Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 07D2110981	**(X3) Date Survey Completed** 05/22/2018
Name of Provider or Supplier Medical Laboratory Diagnostics-East Hartford	**Street Address, City, State** 478 Burnside Ave, East Hartford, 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**
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure all required proficiency testing (PT) data be released to the Centers for Medicare and Medicaid Services. Findings include: 1. Record review on 5/21/18 of the CASPER report 0096D, 'CLIA Application and Survey Summary Report' revealed PT scores were not available for the regulated analytes in the specialty of hematology. 2. Record review on 5/22/18 of the laboratory's America Proficiency Institute, 2018 order confirmation sheet revealed, "CLIA number not on file - Please call customer service." 3. Staff interview with testing personnel #1 on 5/22/18 at 11:30 AM confirmed the above findings. 4. The laboratory performs 11,922 tests annually in the specialty of hematology.
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 take remedial action when unacceptable Proficiency Testing (PT) scores are received. Findings include: 1. Record review of the laboratory's Hematology American Proficiency Institute PT results on 5/22/18 revealed: a. Unacceptable PT scores (80%) for 2016 event 3 and 2017 events 1 and 2. b. The PT events were signed as reviewed. 2. Record review of the laboratory's PT investigation sheets for the above unacceptable scores on 5/22/18 revealed, remedial action to prevent recurrence was not documented. 3. Staff interview with Testing personnel #1 on 5/22/18 at 11:50 AM confirmed the above findings. 4. The laboratory performs 11,922 tests annually in the specialty of hematology.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director (LD) failed to ensure personnel were qualified before designating LD responsibilities. Findings include: 1. Record review on 5/22/18 of a designation of duties letter revealed: a. The LD delegated the review of proficiency testing (PT) and quality control (QC) records to delegate #1(D1). b. The letter was signed by the laboratory director. 2. Record review on 5/22/18 of D1's credentials revealed D1 does not have the minimum requirement of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution. 3. Record review on 5/22/18 of the laboratory's PT and QC records revealed the above functions are performed by the D1. 4. Record review on 5/22/18 of the laboratory's Levy Jennings charts and peer group records from October 2016 through March 2018 revealed a second individual (D2) reviewed and signed off. 5. Staff interview on 5/22/18 at 10:00 AM with D1 confirmed the above findings. 6. Staff interview with the laboratory director on 5/23 /18 at 2:30 PM revealed D2 was not qualified to perform the above duties.
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 ensure that all proficiency testing (PT) reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings include: 1. Record review on 5/22/18 of a designation of duties letter revealed: a. The LD delegated the review of PT records to delegate #1 (D1). b. The letter was signed by the LD. 2. Record review on 5/22/18 of D1's credentials revealed D1 does not have the minimum requirement of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution. 3. Record review of the laboratory's Hematology American Proficiency Institute PT results on 5/22/18 revealed: a. Unacceptable PT scores (80%) for 2016 event 3 and 2017 events 1 and 2. b. The PT events were signed as reviewed by D1. 4. Record review of the laboratory's PT investigation sheets for the above unacceptable scores on 5/22/18 revealed, remedial action to prevent recurrence was not documented. 5. Staff interview on 5/22/18 at 10:00 AM with D1 confirmed the above findings.