Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2030007	(X3) Date Survey Completed 05/15/2024
Name of Provider or Supplier Us Labs Connecticut	**Street Address, City, State** 460 Smith Street, Middletown, 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 have a policy in place to assess the competency of all the laboratory personnel. Findings include: 1. Record review of the laboratory's personnel competency records on 05/15/24 revealed the following: a. The laboratory did not have policy in place to assess the competency of the clinical consultant (CC). b. Competency assessment documentation for the CC was not available. 2. Staff interview with the general supervisor on 05/15/24 at 1:20 PM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on record review and staff interview, the laboratory failed to perform the required biannual comparisons between the Beckman Coulter AU680 chemistry analyzers. Findings include: 1. Record review on 5/15/2024 of the standard operating

	procedure (SOP) 'Correlation Procedure for Instrumentation' revealed the following: a. The laboratory utilizes two Beckman Coulter AU680 chemistry instruments. b. The last instrument comparison was performed on 06/30/2023. c. The SOP stated, "An instrument-to-instrument correlation is performed every 6 months when the laboratory uses more than one instrument/method to test for a given analyte." 2. Staff interview on 5/15/2024 at 2:00 PM with the general supervisor confirmed the above findings. B. Based on record review and staff interview, the laboratory failed to document the temperature of Ammonia samples upon arrival into the laboratory. Findings include: 1. Record review on 5/15/2024 of the SOP for 'Plasma Ammonium Beckman AU680' stated, "keep samples at 2-8C until analysis." 2. Lack of documentation of the temperature of the Ammonia samples upon arrival at the laboratory. 3. Staff interview on 5/15/2024 at 1:30 PM with the general supervisor confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform the required biannual comparisons for the Beckman Coulter iQ200 select urine microscopy analyzer against the manual urine microscopic method. Findings include: 1. Record review on 05/15/24 of the laboratory's test menu revealed the laboratory performed 21 manual urine sediment microscopic analysis annually on 'turbid' urine samples. 2. Record review on 05/15/24 of the laboratory's method comparison documents revealed the lack of biannual comparison between the Beckman Coulter iQ200 select analyzer and the manual microscopic urine sediment analysis. 3. Record review on 05/15/24 of the laboratory's standard operating procedures revealed the lack of policies and procedures in place for the biannual comparison between the automated and the manual methods. 4. Staff interview on 5/15/2024 at 2:00 PM with the general supervisor confirmed the above findings.
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 failed to notify the ordering provider when a corrected report was issued. Findings include: 1. Record review on 05 /15/24 of the laboratory's "Corrected Result Form" log revealed the following: a. On 04/12/22 a corrected report was issued for patient #1 (P1) for 'Triglyceride' and 'LDL

	calculated' results b. Triglyceride was originally reported as 291 mg/dl and later corrected to 203 mg/dl. c. LDL calculated was originally reported as 55 mg/dl and later corrected to 72 mg/dl. d. Lack of documentation of the provider notification of the corrected results. e. This report was reviewed by the laboratory manger on 04/14 /22 and by the laboratory director on 06/27/22 with no corrective action documented. 2. Record review on 05/15/24 of the laboratory's "Corrected Report Procedure" revealed the lack of provider notification when a corrected result was issued. 3. Staff interview with the general supervisor on 05/15/24 at 12:25 PM confirmed the above findings. 4. The laboratory performs 412,6787 tests annually in the specialty of Chemistry.