

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0650270	(X3) Date Survey Completed 01/10/2019
Name of Provider or Supplier Massachusetts Department Of Public Health	Street Address, City, State 305 South St, Jamaica Plain, MA	
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to have written or electronic test requests for Urine and Blood Metals and Arsenic Speciation by ICP-MS and Polychlorinated biphenyl congeners (PCB) by GC-MS/MS testing from a person authorized by Massachusetts State Law to order tests. 105 CMR: Massachusetts Department of Public Health requires patient specimen examinations only be performed at the request of persons authorized under M.G.L c.112. Findings include: 1. Record review conducted on 01/10/2019 of Urine and Blood Metals and Arsenic Speciation testing by ICP-MS and PCB testing by GC-MS/MS test reports issued during April and May of 2018 revealed that test results were reported to the Bureau of Environmental Health (BEH), 250 Washington Street, Boston, MA. The review further revealed that the laboratory failed to have written or electronic requests from an authorized person at BEH for all testing performed April and May 2018. 2. Interview conducted on 01/10/2019 at 11:00 AM with the Quality Assurance (QM) and the Technical Supervisor (TS) confirmed these findings and further revealed that all test results for Urine and Blood Metals by ICP-MS and PCB by GC-MS/MS reported to the BEH issued since October 2016 failed to have written or electronic test requests from an authorized person. 3. The laboratory performed and reported 146 Arsenic Speciation tests, 482 PCB tests, 543 Urine Metals tests, and 502 Blood Metals tests since October 2016 in the subspecialty of Toxicology.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p>

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 record review and staff interview, the laboratory failed to follow specimen acceptability and rejection criteria as stated in the laboratory's standard operating procedures (SOP) for 3 samples received by the Microbiology- STI Laboratory between 07/01/2018 to 12/31/2018. Specimen numbers (18VL25455, 18VL28030, and 18VL42237). Findings include: 1. Record review conducted on 1/10/2019 of the laboratory's SOP "HV.010 Processing of Specimens Submitted to the Laboratory for HIV, Hepatitis C, Syphilis, Chlamydia and Gonorrhea testing, Version 7.0, effective 04/19/2018 stated the following specimen rejection criteria: a) HIV/HCV Rejection Criteria: Specimens received more than 3 days from date of collection. b) Syphilis Rejection Criteria: Specimens received at room temperature and greater than 14 days from collection date. Specimens that have been in frozen storage may be tested beyond 14 days of collection as determined by review of laboratory supervisor. 2. Record review conducted on 1/10/2019 of a "Turnaround Time Report by Specimen Received Date" generated for the period of 07/01/2018 - 12/31/2018 indicating the number of days from specimen collection date to specimen receipt date revealed 2 samples (18VL25455, 18VL28030) were received by the laboratory for HIV Ag/Ab CMIA, Hepatitis C Ab CMIA, and Syphilis Ab CMIA testing greater than 72 hours post collection. The record review further revealed 1 specimen (18VL42237) received for Syphilis RPR testing greater than 14 days post collection date. 3. Record review conducted on 1/10/2019 of specimen test reports 18VL25455, 18VL28030, and 18VL42237 revealed specimens were not reported as unsatisfactory for testing, but instead reported with HIV Ag/Ab CMIA, Hepatitis C Ab CMIA, and Syphilis test results. 4. Staff interview with the technical supervisor (TS) and the quality assurance manager (QM) on 1/10/2019 at 11:30 AM confirmed the above findings.

D5811

TEST REPORT
CFR(s): 493.1291(f)

(f) Except as provided in 493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to release test results for Urine and Blood Metals and Arsenic Speciation by ICP-MS and Polychlorinated Biphenyl Congeners (PCB) by GC-MS/MS to a person authorized by Massachusetts State Law to receive test results. 105 CMR: Massachusetts Department of Public Health requires patient specimen examinations only be performed at the request of persons authorized under M.G.L c.112 to use the report of laboratory examinations. Findings include: 1. Record review conducted on 01/10/2019 of Urine and Blood Metals and Arsenic Speciation by ICP-MS and PCB by GC-MS/MS test reports issued during April and May of 2018 revealed that test results were reported to the Bureau of Environmental Health (BEH), 250 Washington Street, Boston, MA. The

review further revealed that the laboratory failed to have written or electronic requests from an authorized person at BEH to order and receive the test results reported in April and May 2018. 2. Interview conducted on 01/10/2019 at 11:00 AM with the Quality Assurance (QM) and the Technical Supervisor (TS) confirmed these findings and further revealed that all test results for Urine and Blood Metals and Arsenic Speciation by ICP-MS and (PCB) by GC-MS/MS reported to the BEH since October 2016 failed to have written or electronic test requests from an authorized person. 3. The laboratory performed and reported 146 Arsenic Speciation tests, 482 Polychlorinated Biphenyl Congeners (PCB) tests, 543 Urine Metals tests, and 502 Blood Metals tests since October 2016 in the subspecialty of Toxicology.