Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0644555	07/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dr Katherine A Kelley State Public Health Lab	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on record review and staff interview with the Newborn Screening (NBS) Laboratory Technical Supervisor (TS), the laboratory failed to retain copies of preliminary reports generated from the Horizon Laboratory Information System (LIS). Findings include: 1. Record review conducted on 07/20/2021 of a preliminary report copy for patient DPH Lab ID 1022372001 found that the report noted as a "DRAFT", was missing the provider name and address information, and included a "Date Reported" as 07/20/2021, 2:13 pm. 2. Interview with the NBS TS at 2:18 pm revealed that a preliminary report was sent to the patient's provider due to an abnormal 17-hydroxyprogesterone level of 129.3 ng/mL. The NBS TS stated the preliminary report was actually sent on 07/14/2021 and not 07/20/2021. The "Draft" copy of the report was printed 07/20/2021 at 2:13 pm. The NBS TS further revealed that the NBS Laboratory was unable to print copies of preliminary reports issued from the Horizon LIS. The NBS Laboratory was also not able to produce a copy of the original preliminary report sent on 07/14/2021.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on surveyor review of Newborn Screening (NBS) Laboratory records, staff interviews, and surveyor observation, the laboratory failed to include the "result override" process in their approved NBS procedure manual (refer to D5403); failed to determine if the Horizon laboratory information system (LIS) changes performed acceptability before implementing new test methods (refer to D5421 and D5423); failed to follow their Quality Assurance Manual (QAM) after issuing NBS corrected reports due to incorrect analytical results (refer to D5891), and failed to implement effective policies and procedures to prevent the ongoing problem of issuing NBS corrected result reports from the Horizon LIS (refer D5893). The cumulative effect of these systematic problems resulted in the laboratory's inability to ensure the accuracy and reliability of NBS results reported from the Horizon LIS.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to verify the accuracy of Hepatitis A Ribonucleic Acid(RNA) and Candida auris Polymerase Chain Reaction (PCR) at least twice annually. Findings include: 1. Record review on 7/19/2021 of the laboratory's 2020 proficiency testing (PT) records revealed: a. PT for Hepatitis A RNA was not performed in 2020. b. PT for Candida auris PCR was performed once in 2020. 2. Staff interview on 7/19/2021 at 11:30 am with the virology technical supervisor (VTS), confirmed the findings in 1a and 1b. The VTS also stated patient results were reported during that time. 3. The laboratory performs 28 Candida auris PCR and 15 Hepatitis A RNA tests annually.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on surveyor review of Newborn Screening (NBS) Laboratory records, staff interviews with NBS testing personnel (TP1) and the CT DPH Newborn Screening Division Director (NBSDD), and surveyor observation, the laboratory failed to include the "result override" process in their approved NBS procedure manual. Findings include: 1. Record review conducted on 07/21/2021 of five (5) Quality Investigative and Corrective Action Reports for the NBS Laboratory section recorded between 02/11/2020 through 05/27/21 noted problems regarding the "result override process" under the "Investigation & Identification of Root Cause Problem" section of the Quality Investigative and Corrective Action Report on 5 of 5 reports. 2. Surveyor observation on 07/21/2021 at 2:15 pm revealed a 2-page document titled "Overrides-OR condition code" pinned to a wall above the bench in the NBS Laboratory area where testing personnel where processing samples and reviewing results. The document consisted primarily of screen shots and was used to perform the result override process prior to releasing final patient reports in the Horizon laboratory information system (LIS). 3. Record review conducted on 07/21/2021 of the 2-page document titled "Overrides-OR condition code" written directions that was pinned to the wall above the NBS bench revealed a lack of step-by-step directions on how to perform the process and also the Laboratory Director's (LD) approval. 