuracy of C-Reactive Protein (CRP). Findings include: 1. Record review on 4/11/2024 of the laboratory's 2022, 2023 and 2024 to date API Immunology/Immunohematology PT records revealed: a. The laboratory received a score of 50% for the non-regulated analyte CRP

	for 2022, Event 2. The laboratory only repeated the testing and did not investigate or employ corrective action or retraining. b. The laboratory director did not document review of the PT score for 2022 Event 2. c. The laboratory director did not document review of the PT score for 2023 Event 1. 2. Staff interview with the TC and LD on 4 /11/2024 at 3:00 PM confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1251 through 493.1283 for each specialty and subspecialty performed. The cumulative effect of this lack of oversight resulted in the laboratory's inability to ensure accuracy and reliability of patient test results in the specialties of Hematology, Diagnostic Immunology and Chemistry. Refer to D5403, D5415, D5429 and D5481.
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: A. Based on record review and interview with the Technical Supervisor (TC) and Laboratory Director (LD) the laboratory's procedure manuals failed to include quality control (QC) acceptance criteria or steps to take if a QC failure occurs in the specialties of Chemistry, Diagnostic Immunology and Hematology. Findings include:

	1. Record review on 4/11/2024 of the laboratory's Complete Blood Count (CBC) procedure revealed: a. The procedure did not contain acceptable criteria for QC material. b. The procedure did not contain steps to take if QC material is out of acceptable range. 2. Record review on 4/11/2024 of the laboratory's TOSOH Chemistry analyzer procedure revealed: a. The procedure did not contain acceptable criteria for QC material. b. The procedure did not contain steps to take if QC material is out of acceptable range. 3. Record review on 4/11/2024 of the laboratory's Envoy Chemistry and Diagnostic Immunology analyzer procedure revealed: a. The procedure did not contain acceptable criteria for QC material. b. The procedure did not contain steps to take if QC material is out of acceptable range 4. Staff interview on 4/11/2024 at 3:00 PM with the TC and LD confirmed the above findings. B. Based on record review and interview with the Technical Supervisor (TC) the Hematology procedure manual failed to include patient normal values in the specialty of Hematology. Findings include: 1. Record Review on 4/11/2024 of the laboratory Hematology Procedure Manual revealed the manual did not contain patient normal values for CBC testing. 2. Staff interview on 4/11/2024 at 3:00 PM with the TC and LD confirmed the hematology procedure manual did not contain patient normal values for CBC. 3. The laboratory performs 6,534 Hematology, 830 Diagnostic Immunology and 25,843 Chemistry tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and interview with the Technical Consultant (TC) and Laboratory Director (LD) the laboratory failed to label reagents with the appropriate expiration dates in the specialty of Hematology. Findings include: 1. Surveyor observation on 4/11/2024 at 2:30 PM of the laboratory refrigerator revealed the following Hematology controls open and in use without a new expiration date after opening indicated: a. Sysmex EightCheck 3WP X-TRA level 1, lot number 40510711 b. Sysmex EightCheck 3WP X-TRA level 2, lot number 40510712 c. Sysmex EightCheck 3WP X-TRA level 3, lot number 40510713 2. Record review on 4/11/2024 of the Sysmex EightCheck 3WP X-TRA package insert revealed, "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 degrees Celsius after being re-capped." 3. Staff interview on 4/11/2024 at 3:00 PM with the TC and LD confirmed the Sysmex controls listed above were open and in use and did not have a new expiration date indicated. 4. The laboratory performs 6,534 tests annually in the specialty of Hematology.
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 record review and staff interview with the technical consultant (TC) and Laboratory Director (LD) the laboratory failed to perform and document maintenance as required by manufacturer in the specialties of Diagnostic Immunology and Chemistry. Findings include: 1. Record review on 4/11/2024 of the laboratory's TOSOH AIA 360 chemistry analyzer's 2022, 2023 and 2024 to date preventative maintenance logs revealed the laboratory failed to document the required 6-month filter replacement or yearly BF probe replacement from 1/1/2022 through 4/11/2024. 2. Record review on 4/11/2024 of the TOSOH AIA 360 Manufacturer Instrument Manual, Chapter 10 revealed a. "This chapter describes the daily inspection and maintenance procedures that users must perform in order to maintain the peak performance capable of the AIA 360." b. Section 5, 6-Month Maintenance Procedures: Diluent and Wash Lines - "It is effective to clean the diluent and wash lines at the same time to clean the diluent and wash solution bottles." Replacing Filters for Diluent and Wash Solution Bottles - "Make a point of replacing the inline diluent and wash solution bottle filters on a regular basis." 3. Record review on 4/11 /2024 of the laboratory's TOSOH AIA 360 Procedure's maintenance section revealed: 6-month "Decontaminate diluents and wash tubing lines." "Replace filters for diluent and wash bottles." Yearly "Replace BF probe." 4. Staff interview with the TC and LD on 4/11/2024 at 3:00 PM confirmed the above findings. The TC stated, "The laboratory no longer has a service contact for the TOSOH. The 6 month maintenance and yearly maintenance used to be done with the yearly preventative maintenance performed by the service contract company." 5. The laboratory performs 25,843 Chemistry and 830 Diagnostic Immunology and 6,534 Hematology tests annually.
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 laboratory's quality control (QC) records and interview with the Technical Consultant (TC) and Laboratory Director (LD) the laboratory failed to ensure the results of control materials were within the acceptable ranges prior to reporting patient test results in the specialty of Chemistry. Findings include: 1. Record review on 4/11/2024 of the laboratory's Chemistry QC Records revealed: a. Two levels of control material are run daily for the Alkaline Phosphatase (ALP) and Cholesterol (Chol) tests. b. On 10/18/2022, one of two ALP controls was out of acceptable range. This control as repeated and was still found to be outside of the acceptable range. c. On 11/22/2022, one of two Chol controls was out of acceptable range. This control as repeated and was still found to be outside of the acceptable range. d. No further corrective action was performed for the out of range controls reference in 1b and 1c above. 2. Record Review on 4/11/2024 of the laboratory's Daily Summary Report for 10/18/2022 revealed 5 patients had ALP results reported on the final patient test report. 3. Record Review on 4/11/2024 of the laboratory's Daily Summary Report for 11/22/2022 revealed 5 patients had Chol results reported

