Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0193262	12/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Medical Oncology Assocs Of Wyoming Vly	382 Pierce Street, Kingston, 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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). 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 Testing Personnel (TP) #1 (CMS 209 personnel #3), the laboratory failed to verify the accuracy of the PT results obtained for 1 of 3 API Chemistry core testing events performed in 2024. Findings Include: 1. On the day of survey, 12/10/2024 at 09:45 am., review of the laboratory's API PT records revealed the laboratory failed to verify the accuracy for the following analyte that was not scored by the PT agency in 2024: - API 2024 Chemistry-core 1st event: Bilirubin, Total (CH-02, CH-03, CH-05), not graded (result variance). 2. The API Proficiency Testing performance Evaluation form states " Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded.". 3. TP #1 confirmed the findings above on 12/10/2024 at 11:22 am.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented.

	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 Testing Personnel (TP) #1 (CMS 209 personnel #3), the laboratory failed to document the evaluation and verification activities performed for 1 of 3 API PT testing events for hematology/coagulation in 2024. Findings include: 1. On the day of the survey, 12/10/2024 at 9:45 am, review of API PT records revealed the laboratory failed to document the corrective action taken when the laboratory received a score of less than 100% for the following 1 of 3 API PT hematology/coagulation events in 2024: - API 2024 Hematology/Coagulation 1st event: White blood cell differential, score of 92% (Monocytes (%) , 80% , Neutrophils (%), 80%) 2. TP #1 confirmed the findings above on 12/10/2024 at 11:22 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records and interview with the Testing Personnel (TP)#1 (CMS 209 personnel #3), the laboratory failed to monitor daily refrigerator and room temperatures to ensure reagent stability and proper operating conditions for 2 of 2 Cell Dyn Emerald 22 and 1 of 1 Vital Scientific Envoy 500 analyzer from 03/22/2023 to 12/10/2024. Findings Include: 1. On the date of the survey, 12/10/2024 at 09:34 am, review of the laboratory's temperature control logs revealed the laboratory failed to monitor and document refrigerator (acceptable ranges 2-8 degrees Celsius) and room temperatures(acceptable ranges 15 to 30 degrees Celsius) on weekends and holidays to ensure the proper storage of reagents and function of 2 OF 2 CELL-DYN Emerald 22 and 1 OF 1 Vital Scientific Envoy 500 analyzers from 03/22/2023 to 12/10/2024. 2. Observation of the laboratory by the surveyor, on 12/10/2024 at 10:30 am, revealed the following reagents were stored in the refrigerators: Basement Refrigerator: Chemistry Reagents: - 1 of 1 box Bio Rad Lyphochek Assayed Chemistry Control 1 - 1 of 1 box Bio Rad Lyphochek Assayed Chemistry Control 2 - 1 of 1 box Envoy 500 Direct Bilirubin Reagent Kit - 2 of 2 boxes Envoy 500 BUN Reagent Kit - 1 of 1 box Envoy 500 Iron Reagent Kit - 3 of 3 boxes Envoy 500 Glucose Reagent Kit - 2 of 2 boxes Envoy 500 Magnesium Reagent Kit - 2 of 2 boxes Envoy 500 Uric Acid Reagent Kit - 1 of 1 box Envoy 500 Serum Calibrator Kit - 1 of 1 box Envoy 500 Serum Control Kit - 1 of 1 box Envoy 500 Total Bilirubin Reagent Kit - 2 of 2 box Envoy 500 GGT Reagent Kit - 2 of 2 boxes Envoy 500 Creatine Reagent Kit - 2 of 2 box Envoy 500 ISE Calibrator Kit - 2 of 2 box Envoy 500 LDH Reagent Kit - 3 of 3 boxes Envoy 500 ALT Reagent Kit - 2 of 2 box Envoy 500 AST Reagent Kit - 2 of 2 boxes Envoy 500 ALP Reagent Kit - Hematology reagents: 2 of 2 boxes CELL-DYN 22 Plus Control CBC Room Refrigerator: - 1 of 1 box Envoy 500 Total Bilirubin Reagent Kit - 1 of 1 box Envoy 500 Creatine Reagent Kit - 2 of 2 box Envoy 500 Calcium Reagent Kit - 1 of 1 box Envoy 500 Glucose Reagent Kit - 1 of 1 box Envoy 500 Serum Calibrator Kit - 1of 1 box Envoy 500 ISE Calibrator Kit - 1 of 1 box Envoy 500 Wash Solution Kit - 1 of 1

	box Envoy ISE Baseline Solution Kit - 1 of 1 box Envoy ISE Diluent Kit - Hematology reagents: 2 of 2 boxes CELL-DYN 22 Plus Control Room Temperature: 2 of 2 boxes Cell DYN Emerald 22 Diluent 2 of 2 bottles Cell DYN Emerald 22 Lyse 3. The TP#1 (CMS 209 personnel #3), confirmed the above findings on 12/10/2024 at 11:00 am.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's Envoy 500 chemistry analyzer verification of performance specifications records and interview with Testing Personnel (TP) #1 (CMS 209 personnel #3), the laboratory failed to establish criteria for acceptable performance specifications and perform a reference range study to verify the manufacturer's normal values are appropriate for the laboratory's patient population for chemistry testing performed on the 1 of 1 Envoy 500 analyzer from 08/30/2023 to the date of the survey. Findings Include: 1. On the day of the survey, 12/10/2024 at 10:33 am, a review of the laboratory's verification of performance specifications records for the 1 of 1 Envoy 500 chemistry analyzer (s/n 48236090) performed on 08/30/2023 revealed the laboratory failed to perform a reference range/normal value study appropriate for the laboratory's patient population prior to reporting patient test results for the following analytes from 08/30/20233 to 12/10/2024: - Albumin - Alanine aminotransferase (ALT) - Alkaline Phosphatase (ALP) - Aspartate aminotransferase (AST) - Bilirubin, Total - Blood urea nitrogen (BUN) - Calcium, total - Carbon dioxide (CO2) - Chloride - Creatinine - Gamma Glutamyl Transferase (GGT) - Glucose - Iron, total - Lactate dehydrogenase (LDH) - Magnesium - Phosphorus - Potassium - Sodium - Total Protein - Uric Acid 2. The laboratory could not provide documentation of a procedure for validation of new instruments, analytes, methodology or relocation of instruments. 3. TP#1 confirmed the findings above on 12/10/2024 at 11:22 am.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the Laboratory Information System (LIS) policy, lack of documentation and interview with testing personnel (TP) #1 (CMS 209 personnel #3), the laboratory failed to follow written policies for an ongoing mechanism to monitor and ensure the integrity of Chemistry and Hematology test results reported from the 1

	of 1 LIS system (CGM MEDICUS) from 03/22/2023 to the day of survey. Findings include: 1. The laboratory's LIS Data Corruption Protocol states, "To ensure that data cannot be altered on stored requisitions or electronic results, patient results will be printed out from the LIS system, the chart and the instruments. They will be kept in a file and then be checked again in six months. Results will be printed out again and compared to ensure nothing was altered." 2. On the date of the survey, 12/10/2024 at 11:00am, review of the laboratory's LIS policy revealed that the laboratory failed to follow written procedures to periodically ensure the integrity of patient results reported when basic/complete metabolic panels (BMP/CMP) for chemistry and complete blood count (CBC) for hematology were performed from 03/22/2023 to 12 /10/2024. 3. The laboratory failed to provide documentation for the six months check performed to verify the integrity of its interfaced results as per policy. 4. TP #1 confirmed the findings above on 12/10/2024 at 11:22 am.