Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0984131	10/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sudipta And Bindu Dey, Md, Inc	127 Pines Bridge Rd, Beacon Falls, CT	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to perform proficiency testing (PT) samples exactly as patient samples in the specialty of hematology. Findings include: 1. Record review on 10/12/23 of the Horiba Micros 60CS instrument printouts (result report) for 2022 event 1 PT revealed testing personnel ran 5 of 5 PT samples twice on 03/30/2022. 2. Record review on 10/12/23 of the laboratory's procedure manual for "Proficiency Testing Policy" revealed "samples must be tested the same number of times as patient samples." 3. Staff interview with testing personnel#1 (TP1) on 10/12/23 at 11:30 AM confirmed the above findings. TP1 further stated routine patient samples are run only once in the laboratory.
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 record review and staff interview the laboratory failed to investigate and take remedial action when unacceptable Proficiency Testing (PT) scores are received in the subspecialty of routine chemistry. Findings include: 1. Record review on 10/12 /2023 of the American Proficiency Institute (API) PT scores revealed the following: a. For 2023 Event 1, an unacceptable PT score of 80% for magnesium for 1 of 5 PT samples was obtained. c. Investigation and remedial action was not documented for the unacceptable result listed in 1a above. 2. Staff interview on 10/12/2023 on 12:15 PM with testing personnel #1 (TP1) confirmed the above findings and TP1 further commented he/she was unaware an investigation was required for PT scores less than 100%. 3. The laboratory performs 500 magnesium tests annually in the subspecialty of routine chemistry.
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 on record review, telephone interview and staff interview the laboratory failed to perform red cell distribution width (RDW) calibration as required by the manufacturer in the specialty of hematology. Findings include: 1. Record review on 10 /12/23 of the Horiba Micros 60CS operator's manual revealed "the RDW calibration is a separate calibration outside the auto-calibration menu." The Horiba Micros 60CS operator's manual further provided detailed information in performing RDW calibration. 2. Record review on 10/12/23 of the laboratory's procedure manual for Horiba Micros 60CS instrument revealed lack of documentation for RDW calibration procedures. 3. Telephone interview with Horiba Micros 60CS technical service personnel on 10/12/23 at 9:50AM confirmed RDW is a separate calibration procedure, and it needs to be performed semiannually. 4. Staff interview with the technical consultant on 10/12/23 at 10:00 AM confirmed the above findings. 5. The laboratory performs 4,000 RDW tests annually in the specialty of hematology.
D5783	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when quality control was not performed, and calibration material failed to meet acceptable criteria in the subspecialty of routine chemistry. Findings Include: 1. Record review on 10/12/2023 of the HORIBA Pentra C400 monthly quality control (QC) result log revealed lack of acceptable QC performance for carbon dioxide (CO2) test on June 20th, 2023. 2. Record review on 10/12/2023 of the HORIBA Pentra C400 monthly calibration record revealed a failed calibration for CO2 test on June 20th, 2023. 3. Record review on 10/12/2023 of the June 2023 corrective action log revealed lack of documentation of corrective action for 1 and 2 listed above. 4. Staff interview on 10/12/2023 at 11:30 AM with testing personnel #1 confirmed the above findings and further commented that no patient testing for CO2 was conducted on that day. 5. The laboratory performs 1000 CO2 tests annually in the subspecialty of routine chemistry.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on record review and staff interview the technical consultant failed to ensure corrective actions are taken and documented when calibration verification failed to meet the laboratory's established protocol in the subspecialty of routine chemistry. Findings include: 1. Record review on 10/12/2023 of the corrective action log for June 20th, 2023, revealed lack of documentation of corrective action when calibration verification for CO2 failed to meet acceptable criteria. 2. Record review on 10/12 /2023 of the most recent 'Technical Consultant/Supervisor Competency Evaluation' form completed on 10/04/2023 revealed 'Resolves technical problems and ensure corrective actions are taken whenever test systems deviate from the laboratory's established performance specifications'. 3. Staff interview on 10/12/2023 at 11:40 AM with the technical consultant confirmed the above findings. 4. The laboratory performs 1000 CO2 tests annually in the subspecialty of routine chemistry.