Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0644555	07/12/2023
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform annual competency assessments for the General Supervisors. Findings include: 1. Review on 7/10/2023 of the laboratory's competency records revealed lack of documentation of annual competencies for nine of nine General Supervisor's (GS) for the year 2021 and 2022. 2. Staff interview on 7/11/2023 at 1:30 PM with the Quality Assurance Manager (QAM) confirmed the laboratory did not have the competency of GS. The QAM further stated that he/she was unaware of the requirement of annual competency assessments for the GS.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) 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: A. Based on record review, client service manual (laboratory services), patient test

requisition, final patient report, and interview with Toxicology Testing Person #1 (TP#1), the laboratory failed to ensure specimen integrity was maintained (collection, storage and transport conditions) per their own written procedures for one of four patients. Findings include: 1. Interview on 07/11/2023 at 11:20 AM with Toxicology TP#1 confirmed the laboratory performed Opioid and Illicit Drug Metabolite Screening in urine using Liquid Chromatography and Quadrupole Time of Flight Mass-Spectrometry. 2. Review of the client service manual (laboratory services) titled, "Fentanyl Plus Drug Screen" (screening assay for the presumptive identification of opiates, opioids, prescription drugs, illicit drugs, and their metabolites in urine) under the section "Specimen Handling & Transport" stated, "Store specimens at 2-8C for up to 24 hours. If a delay is expected, store specimens at -20C or lower. Transport specimens using cold packs." 3. Review of the laboratory's "CLINICAL TEST REQUISITION" revealed the following for one of four patients: a. No documentation of "Specimen Storage (prior to Delivery)" on the test requisition. b. No documentation of "Specimen Transport/Delivery" on the test requisition. c. No documentation of "Date Collected" on the test requisition. 4. Review of the patient (1098670001) test reported on 08/26/2022 at 11:29 AM and interview on 07/11/2023 at 11:45 AM with Toxicology TP#1, confirmed the laboratory failed to ensure collection, storage, and transport conditions were maintained and documented to ensure specimen integrity. 5. The laboratory performed 222 Opioid and Illicit Drug Metabolite Screenings in 2022. B. Based on record review, laboratory standard operating procedure, client service manual (laboratory services), patient test requisition, final patient report, and interview with Lead Testing Person #1 (TP#1), the laboratory failed to ensure specimen integrity was maintained (collection, storage and transport conditions) per their own written procedures for three of three patients. Findings include: 1. Interview on 07/11/2023 at 11:05 AM with Lead TP#1 confirmed the laboratory performed Whole Blood Lead testing by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) on the Perkins Elmer NexION 2000 analyzer. 2. Review of the laboratory's standard operating procedure titled, "Determination of Lead in Whole Blood by Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)" under the section, "B. SPECIMEN HANDLING, HOLDING TIME AND STORAGE:" stated, "Specimens can be transported at ambient temperature. Specimens can be stored at 2-8C for up to 10 weeks or at -30 to -10C for up to one year ..." 3. Review of the client service manual (laboratory services) titled, "Lead Confirmation" under the section, "Specimen Handling & Transport" stated, "Store specimen at 2-8C. Transport at ambient temperature.". 4. Review of the laboratory's "CLINICAL TEST REQUISITION" revealed the following for three of three patients: a. Patient 114415501 test reported on 03/21/2023 - No documentation of "Specimen Storage (prior to Delivery)" on the test requisition. No documentation of "Specimen Transport/Delivery" on the test requisition. b. Patient 1153341001 test reported on 05/10/2023- No documentation of "Specimen Transport/Delivery" on the test requisition. No documentation of "Date Collected" on the test requisition. c. Patient 1159876001 test reported on 06/15/2023 - No documentation of "Specimen Transport/Delivery" on the test requisition. 5. Interview on 07/11/2023 at 11:35 AM with Lead TP#1, confirmed the laboratory failed to ensure collection, storage, and transport conditions were maintained and documented to ensure specimen integrity 6. The laboratory performed 13 Lead tests between January 2023 through June 2023. C. Based on laboratory standard operating procedure, observation, and interview with New Born Screening (NBS) Technical Supervisor #1 (TS #1), and the Assistant Supervisor of Specimen Receiving, the laboratory failed to ensure specimen integrity was maintained during transportation per their own written procedures for eight of eight patients. Findings include: 1. Interview with NBS TS #1 on 07/10/2023 at 01:00 PM confirmed the laboratory performed New Born Screening Bloodspot testing for the detection of 60 metabolic