4. Interview with TP1 on 07/21/2021 at 2:30 pm confirmed that the 2-page document titled "Overrides-OR condition code" to perform the result override process prior to releasing final patient reports in the Horizon LIS was not part the NBS Laboratory procedure manual approved by the LD. TP1 further revealed that the override process was not performed the same way for each of the NBS sections and that the way to perform the override process for each NBS section was not included in the unapproved override process 2-page written document. 5. Interview with the NBSDD on 07/20/2021 at 3:00 pm further revealed that all critical and abnormal NBS results are sent to the NBS Follow-up and Tracking group using a separate report generated by the NBS Laboratory and that the Horizon final reports are generated primarily for the birthing hospital and the patient's primary care provider.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review, surveyor observation and staff interview, the laboratory failed to ensure antimicrobial susceptibility disks utilized for patient testing did not exceed their expiration date in the subspecialty of bacteriology. Findings include: 1. Record review on 7/19/2021 of the weekly Disk Diffusion QC logs revealed the following results for the antibiotic Doripenem, Lot # 0169732, expiration date 6/30 /2021: Date Organism Zone size 7/7/21 Escherichia coli 32 mm Pseudomonas aeruginosa 31 mm 2. Surveyor observation on 7/19/2021 at 3:10 pm of the Kirby Bauer (KB) Disk Dispenser revealed no Doripenem cartridge was present. 3. Surveyor observation on 7/19/2021 at 3:10 pm of the minus 20-degree Celsius freezer containing antibiotic disks revealed an unopened box of Doripenem Lot #1060623, expiration date 3/31/22 with 10 of 10 unopened sealed cartridges. 4. Record review on

	7/19/2021 of a 'Detailed Multi Isolate Report' for Specimen # 1020621 dated 7/7/21 revealed a Doripenem result of 20 mm with an interpretation of 'I'. 5. Staff interview with the bacteriology general supervisor (BGS) and bacteriology testing personnel#1 (BTP1) on 7/19/2021 at 3:10 pm confirmed the following: a. The QC results could not have been Lot # 1060623 because the box was unopened. b. The Doripenem cartridge was missing out of the dispenser because it was expired and had not been replaced with the new lot. c. Two patient isolates were tested and reported between 7/1/2021 and 7/15/2021. d. The current laboratory protocol requires the comparison of the disk diffusion (KB) to the minimum inhibitory concentration (MIC) results with only the final interpretation being reported to the provider. If a discrepancy exists between the MIC and KB result, the lab reports the most conservative result.
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 with the Diagnostic Immunology and Bacteriology Technical Supervisor (DIBTS), the laboratory failed to verify that changes to the Horizon Laboratory Information System (LIS) interface with the Hologic Panther instrument were acceptable before implementing the changes into routine testing and reporting of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) patient results. Findings include: 1. Record review conducted on 07/20/2021 of corrected reports issued by the STD Laboratory from 01/10/2020 through 06/25/2021 revealed 20 corrected results issued with the following corrected report comment, "Analytical result(s) as indicated above are correct. Result was not previously reported." 2. Interview with the Diagnostic Immunology and Bacteriology Technical Supervisor (DIBTS) on 07/20/2021 at 10:20 am revealed that the updated interfacing between the Horizon LIS and the Hologic Panther instrument was tested on the "live" Horizon LIS which caused the CT/GC results not to appear on patient result reports, meaning "blank" results were reported. The corrected reports were issued after the CT and GC results were re-entered manually into the Horizon LIS. 3. Record review of an email sent from the DIBTS to an IT staff member and the QA Manager on Monday, 06/01/2020 at 12:08 pm titled "Panther STD Batch review" confirmed the findings above and identified Batch STD/5150 as the batch of affected patient results.
