Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0187192	07/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dallastown Medical Associates	1010 Blymire Rd, Dallastown, PA	

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 the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and interview with the technical consultant (CMS 209 TC #2), the testing personnel (TP) failed to attest to 6 of 6 API PT testing events for hematology testing performed in 2022, 2023, and 2024. 1. The API PT instructions state, "for all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years. Either the attestation statement below or the form provided online can be used. Electronic signatures must have evidence that only the authorized person can utilize the signature." 2. On the day of the survey, 07/31/2024 at 12:30 pm, the laboratory failed to provide attestation statements signed by testing personnel for all PT results: - 2022 Hematology/Coagulation urinalsysis sediment identification 1st event, 2nd event, and 3rd event. - 2023 Hematology/Coagulation urinalsysis sediment identification 1st event, 2nd event, and 3rd event. - 2024 Hematology/Coagulation urinalsysis sediment identification 1st event, 2nd event, and 3rd event. 3. TC #2 confirmed the findings above on 07/31/2024 at 01:30 pm.
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 upon review of the Biorad D10 calibration verification records, and interview with technical consultant (CMS 209 TC #2), the laboratory failed to perform calibration verification (CV) as required by 493.1255(b) on the Biorad D10 analyzer used to perform hemoglobin A1c (HbA1c) tests from 11/04/2022 to 07/25/2024. Findings Include: 1. The manufacturer instructions for the Biorad D10 analyzer states that two levels of calibrators, HbA1c Calibrator Level 1 Calibrator 1 and HbA1c Calibrator, Level 2 Calibrator 2 are used to calibrate the analyzer "Calibration must be performed once, following the installation and priming of every new analytical cartridge. Additional calibration may be performed at the discretion of the laboratory." 2. On the day of the survey, 07/31/2024, review of the Biorad D10 analyzer calibration records revealed the laboratory did not perform calibration verification at least every 6 months from 11/04/2022 to 07/25/2024. 3. TC #2 confirmed the finding above on 07/31/2024 around 12:00 pm.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of patient results, procedure manual, competency records and interview with the technical consultant (CMS 209 TC #2) the laboratory director (LD) failed to ensure that the competency assessment of laboratory testing personnel (TP) who performed performed microscopic urinalysis (sediment) from 11/04/2022 to day of survey was performed. Findings include: 1. The laboratory's urinalysis procedure states the following "the physician should review any crystals, granular casts, yeast, trichomonas, or renal/transitional epithelial cells." 2. On the day of survey, 07/31 /2024 at 2:30 pm Urinalysis microscopy sediment patient result review revealed that non-physician TP CMS 209 #5, #6, #12, #13, #14, #15, #16, #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, and #27 were performing urinalysis sediment analysis and reporting results from 11/04/2022 to 07/31/2024. 3. Competency records for TP CMS

	209 #5, #6, #12, #13, #14, #15, #16, #17, #18, #19, #20, #21, #22, #23, #24, #25, #26, and #27 revealed that they were not evaluated on the reporting of urinalysis sediment results from 11/04/2024 to 07/31/2024. 4. TC #2 confirmed the above findings on 7/31 /2024 at 2:30 pm.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of competency assessment records, and interview with Technical Consultants #2 (CMS 209 TC #2), the TC failed to provide documentation of the direct observation of performance of instrument maintenance and function checks for 27 of 27 testing personnel (TP) that perform microscopic urinalysis (sediment) testing from 11/04/2024 to the date of survey. Findings include: 1. The laboratory's policy Competency Assessment of Testing Personnel states the following, "All testing personnel in PPM laboratories are required to have annual competency. Therefore, all physicians and Physician Assistants will also be required to participate in annual competency for Urine Microscopic examination and Wet/KOH prep examinations. Competency assessment must include the following 6 components for each test or test platform: 1. Direct Observation of routine patient test performance, including patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing 2. Direct observation of instrument maintenance and function checks 3. Monitoring test results reporting 4. Review of records- i.e., test results, worksheets, quality control (QC) records, proficiency testing results, and maintenance records 5. Assessment of test performance- i.e., proficiency testing, blind sample testing 6. Assessment of problem-solving skills- e.g., evaluate problem/action logs, QC corrective action, specimen rejection events, or written quiz." 2. On the day of survey, 07/31/2024 at 10:00 am, review of the competency assessment records revealed the TC failed to document the direct observation of performance of instrument maintenance and function checks of 27 of 27 TP in 2023 and 2024 for the following: - microscopic urinalysis (sediment) testing 3. The TC #2 confirmed the findings above on 07/31/2024 around 02:45 pm.
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 review of the laboratory's competency assessments and interview with technical consultant #2 (CMS 209 TC#2), the TC failed to evaluate and document the competency of 27 of 27 testing personnel (TP) through internal blind testing or external proficiency testing (PT) samples for microscopic urinalysis (sediment) testing performed from 11/04/2022 to the day of the survey. Findings include: 1. The laboratory's policy Competency Assessment of Testing Personnel states the following,

	"All testing personnel in PPM laboratories are required to have annual competency. Therefore, all physicians and Physician Assistants will also be required to participate in annual competency for Urine Microscopic examination and Wet/KOH prep examinations. Competency assessment must include the following 6 components for each test or test platform: 1. Direct Observation of routine patient test performance, including patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing 2. Direct observation of instrument maintenance and function checks 3. Monitoring test results reporting 4. Review of records- i.e., test results, worksheets, quality control (QC) records, proficiency testing results, and maintenance records 5. Assessment of test performance- i.e., proficiency testing, blind sample testing 6. Assessment of problem-solving skills- e.g., evaluate problem/action logs, QC corrective action, specimen rejection events, or written quiz." 2. On the day of the survey, 07/31/2024 at 10:00 am, review of the competency assessment records revealed the TC failed to evaluate and document the test performance of 27 of 27 TP through internal blind sampling, external proficiency testing or previously analyzed samples for the following from 11/06/2022 to the day of the survey: - microscopic urinalysis (sediment) testing 3. The laboratory performed 1220 PPM tests in 2023 (CMS-116 annual volume). 4. TC #2 confirmed the findings above on 07/31/2024 at 02:30 pm.