Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2264781	12/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hmcs Inc - Home Med Diagnostic & Lab Svcs	3500 W Peterson Ave - Unit 404, Chicago, IL	

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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the laboratory director; the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process on five of seven pages reviewed utilized for creating coversheets (See D5201), failed to establish and follow written policies and procedures to ensure optimum integrity of one of four patients' hematology specimen from the time of collection through completion of testing and reporting of results (See D5203), and failed to ensure accuracy of 22 of 22 PT samples not evaluated by the PT provider in the subspecialties of routine chemistry and endocrinology in 2025 (See D5213).
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by:

	Based on direct observation, review of laboratory records, and interview with the laboratory director (LD); the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process on five of seven pages reviewed utilized for creating coversheets. Findings include: 1. Upon review of laboratory records on 12/09/2025, at 12:36 pm, surveyors observed that five of seven coversheets reviewed were handwritten on the back of patient reports which included patients' names, dates of birth, specimen numbers, names of the test(s) ordered, and test results. 2. Interview with the LD on 12/09/2025, at 2:26 pm, confirmed the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process on five of seven pages reviewed utilized for creating coversheets.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of documentation, manufacturer's instructions for use (IFU), laboratory records, and interview with the laboratory director (LD); the laboratory failed to establish and follow written policies and procedures to ensure optimum integrity of one of four patients' hematology specimen from the time of collection through completion of testing and reporting of results. Findings include: 1. Review of laboratory policies and procedures revealed a lack of documentation of requirements for specimen preservation, handling, and analysis within the limitations of the test methodology (See D5403). 2. Review of the manufacturer's IFU for the Diatron Abacus 5 hematology analyzer (Serial Number: (21)512000106) revealed, under "8 Sample Measurement ....8.1.4 Sample Collection and Handling", "Analyze blood samples within 7 hours of collection." 3. Review of patient test records revealed the laboratory failed to perform the hematologic analysis within the manufacturer's established timeframe for one of four patients reviewed. Patient: NJ723214 Sample: 250516001 Specimen Collected: 05/16/2025 at 09:02 am Specimen Received: 05/16/2025 at 10:20 pm Specimen Analyzed: 05/18/2025 at 2:47 pm 4. Interview with the LD on 12/09/2025, at 2:26 pm, confirmed the laboratory failed to establish and follow written policies and procedures to ensure optimum integrity of one of four patients' hematology specimen from the time of collection through completion of testing and reporting of results.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, lack of documentation, and

	interview the laboratory director (LD); the laboratory failed to ensure accuracy of 22 of 22 PT samples not evaluated by the PT provider in the subspecialties of routine chemistry and endocrinology in 2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled "Proficiency Testing", which indicated, under "Details of Policy", "PT results that are not graded will be self-graded by comparing the results to the expected results of the PT agency or peer results." 2. Review of API comparative evaluation summaries for the following PT events in 2025 revealed the following 22 un-graded PT samples: PT Event: Analyte: Sample: 2025 Event 1 LDL* CH***-01 2025 Event 1 LDL CH-02 2025 Event 1 LDL CH-03 2025 Event 1 LDL CH-04 2025 Event 1 LDL CH-05 2025 Event 2 TBil** CH-07 2025 Event 2 TBil** CH-09 2025 Event 2 TBil** CH-10 2025 Event 2 Folate IA****-07 2025 Event 2 Folate IA-09 2025 Event 3 TBil CH-12 2025 Event 3 TBil CH-15 2025 Event 3 LDL CH-11 2025 Event 3 LDL CH-12 2025 Event 3 LDL CH-13 2025 Event 3 LDL CH-14 2025 Event 3 LDL CH-15 2025 Event 3 Free Thyroxine CH-11 2025 Event 3 Free Thyroxine CH-12 2025 Event 3 Free Thyroxine CH-13 2025 Event 3 Free Thyroxine CH-14 2025 Event 3 Free Thyroxine CH-15 * = Low Density Lipoprotein ** = Total Bilirubin *** = Routine Chemistry **** = Endocrinology 3. Review of laboratory records found no documented review of the 22 ungraded PT samples in the subspecialties of routine chemistry and endocrinology in 2025. 4. Interview with the LD on 12/09/2025, at 11:06 am, confirmed the laboratory failed to ensure accuracy of 22 of 22 PT samples not evaluated by the PT provider in the subspecialties of routine chemistry and endocrinology in 2025.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 laboratory policies and procedures, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to outline all required components of the test procedures for two of two procedures, routine chemistry testing on the Envoy 500+ analyzer and hematology testing on the Diatron Abacus 5 analyzer. Findings include: 1. Review of laboratory policies and procedures revealed the procedure for routine chemistry testing on the Envoy 500+ analyzer,

	which failed to outline the following required components of a test procedure: a. Requirements for patient preparation; specimen collection, preservation, processing, and referral; b. Step-by-step performance of the procedure, including test calculations and interpretation of results; c. Preparation of solutions, calibrators, controls, reagents, and other materials used in testing; d. Calibration verification procedures; e. The laboratory's system for entering results in the patient record and reporting patient results. 2. Review of laboratory policies and procedures revealed the procedure for hematology testing on the Diatron Abacus 5 analyzer, which failed to outline the following required components of a test procedure: a. Requirements for patient preparation; specimen collection, preservation, processing, and referral; b. Step-by-step performance of the procedure, including test calculations and interpretation of results; c. Preparation of solutions, calibrators, controls, reagents, and other materials used in testing; d. Control procedures; e. The laboratory's system for entering results in the patient record and reporting patient results. 3. Interview with the LD on 12/09 /2025, at 2:26 pm, confirmed the laboratory failed to outline all required components of the test procedures for two of two procedures, routine chemistry testing on the Envoy 500+ analyzer and hematology testing on the Diatron Abacus 5 analyzer.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to perform calibration verifications every six months for 21 of 21 applicable routine chemistry analytes performed on the Envoy 500+ analyzer from the beginning of testing in July 2024 through the date of survey, 12/09/2025. Findings include: 1. Review of laboratory calibration records revealed the following routine chemistry analytes performed on the Envoy 500+ analyzer (Serial Number: 48236279) contained only one-point calibrations and therefore require calibration verification every six months: a. Alanine Transaminase (ALT) b. Albumin c. Alkaline Phosphate (ALP) d. Aspartate Aminotransferase (AST) e. Bilirubin, Total f. Blood Urea Nitrogen (BUN) g. Calcium h. Carbon Dioxide i. Chloride j. Cholesterol k. Creatinine l. Glucose m. High Density Lipoprotein (HDL) n. Iron, Total o. Magnesium p. Phosphorus q. Potassium r. Protein, Total s. Sodium t. Triglyceride u. Uric Acid 2. Review of laboratory records revealed a lack of

	calibration verification documentation for 21 of 21 applicable routine chemistry analytes. 3. Interview with the LD on 12/09/2025, at 11:22 am, confirmed the laboratory failed to perform calibration verifications every six months for 21 of 21 applicable routine chemistry analytes performed on the Envoy 500+ analyzer from the beginning of testing in July 2024 through the date of survey, 12/09/2025.