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 lack of documentation and staff interview with the Quality Assurance Manager (QAM), Information Technology Analyst (ITA), and the CT DPH Newborn Screening Division Director (NBSDD) , the laboratory failed to document changes to the Horizon Laboratory Information System (LIS) before implementing the Newborn Screening (NBS) Laboratory methods, Acid a-Glucosidase (GAA) and a-lduronidase (IDUA) Enzyme Activity in Dried Blood Spots to Detect the Lysosomal Storage Disorders Pompe Disease (GAA) and Mucopolysaccharidosis-1 (MPS-I) (IDUA) using the AB Sciex (Trademark) API4500 (Trademark) Tandem Mass Spectrometer (Pompe MPSI LSD) and TREC, SMNl and RNase P using the QuantStudio (Trademark) 6 Flex Real Time QPCR System (SCID SMA) into routine testing and reporting of patient results. Findings include: 1. Record review on 7/21/2021 of the method validation documentation of the NBS Pompe MPSI LSD method approved by the Laboratory Director (LD) on 12/30/2020, and the SCID SMA method approved by the LD on 12/23/2019 revealed a lack of documentation showing these new methods were tested on the Horizon LIS for acceptability prior to implementing the methods into the Horizon LIS for routine patient testing. 2. Interview with the (ITA) on 07/21 /2021 at 12:50 pm confirmed that the NBS Pompe MPSI LSD method was tested on the Horizon LIS test system, but the test data was deleted when the test system was upgraded to Horizon version 12.9. The ITA further revealed that the Horizon 12.9 version upgrade includes NBS changes to allow NBS diseases to be linked to their respective analytes. 3. Interview with the CT DPH Newborn Screening Division Director (NBSDD) on 07/21/2021 at 3:25 pm also confirmed that the NBS laboratory lacked testing documentation for the Pompe MPSI LSD method because the test data was overridden when the Horizon LIS test system was upgraded to version 12.9. 4. Email communications with the QAM on 7/28/2021 at 11:34 am confirmed the following regarding the Horizon LIS SCID SMA method changes: a. On 11/26/2019 an initial email was sent within NBS to discuss the SCID SMA method. b. On 12/5 /2019 a LIMS Development of Clinical Laboratory Test of Analysis Code (Acode) in Horizon Laboratory Information System (LIMS) was submitted via email with the analyte and cutoff information to QA and Horizon LIMS IT. c. Testing was carried out within the Horizon Test LIMS environment. Unfortunately, this data has been overwritten with the Horizon 12.9 version of the software and all testing data has been lost. d. Official start of new testing A-Code begins on 1/2/2020. 5. Record review conducted on 07/21/2021 of NBS patient results reports from July 2021 confirmed that both the Pompe MPSI LSD and the SCID SMA methods were both being performed as part of routine patient testing.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result

	reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review, surveyor observation, and staff interview, the laboratory failed to establish and follow a maintenance program for laboratory equipment in the Newborn Screening section in the specialty of routine chemistry. Findings include: 1. Record review on 7/21/2021 of the laboratory's policy, 'Quality Assessment Program for Clinical Testing, QA-CLIA' Section 6.6.2 Maintenance revealed: "The laboratory must establish a maintenance program for each piece of equipment ... Maintenance must be performed as defined by the manufacturer and with at least the frequency specified by the manufacturer." 2. Record review on 7/21/2021 of the 'Chemical Hygiene Plan', Section 6.1 for Chemical Fume Hoods revealed the laboratory did not establish a maintenance program for ductless fume hoods. 3. Record review on 7/21 /2021 of the posted 'Evaporex Unit Maintenance Logs' revealed: a. Weekly maintenance log for Evaporex #1 was last completed on 7/6/2020. b. Weekly maintenance log for Evaporex #2 was last completed on 8/2/2019 c. Weekly maintenance log for Evaprorex #3 was last completed on 2/17/2020. d. The laboratory did not have maintenance log for Evaporex #4. 4. Surveyor observation on 7/21/2021 at 12:30 pm revealed: a. Two of two Air Science ductless hoods were certified on 9/16 /2019. b. Two of two Air Science ductless hoods were installed on 10/18/2019. 5. Staff interview with the Connecticut DPH Newborn Screening Division Director on 7 /21/2021 at 12:50 pm confirmed the following: a. The laboratory did not have established maintenance procedures for the Evaporex instruments or Air Science ductless hoods. b. Posted 'Evaporex Unit Maintenance Logs' were not part of an official procedure and were not consistently completed. c. The laboratory received the 2 Air Science ductless hoods from another laboratory department in the building. d. Maintenance has not been performed on 2 of 2 Air Science hoods since installation date of 10/18/2019.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to check 5 batches /shipments of plated media for sterility and its ability to support, select or inhibit microorganisms in the subspecialty of bacteriology. Findings include: 1. Record review on 7/19/2021 of the Commercial Media Quality Control (QC) binder revealed QC instructions indicated to "test each new lot and shipment". 2. Record review on 7 /19/2021 of individual Commercial Media Quality Control logs for 2019, 2020 and 2021 revealed the following: Media Date Received Lot # TCBS Agar 3/24/2020 944686 TCBS Agar 10/20/2020 142166 TCBS Agar 1/5/2021 Lot # not specified Haemophilus Identification Quad 5/19/2020 978796 Chocolate Agar 7/24/2019

	605130 Charcoal Blood Agar (Reagan Lowe) 7/30/2019 552582 The above shipments specified "same lot #" and did not have documentation of sterility and growth /inhibition checks. 3. Staff interview with the bacteriology general supervisor (BGS) on 7/19/2021 at 2:05 pm confirmed the above findings. BGS stated it had been common practice among testing personnel to record "same lot" and not perform required QC when a lot had been previously received and tested.