	on the final patient test report. 4. Staff interview with the TC and LD on 4/11/2024 at 3:00 PM confirmed the above QC material was out of the acceptable range on the dates noted in 1b and 1c above and final patient results were reported.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and staff interview the Laboratory Director (LD) failed to ensure that prior to testing patients' specimens, all testing personnel (TP) received the appropriate training for the type and complexity of the services in the specialty of Hematology. Findings include: 1. Record review on 4/11/2024 of the current survey CMS form 209 revealed one new TP (TP2) hired since the last CLIA survey was performed. 2. There were no records maintained for the TP2 to confirm TP2 had received the appropriate training to perform testing in the specialty of Hematology, and had demonstrated that TP2 could perform all testing operations reliably to provide and report accurate results. 3. Interview with the LD and Technical Consultant (TC) on 4/11/2024 at 3:00 PM confirmed the above findings. The TC stated, "We did it, but did not document it." 4. The laboratory performs 6,534 tests annually in the specialty of Hematology.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on lack of documentation, record review and staff interview, the Technical Consultant failed to provide overall management and direction in accordance with 493.1413. The cumulative effect of this lack of oversight resulted in the Technical Consultant's inability to ensure the accuracy and reliability of patient test results in the specialties of Chemistry, Hematology and Diagnostic Immunology. Refer to D6042, D6044, D6051, and D6053.
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 record review and staff interview the Technical Consultant failed to establish and maintain a Quality Control program. Refer to D5403.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and staff interview the Technical Consultant failed to ensure patient test results were not reported when quality control results were out of range. Refer to D5481.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and staff interview the Technical Consultant failed to evaluate the competency of testing personnel through testing previously analyzed, internal blind or external proficiency testing samples. Refer to D2007
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant (TC) and Laboratory Director (LD) the TC failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens in the specialty of Hematology. Findings include: 1. Record review on 4/11/2024 of the laboratory's CMS form 209 for the current survey revealed one new testing personnel (TP) hired since the last CLIA survey. 2. Record review on 4/11/2024 of the laboratory's TP competency records revealed: a. TP2, hired on 10/24/2022 only had one competency assessment performed in the first year of patient testing that was signed by TP3 in the observed by section 11/13/2023. The form was also signed by the TC on 11/30/2023. 3. Record

	review on 4/11/2023 of the credentials for TP3 revealed TP3 has an Associates Degree and dos not qualify to be a TC or perform the duties of a TC. 4. Staff interview on 4/11/2024 at 3:00 PM with the TC and LD confirmed the above findings. The TC stated, "I did not know that the observer has to be qualified as a TC in order to evaluate and observe TP for competency."