

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0644555	<b>(X3) Date Survey Completed</b>  07/17/2019
<b>Name of Provider or Supplier</b>  Dr Katherine A Kelley State Public Health Lab	<b>Street Address, City, State</b>  395 West St, Rocky Hill, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to test proficiency testing (PT) samples in the same manner as routine patient samples by personnel who routinely perform the testing in the sub-specialty of syphilis serology. Findings include: 1. Record review of the College of American Pathologists syphilis serology PT records for 2017 and 2018 on 7/16/19 revealed the following: a) 2017 - two PT events were tested by testing personnel (TP) #1 and one PT event by TP#2. b) 2018 - all three PT events were tested by TP#2. c) No PT events were tested by TP#3 in 2017 and 2018. 2. Staff interview with the Diagnostic Immunology Section Supervisor (DISS) on 7/16/19 at 11:00 AM confirmed the above findings. The DISS further stated all three TP did not participate in PT events each calendar year although patient samples were tested by three TP. 3. The laboratory performs 9,595 syphilis serology tests annually.</p>
<b>D3003</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor observation and staff interview, the laboratory failed to take adequate safety precautions to prevent potential biological contamination of floor covering during specimen receipt and data entry. Findings include: 1. Surveyor observation of the specimen processing area on 7/15/19 at 2:25 PM, revealed the processing was being performed in Room 1515 labeled 'Data Entry'. This room consisted of wall to wall carpeting with multiple workstations for data entry. 3 of 3 laboratory staff had specimen requisitions along with biological specimens at their workstations. Coverage of the carpeting with non-porous material was not present for proper decontamination and clean-up in event of a biological spill. 2. Staff interview with the Laboratory Administrative & Scientific Support Services Director (LASSD) on 7/15/19 at 2:25 PM confirmed the above findings. In addition, LASSD revealed the following: a. The laboratory specimen processing area had been relocated to Room 1515 due to a fire. b. Room 1515 is a temporary situation while repairs are being completed. c. The carpet was not removed because of the safety hazard due to carpet glue. d. If a spill occurs staff have been directed to pour bleach on the carpet and the carpet would be replaced.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
 Based on record review and staff interview, the laboratory failed demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for precision using operator variance. Findings include: 1. Record review on 7/15/19 of the laboratory's validation protocol for the Aptima HIV-1 Quant Assay, Verification Protocol section revealed, "A laboratory analyst who was adequately trained in the use of the Aptima HIV-1 Quant Assay on the Panther System by a Hologic Field Application Specialist performed the verification study." 2. Record review on 7/16/19 of the Aptima HIV-1 Quant Assay validation's raw data revealed only one testing personnel (TP) performed testing and participated in the validation. 3. Staff interview on 7/16/19 at 10:00 AM with the virology technical supervisor (TS) confirmed the above findings. The TS stated, "Two TP perform routing patient HIV Quant testing, but only one TP participated in the validation." 4. The laboratory performs 20 Aptima HIV-1 Quant Assays annually.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
 CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as

applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to establish performance specifications for the new Nexion 2000P ICP-MS instrument used for high complexity testing in the specialty of chemistry. Findings include: 1. Record review of the laboratory's CMS List of tests performed on-site & Annual test volume report on 7/17/19 revealed the Nexion 2000P ICP-MS instrument was a new instrument used to perform blood/urine metal testing for cadmium (Cd), lead (Pb) and mercury (Hg). 2. Record review of the laboratory's validation studies for the above on 7/17/19 revealed the performance specification studies for the Nexion 2000P ICP-MS instrument were not available or approved by the laboratory director for Cd, Pb, and Hg prior to the start of patient testing in February of 2019. 3. Staff interview with the department manager (DM) on 7/17/19 at 2:00 PM confirmed the laboratory failed to conduct the performance specifications listed above for the Nexion 2000P ICP-MS instrument. DM stated he/she was not aware that new instrumentation needed to be validated if it was the same platform. 4. The laboratory performs 72 blood/Urine metal testing annually.