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 follow the laboratory's Quality Assurance Manual (QAM) after issuing Newborn Screening (NBS) corrected result reports. Findings include: 1. Record review conducted on 07/21 /2021 of NBS corrected result reports issued between 01/03/2020 through 06/30/2020 revealed four corrected result reports that lacked documented corrective actions (Lab IDs 909872001, 920584001, 898261001, and 904096001). 2. Record review conducted on 7/21/2021 of the Connecticut Department of Public Health, Laboratory Branch (CTPHL) Quality Assurance Manual (QAM), effective 2019, Section 4.8.2 Quality Investigations and Corrective Actions, "Types of problems to which this procedure applies, (d) Reporting errors (such as reporting incorrect results)". 3. Interview with the NBS Technical Supervisor on 07/21/21 at 11:30 am confirmed the findings above.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on staff interviews, surveyor observation, and record review of Newborn Screening (NBS) Laboratory corrective actions issued in 2020 and 2021, the laboratory failed to implement effective policies and procedures to prevent the reoccurring problem of issuing NBS corrected results from the Horizon laboratory information system (LIS), and discuss the quality assessment review results with appropriate staff. Findings include: 1. Record review conducted on 07/20/2021 of the "Assessment of Effectiveness of Corrective Actions NBS Reporting 2020" performed by the Supervising Microbiologist, Quality Assurance (SMQA), stated that "inaccuracies in NBS reporting discovered after a report is released is a re-current and chronic issue. Corrective actions have not been effective in remedying the problem or root cause of the problem not uncovered." The Assessment further revealed the additional suggested corrective actions listed below be implemented to prevent recurrence of the problem, but the corrective actions listed were not effectively

	implemented nor assessed for effectiveness: a. "Write a simple, specific, step-by-step procedure describing the overwriting and reporting process to include, deletion of results in Horizon, verification of successful override, proper documentation of the process, and how to do a corrected report in Horizon. Train staff. Make procedure available at each bench where overrides are done. Some of the specific errors that have occurred should be included in the procedure. These have been identified in the "Assessment of effectiveness of corrective actions." b. Review Horizon after the override is done to ensure the correct result will be reported. 2. Surveyor observation on 07/21/2021 at 2:12 pm revealed a 2-page document titled "Overrides-OR condition code" pinned to a wall above the bench in the NBS Laboratory area where testing personnel where processing samples and reviewing results. The document consisted primarily of screen shots. 3. Record review conducted on 7/21/2021 of the written 2-page document titled "Overrides-OR condition code" revealed a lack of step-by-step directions on how to perform the process. The document consisted primarily of screen shots, and lacked the Laboratory Director's approval. The document also lacked specific steps describing how to perform the overwriting and reporting process, deleting results in the Horizon LIS, documenting the process, and how to create a corrected report. 4. Record review conducted on 7/21/2021 of the laboratory's Quality Assurance Manual (QAM) under section 4.8.5.4 revealed: b. "All parties (e.g., clients, Support Services personnel, program staff, vendors, etc..) who may be affected by a corrective action plan shall be notified within 24 hours of approval of the plan." c. "Corrective action requiring changes in QA or technical procedures shall follow the standard procedure for review and authorization of changes to controlled documents (4.2.3 Document changes)." 5. Record review was conducted on 07/21/2021 of the QC Committee Agenda/Minutes listed below that were submitted to the surveyor by the QA Manager for review. The review revealed a lack of documented evidence showing that the review "Assessment of Effectiveness of Corrective Actions NBS Reporting 2020" performed by the Supervising Microbiologist, Quality Assurance (SMQA) was discussed and reviewed with appropriate staff during the Laboratory's QC Committee meetings. December 19, 2019 January 16, 2020 February 20, 2020 April 16, 2020 July 16, 2020 August 20, 2020 September 24, 2020 October 28, 2020 December 3, 2020 February 25, 2021 July 15, 2021 6. Interview with the Laboratory Director on 07/20/2021 at 2:30 pm confirmed that suggested corrective actions to prevent recurrence of the problem were not effectively implemented.