Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0100927	01/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Danbury Medical Group Llc	100 Reserve Rd, Ste 4a, Danbury, 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
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 or take remedial action when unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. Record review of the American Association of Bioanalysts (AAB) PT reports on 1/15/19 revealed unacceptable scores were obtained for the following events: a. 2017- Event 2 for iron and sodium. b. 2018- Event 1 for cholesterol, HDL and event 2 for iron. c. Investigation or remedial action was not documented for the above unacceptable results. 2. Staff interview with testing personnel #1 (TP#1) on 1/15/19 at 11:00 AM confirmed the laboratory did not investigate and take remedial action for the unacceptable PT results. TP#1 also stated they were unaware an investigation was required for PT scores less than 100%. 3. The laboratory performs 1,594 iron, 4,137 sodium and 3,193 cholesterol, HDL tests annually in the specialty of routine chemistry.
D2128	HEMATOLOGY CFR(s): 493.851(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 or take remedial action when unacceptable proficiency testing (PT) scores are received. Findings include: 1. Record review of the American Association of Bioanalysts (AAB) PT evaluation reports on 1/15/19 revealed the laboratory obtained unacceptable PT scores for the following events: a. 2017- Event 2 for platelets. b. 2018- Event 3 for hematology cell identification. c. Investigation or remedial action was not documented for the above unacceptable PT results. 2. Staff interview with testing personnel #1 (TP#1) on 1/15/19 at 11:00 AM confirmed the laboratory did not investigate or take remedial action for the unacceptable PT results. TP#1 also stated they were unaware an investigation was required for PT scores less than 100%. 3. The laboratory performs 74,080 tests annually in the specialty of hematology.
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 record review and staff interview the laboratory failed to document daily temperature function check of equipments in the specialty of chemistry and hematology. Findings include: 1. Record review of the temperature logs on 1/15/19 revealed: a. Temperatures were not being recorded daily in 2017 and 2018 for freezer with model #253.65812508. b. Temperature for "small refrigerator", "Nur fridge" and "Freezer" were not recorded daily in 2017 specifically on weekends and when testing personnel #1 (TP#1) was on vacation. c. Room temperature readings were not documented from February through May in 2017. d. In-use reagents, calibrators, quality control and patient specimens to be tested are currently stored in the above refrigerators and freezer. 2. Interview with TP #1 on 1/15/19 at 2:00 PM confirmed the above findings. 3. The laboratory performs approximately 152,212 moderately complexity tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document maintenance(s) for laboratory equipment(s) to ensure accurate and reliable test results. Findings include: 1. Record review on 1/15/19 of the equipment(s) preventive maintenance (PM) log revealed annual PM of the Horiba ABX Micros 60 Hematology analyzer was not performed or documented after 2/27/17 as recommended by the manufacturer. 2. Staff interview with the testing personnel (TP) #1 on 1/15/19 at 11: 00 AM confirmed the above finding. 3. The laboratory performs 74,080 tests in the specialty of hematology annually.
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 and staff interview, the laboratory failed to perform calibration of the hematology analyzer at the required frequency. Findings include: 1. Calibration record review on 1/15/19 revealed the following: a. Horiba ABX Micros 60 Hematology analyzer was calibrated on 3/23/16 when installed and then on 2/27/17 when preventive maintenance was performed. Documentation for calibration after 2/27 /17 was not available. b. Records of semi-annual calibration was not available for the period of March 2017 through 1/15/19 at the time of onsite inspection. 2. Staff interview with the testing personnel #1 (TP#1) on 1/15/19 at 11:30 AM confirmed the six months calibrations were not performed in a timely manner for the above indicated period. TP#1 stated he/she was unaware calibration was required every six months. 3. The laboratory performs 74,080 tests annually in the specialty of hematology.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if

	applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to maintain both the original and corrected test result when corrections are made to patient final test reports. Findings include: 1. Record review of 2 of 2 corrected patient final test reports on 1/15/19 revealed the reports did not clearly indicate the original result that was previously reported. It was further revealed the original report was not available for review. 2. Record review of the laboratory procedure "Laboratory Policy" section for "Patient Reports" on 1/15/19 revealed: a. The laboratory must maintain copies of the original report as well as the corrected report. b. A log must be kept for result modifications which was unavailable. 3. Staff interview with testing personnel #1 on 1 /15/19 at 1:10 PM confirmed the original result was not indicated in the corrected report and a log for result modification is not available.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory director (LD) failed to review Proficiency Testing (PT) evaluation reports when results were received in 2017 and 2018. Findings include: 1. Record review of the American Association Bioanalysts (AAB) PT evaluation reports for chemistry and non-chemistry events in 2017 and 2018 on 1/15/19 revealed the lack of documentation for LD review. 2. Staff interview with testing personnel #1 on 1/15/19 at 1:15 PM confirmed the above finding. 3. The laboratory performs approximately 78,132 chemistry and 74,080 hematology tests annually.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical consultant failed to ensure new testing personnel (TP) received training in order to perform moderate complexity

	testing in the specialty of hematology. Findings include: 1. Record review of TP files on 1/15/19 revealed the laboratory failed to provide evidence of documentation for training of 1 of 3 new TP who performed complete blood count (CBC) tests in 2018 and 2019. 2. Record review of the laboratory's "Quality Assurance policy" on 1/15/19 revealed "All laboratory personnel will receive detailed training for the performance of all duties and tasks that they perform." 3. Staff interview with the TP#1 on 1/15/19 at 10:30 AM confirmed 1 of 3 new TP did not have training documentation available for CBC testing. 4. The laboratory performs approximately 74,080 CBC tests annually.
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 record review and staff interview, the technical consultant (TC) failed to evaluate the competency of testing personnel (TP) to perform moderate complexity testing annually in 2017 and 2018. Findings include: 1. Record review of the laboratory's TP competency records on 1/15/19 revealed 7 of 7 TP performing moderate complexity testing were not evaluated for 5 of the 6 elements required to assess their competency in 2017 and 2018. 2. Staff interview with the laboratory director (LD) and TC on 1/15/19 at 11:00 AM confirmed 7 of 7 TP were not evaluated in all six required competency assessment criteria in 2017 and 2018 to perform moderate complexity testing. TC stated he/she took the TC position on 8/20/17 and the LD stated he/she took on the LD position 12/30/18. 3. Laboratory performs 152,212 moderate complexity tests annually.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to assess and document new testing personnel (TP)competency to perform hematology, routine chemistry and endocrinology tests twice in the first year of performing patient testing. Findings include: 1. Record review of the CMS Laboratory Personnel Report (CMS-209) form on 1/15/19 revealed 3 new TP were hired since the last onsite survey. 2. Record review of the TP competency records on 1/15/19 revealed 2 of 3 new TP were not assessed for their competency to perform patient testing twice during the first year of employment. 3. Staff interview with testing personnel #1 on 1/15/19 at 10:30 AM confirmed the above findings. 4. The laboratory performs 74,080 hematology, 74,198 routine chemistry and 3,934 endocrinology tests annually.