**D5801**

**TEST REPORT**

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on test record review and staff interview with the Quality Assurance Manager (QAM) and Laboratory Director (LD), the laboratory failed to ensure that test results were accurately and reliably sent to the final report destination. Findings include: 1. Record review conducted on 7/16/19 of the test report records from 04/01/19 to 06/30/19 revealed that that the laboratory failed to perform routine checks to verify that test results were accurately transmitted to their final report destination after the laboratory released test results for reporting. 2. The record review conducted on 7/16/19 of Newborn Screening Laboratory (NBS) test reporting records revealed that the NBS released 862 test results on June 12, 2019 to be reported. The record review further revealed that the laboratory was unable to provide documentation demonstrating that the 862 NBS test results were accurately and reliably transmitted by fax or email to the health care providers authorized to receive the test results. 3. Record review conducted on 7/16/19 of test records for July 11, 2019 and June 28, 2019 also revealed that the laboratory was unable to provide documentation demonstrating that Connecticut Department of Public Health, Laboratory Branch (CTPHL) ensured test results released for reporting on 7/11/19 and 6/28/19 were accurately and reliably

transmitted by fax or email to their final report destination. 4. Interview with the QAM and the LD on 7/16/2019 at 11:17 AM confirmed the findings above.

**D5805**

TEST REPORT  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

A. Based on record review and staff interview with the Newborn Screening Laboratory (NBS) Technical Supervisor (TS) and the Laboratory Director (LD), the laboratory failed to include the name and address of the laboratory where the amino acids, succinylacetone and acylcarnitines in dried blood spots by Tandem Mass Spectrometry (MS/MS) was performed. A. Findings include: 1. Record review conducted on 7/16/19 of June 2019 and July 2019 NBS test result records revealed the "CT NBS Contact Information report used to send abnormal the amino acids, succinylacetone and acylcarnitines MSMS results to the NBS Tracking Unit Nurse was missing the address where the tests were performed. 2. Interview with the NBS TS and LD on 7/16/19 at 3:30 PM confirmed the findings above. B. Based on record review and staff interview with the newborn screening technical supervisor (TS) and the laboratory director (LD), the laboratory failed to follow its procedure for reporting abnormal amino acids, succinylacetone and acylcarnitines in dried blood spots by Tandem Mass Spectrometry (MS/MS) on Connecticut Department of Public Health, Laboratory Branch (CTPHL) Newborn Screening (NBS) test reports. B. Findings include: 1. Record review conducted on 7/16/19 of the CTPHL Detection of Amino Acids, Succinylacetone and Acylcarnitines in Dried Blood Spots by Tandem Mass Spectrometry (MS/MS), Document ID NBS-02-5, Effective date 8/15/2016, Section 10.0, " ... results where 2 out of the 3 analyses generate an abnormal tool score then the final reported result is abnormal". 2. Record review conducted on 7/16/19 of randomly selected CTPHL NBS abnormal test reports issued between May 2019 and June 2019 Lab IDs 853754001 and 855983001 revealed a single result value reported for each abnormal acylcarnitines. The review further revealed that the calculation used to determine the single abnormal acylcarnitines result value was not documented in the CTPHL Detection of Amino Acids, Succinylacetone and Acylcarnitines in Dried Blood Spots by Tandem Mass Spectrometry (MS/MS) approved procedure. 3. Interview with the NBS TS and LD on 7/16/19 at 3:30 PM confirmed the findings above.

**D5807**

TEST REPORT  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
 Based on record review and staff interview, the laboratory failed to ensure the final interpretation reported on the final patient test report correlates with the interpretation in the procedure manual in the specialty of virology. Findings include: 1. Record review on 7/16/19 of the 'CMV IgM Detection in Serum Using the Captia EIA Kit' procedure revealed: a. Section 6.0 Reporting Results: 6.1 Analysis: "0.91 -1.09 Equivocal Sample should be retested" 6.1.2: "Samples that remain equivocal after repeat testing should be retested on a alternate method, e.g. immunofluorescence assay (IFA)." b. Section 8.0 Limitations: 8.4: "Samples that remain equivocal after repeat testing should be retested on a alternate method, e.g. immunofluorescence assay (IFA). If results remain equivocal upon further testing, an additional sample should be taken." 2. Record review on 7/16/19 of the 'Trinity Biotech Captia Cytomegalovirus IgM' package insert revealed: a. Analysis: "0.91 -1.09 Equivocal Samples should be retested. See number 2 below." "Samples that remain equivocal after repeat testing should be retested on an alternate method, immunofluorescence assay (IFA)." b. Limitations Of Use: "Samples that remain equivocal after repeat testing should be retested on an alternate method, immunofluorescence assay (IFA)." If results remain equivocal upon further testing, an additional sample should be taken." 3. Record review of a final test report on 7/16/19 revealed: "Cytomegalovirus IgM 1.069 ISR, Final Interpretation: Equivocal, Please submit another sample to confirm analysis." "0.91 - 1.09 Equivocal" 4. Staff interview with the virology technical supervisor (TS1) on 7/16/19 at 11:00 AM confirmed the above findings. The TS1 stated the laboratory does not have an alternate method to retest equivocal specimens. Currently equivocals are repeated using the same method.

**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's amended reports failed to indicate what corrections were made on their Newborn Screening (NBS) patient final test reports. Findings include: 1. Record review on 7/17/19 of the laboratory's corrected final patient report log from 6/1/19 through 6/30/19 revealed the following: a. 6 of 6 NBS amended reports reviewed failed to indicate what corrections were made on the final reports. b. 8 of 8 NBS reports revealed no corrections were made but indicated report was amended. 2. Staff interview with the quality assurance manager (QAM) on 7/17/19 at 1:30 PM confirmed the above findings. 3. The laboratory performs 362,000 NBS tests annually.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
 CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to monitor and assess the accuracy of the laboratory's corrected reports issued to ensure compliance with the laboratory's approved corrected test report policy and procedure. Findings include: 1. Record review conducted on 7/17/19 of the Connecticut Department of Public Health, Laboratory Branch (CTPHL) Module 1A Quality Assessment Program for Clinical Testing Manual (QAM) 4th edition, document ID QA-CLIA, effective June 20, 2017, revealed in section 7.4 Correction of Test Reports "The reason for a corrected report must be inserted as a comment when the report is changed in the LIMS." 2. Record review of corrected reports from 4/1/19 to 6/30/19 revealed that 178 of 531 corrected reports issued during this time period were missing comments. 3. Interview with the Quality Assurance Manager on 7/16/19 at 3:30 PM confirmed the findings above.

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of 2018 and 2019 proficiency testing (PT) records and staff interview with the laboratory director (LD) and technical supervisors (TS1) and (TS2), the laboratory failed to follow its approved procedures for proficiency testing (PT) event result scores less than >100% for PT events VR1-A 2019, VR3-B 2018, and (LIZ add GC Culture PT). Findings include: 1. Record review conducted on 7/16/19 of the Connecticut Department of Public Health, Laboratory Branch (CTPHL) Module 1A Quality Assessment Program for Clinical Testing Manual (QAM) 4th edition, document ID QA-CLIA, effective June 20, 2017, revealed in section 6.2 Proficiency Testing, "After a Corrective Action report Form (CARF) is completed, it must be signed off on by the Section Manager and then submitted to the Laboratory Director for final approval. After approval CARFs are given to the QA Manager for monitoring to ensure the corrective action has been effective in fixing the problem." 2. Record review conducted on 7/16/19 of CARF for CAP PT event VR1-A 2019 for specimen number VR1-04 that CTPHL incorrectly reported as "Enterovirus found" revealed no QA follow-up for the following corrective actions: a) "Re-analysis of sample by cell culture isolation is pending at this time." b) "SOP should be updated to reflect current practices; i.e. respiratory specimens are not tested by cell culture". 3. Record review conducted on 7/16/19 of the CARF for CAP VR3-B 2018 for specimen VR3-09 CMV, IgG revealed that the laboratory reported a result of "Indeterminate". The CAP PT ungraded intended response for this specimen was CMV antibody present and the QA follow-up for the CARF was listed as "N/A" and not conducted. 4. Interview conducted with the LD and the TS1 conducted on 7/16/19 at 10:50 AM confirmed the above findings. 5. Record review conducted on 7/16/19 of the CARF for CAP PT event D3-C 2017 for specimen number GC-13 revealed that the laboratory reported an unacceptable result of "Negative for GC". The investigation was incomplete and no corrective action of policy and/or procedural changes to prevent recurrence was documented. The CARF was not signed by the LD for final

approval. 6. Interview conducted with the TS2 on 7/16/19 at 9:20 AM confirmed the findings in #5 above. In addition, TS2 stated the GC-13 isolate was not held therefore retesting was not performed.