	and genetic disorders. 2. Review of the laboratory's standard operating procedure for one NBS test titled, "Analysis of C26:0-Lysophosphatidylcholine in Dried Blood Spots Using Tandem Mass Spectrometry (MS/MS) for the Detection of X-Linked Adrenoleukodystrophy (V-ALD)" under "4.0 Specimen" stated "4.2 Specimens should be stored at room temperature (15-22C.) until transport to the laboratory, which should occur within 24 hours of specimen collection. Samples are transported at room temperatures by mail, delivery service or courier service. Humidity or moisture are detrimental to the stability of the dried blood spots and must be avoided. High temperatures may result in degradation of certain analytes and must also be avoided." 3. Observation on 07/12/2023 at 09:00 AM of 8 NBS Blood-Spot specimen cards revealed the following for eight of eight patients: a. Patient 74289860 - No documentation the specimens were transported at room temperature (15-22C.). b. Patient 74289861 - No documentation the specimens were transported at room temperature. c. Patient 74289862 - No documentation the specimens were transported at room temperature. d. Patient 75293401 - No documentation the specimens were transported at room temperature. e. Patient 75293397 - No documentation the specimens were transported at room temperature. f. Patient 75293387 - No documentation the specimens were transported at room temperature. g. Patient 75293399 - No documentation the specimens were transported at room temperature. h. Patient 75293400- No documentation the specimens were transported at room temperature. 4. Interview on 07/12/2023 at 09:20 AM with the Assistant Supervisor of Specimen Receiving, confirmed the findings above. 6. The laboratory performed 13,106 NBS tests between January 2023 through June 2023.
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: A. Based on record review, laboratory standard operating procedure, and interview with Technical Supervisor #1 (TS#1), the laboratory failed to ensure the heat block temperature was monitored for 12 of 12 months. Findings include: 1. Interview with TS#1 on 07/12/2023 at 11:00 AM confirmed the laboratory used Real-Time PCR for the Detection of Shiga Toxins in Enterohemorrhagic Escherichia coli. 2. Record review conducted on 07/12/2023 from January 2022 through December 2022 revealed that the laboratory failed to document the VWR heat block temperature for 12 of 12 months. 3. Review of the laboratory standard operating procedure titled, "Real-Time PCR for the Detection of Shiga Toxins in Enterohemorrhagic Escherichia coli" under section, "8. PROCEDURE" stated: a. "8.1 DNA Extraction" b. "8.1.1 Preheat a heating block to 100 5C" c. "8.1.6 Place in heat block at 100 5C for 10 minutes" 4. Interview with TS#1 on 07/12/2023 at 11:30 AM confirmed the findings as indicated above. 5. The laboratory performed 199 Shiga Toxins in Enterohemorrhagic Escherichia coli patient tests in 2022. B. Based on record review, manufacturer's instruction, and interview with Technical Supervisor #1 (TS#1), the laboratory failed to ensure the BD Paper Discs were maintained according to the manufacturer's

	requirement for five of six months. Findings include: 1. Interview with TS#1 on 07/12 /2023 at 12:00 PM confirmed the laboratory used BD Paper Disc for the detection of Streptococcus pneumoniae. 2. Review of the manufacturer's storage requirement on 07 /12/23 revealed a storage requirement between 8 to -20C. 3. Record review conducted on 07/12/2023 from January 2023 through June 2023 revealed temperatures were colder than -20C for five months of six months: a. February - 3 of 16 freezer temperatures were documented colder than -20C. b. March - 20 of 26 freezer temperatures were documented colder than -20C. c. April - 22 of 25 freezer temperatures were documented colder than -20C. d. May - 4 of 27 freezer temperatures were documented colder than -20C. e. June - 21 of 25 freezer temperatures were documented colder than -20C. 4. Interview with TS#1 on 07/12 /2023 at 12:30 PM confirmed the findings as indicated above. 5. The laboratory performed 141 Streptococcus pneumoniae patient tests between January 2023 and June 2023. C. Based on record review, manufacturer's instruction, and interview with Technical Supervisor #2 (TS#2), the laboratory failed to ensure the invitrogen Express qPCR SuperMixes and Two-Step qRT-PCR Kits were maintained according to the manufacturer's requirement for six of six months. Findings include: 1. Interview with TS#2 on 07/12/2023 at 12:15 PM confirmed the laboratory used the Invitrogen Express qPCR SuperMixes and Two-Step qRT-PCR Kits on the ABX 7500 instruments. 2. Review of the manufacturer's storage requirement on 07/12/23 under the section, "Kit Components and Storage" stated, "Storage: Store all components at -20C for long-term storage." 3. Record review conducted on 07/12/2023 from January 2023 through June 2023 revealed temperatures were colder than -20C for six months of six months: a. January - 20 of 20 freezer temperatures were documented colder than -20C. b. February - 17 of 17 freezer temperatures were documented colder than -20C. c. March - 22 of 22 freezer temperatures were documented colder than -20C. d. April - 18 of 18 freezer temperatures were documented colder than -20C. e. May - 22 of 22 freezer temperatures were documented colder than -20C. f. June - 22 of 22 freezer temperatures were documented colder than -20C. 4. Interview with TS#2 on 07 /12/2023 at 12:40 PM confirmed the findings as indicated above.