Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2174034	10/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Millennium Physicians- Cypress Station	1250 Cypress Station Dr, Ste B, Houston, TX	

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
D0000	An announced survey of the laboratory was conducted on 10/19/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories. STANDARD LEVEL DEFICIENCIES were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory's specimen transport verification studies, laboratory's instructions to clients for specimen collection and handling and staff interview, the laboratory failed to ensure written instructions were available to clients and couriers for appropriate packaging/shipping of samples in order to ensure samples' stability during transport for two of two sample types tested by the laboratory, blood and bone marrow. Findings included: 1. Review of laboratory's specimen transport verification studies (signed off on 03/16/2022) revealed: "This process validation has established that the specified cooler (14.25"x9.5"x11" Hopkins Medical Products MarketLab Hardside Cooler) can maintain the temperature between 2-8C for 5.5 hours total after placing the (six 12oz) ice packs in the cooler." Note: In the study the laboratory used a maximum of 10 samples per cooler. 2. Review of laboratory's instructions to clients for specimen collection and handling revealed there were no written instructions to clients/couriers regarding requirements for number and size of icepacks, specific placement of ice packs in the coolers, how to ensure samples were not placed directly on top of the ice packs, maximum number of samples allowed per cooler, or

	maximum transport time allowed. 3. In an interview on 10/19/2023 at 1110 hours in the office, the General Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid C - Degrees Celsius " - Inch oz - Ounce
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's specimen transport verification studies, specimen transport logs from June to October of 2023, quality assurance records and staff interview, the laboratory's Quality Assurance (QA) failed to identify issues with verification of specimen transport conditions for 4 of 4 months reviewed. Findings included: 1. Review of laboratory's specimen transport verification studies (signed off on 03/16/2022) revealed: "This process validation has established that the specified cooler (14.25"x9.5"x11" Hopkins Medical Products MarketLab Hardside Cooler) can maintain the temperature between 2-8C for 5.5 hours total after placing the (six 12oz) ice packs in the cooler." Note: In the study the laboratory used a maximum of 10 samples per cooler. 2. Review of laboratory's specimen transport logs from June to October of 2023 revealed the laboratory documented the following transport parameters: Date of Delivery Courier Name Route Time Started Time of Delivery to Flow Lab Number of Specimens Delivered Specimens Kept at 2-8 while in courier's possession (Y or N) 3. Further review of the specimen transport logs revealed there was no documentation of verification of the number and condition of the transport cooler's icepacks (frozen, melted cold, melted room temperature, etc.), or verification of specimens' temperature upon arrival at the laboratory. 4. Review of the above specimen transport logs and QA records also revealed the laboratory did not document that it identified and addressed transport log discrepancies and deviations from the parameters established by laboratory's specimen transport stability study. The laboratory did not document whether it evaluated how and/or if those discrepancies /deviations had affected transported samples for the following deliveries: Date of Delivery: 06/20/2023 Route Time Started: 4:00pm (after noon) Time of Delivery to Flow Lab: 6:30pm Number of Specimens Delivered: 14 Specimens Kept at 2-8 while in courier's possession (Y or N): y (yes) QA did not document addressing number of specimens exceeding that of the number established during sample transportation stability study. Date of Delivery: 07/05/2023 Route Time Started: 4:00pm Time of Delivery to Flow Lab: 6:01pm Number of Specimens Delivered: 11 Specimens Kept at 2-8 while in courier's possession (Y or N): y QA did not document addressing number of specimens exceeding that of the number established during sample transportation stability study. Date of Delivery: 09/18/2023 Route Time Started: 4: 00pm Time of Delivery to Flow Lab: 6:25pm Number of Specimens Delivered: 11 Specimens Kept at 2-8 while in courier's possession (Y or N): y QA did not document addressing number of specimens exceeding that of the number established during sample transportation stability study. Date of Delivery: 09/19/2023 Route Time Started: 6:15 Time of Delivery to Flow Lab: 6:15 Number of Specimens Delivered: 7 Specimens Kept at 2-8 while in courier's possession? (Y or N): No response was documented. QA did not document addressing time of transport discrepancy and lack of transport temperature verification. 5. In an interview on 10/19/2023 at 1110 hours

	in the office, the General Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records, policies/procedures and staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties of each laboratory personnel, for 4 of 5 positions within a high complexity testing laboratory. Findings included: 1. Review of laboratory's personnel records and policies/procedures revealed the following laboratory personnel positions did not have delegation of all duties specified in writing: Clinical Consultant Technical Supervisor General Supervisor Testing Personnel 2. In an interview on 10/19/2023 at 1045 hours in the office, the General Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid