Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0872283	06/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Drs Ahern And Galban	77 Danbury Rd, Ridgefield, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, the laboratory failed to ensure positive identification of a patient's specimen from the time of collection through completion of testing. Findings include: 1. Surveyor observation on 6/1/22 at 12:00 PM of the laboratory work bench area revealed the following: a. Four urinalysis samples were kept in a tray at the work bench. b. Two urinalysis samples were marked with patient initials and date of birth. One sample was marked as "MC" and other one was marked as "MN". 2. Record review of the laboratory's individualized quality control plan (IQCP) documents for "microscopic observations-urine sediments" on 6/1/22 revealed "Urine samples obtained by patient in cup labeled with patient's full name and DOB." 3. Staff interview on 3/21/19 at 12:05 PM with the technical consultant confirmed two urinalysis samples were not labeled with two unique patient identifier as listed in item 2 above and one of the staff usually put the initials on the cup.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system

	performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document function checks per establish laboratory procedure to ensure proper functioning of the laboratory equipment prior to patient testing. Findings include: 1. Record review on 6 /1/22 of the laboratory's incubator temperature log for incubating throat culture specimens revealed the laboratory did not monitor and document incubator temperatures as follows: (a) 20 of 31 days in March 2022. (b) 17 of 30 days in April 2022. 2. Record review on 6/1/22 of the laboratory's selective Strep select agar (SSA) individualized quality control plan (IQCP) documents revealed "Incubator temperatures are documented AM and PM, Monday through Friday and AM on Saturday." 3. Staff interview with testing personnel #3 on 6/1/22 at 12:30 PM confirmed: (a) Incubator temperature recording were missing as listed in item 1 above. (b) The laboratory was recording incubator temperature only once per day and not following their approved IQCP listed in item 2 above. 4. The laboratory performs 43 throat cultures annually.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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 follow and monitor the accuracy and precision of the complete analytic process for the selective Strep select agar (SSA) quality control plan (QCP) section of the individualized quality control plan (IQCP). Findings include: 1. Record review on 6/1/22 of the laboratory's QCP for SSA IQCP revealed: (a) The quality control (QC) data to be reviewed and monitored quarterly for accuracy and precision. (b) A certificate of analysis generated by the manufacturer is obtained for each lot of SSA media. 2. Record review of the SSA QC logs on 6/1/22 revealed: (a) Lack of documentation of quarterly review of QC data. (b) Lack of documentation of certificate of analysis for each lot number of the SSA media in use. 3. Staff interview with the laboratory technical consultant on 6/1/22 at 11:05 AM confirmed the laboratory's SSA QCP was not followed as indicated in item 1 above. 4. The laboratory performs 43 throat cultures annually.
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 document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer in the specialty of Bacteriology. Findings include: 1. Record review on 6/1/22 of the laboratory's quality control (QC) logs for selective Strep agar (SSA) revealed documentation for the physical characteristics of the SSA media were not recorded since 1/15/21. 2. Staff interview with testing personnel #3 on 6/1/22 at 10:30 AM confirmed the following: a. He/She is unaware why the physical characteristics were not documented when new SSA media were received since 1/15/21. b. He/She did not have have documentation how many SSA media were arrived since 1/15/21. c. He/She further stated some of the receiving staff members were new and needs retraining. 3. The laboratory performs 43 throat cultures annually.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document annual competency of testing personnel (TP) to assess their knowledge and skills necessary to perform moderate complexity testing. Findings include: 1. Record review of TP competency records on 6/1/22 revealed the laboratory did not have annual competency documentation for 3 of 3 TP performing throat cultures and urine microscopic studies in 2020 and 2021. 2. Staff interview with the technical consultant on 6/1/22 at 11:15 AM confirmed the laboratory failed to perform and document annual competency for throat cultures and urine microscopic studies in 2020 and 2021. 3. The laboratory performs 123 moderate complexity tests annually.