Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0078775	02/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Rhonda S Fogle Md, Pc	50 Tremont Street, Melrose, MA	

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
D0000	An onsite recertification survey conducted on February 18, 2026 found the Rhonda S Fogel MD, PC Laboratory in non compliance with the following CONDITIONS with 42 CFR Part 493, Requirements for Laboratories: D2000- 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples D5400 - 42 C.F.R. 493.1250 Condition: Analytical Systems
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of Bacteriology proficiency testing (PT) records and staff interview conducted on 1/18/2026, the laboratory failed to enroll in a CMS approved proficiency testing (PT) Program for Bacteriology. Findings include: 1 Record review of the laboratory's 2024 and 2025 graded PT results (STAS435) revealed the laboratory used Oneworld Accuracy AccuTest as their PT Program provider for their Streptococcus A Culture testing. 2. Record review of CMS PT data report (CASPER Report 155) printed on 1/17/2026 revealed no results reported to CMS for the analyte 0005 BACTERIOLOGY for 2024 and 2025. 3. Record review of the CMS APPROVED PROFICIENCY TESTING PROGRAMS FOR CLIA listing revealed that Oneworld Accuracy is not a CMS approved PT Program provider.

D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) (2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1). This STANDARD is not met as evidenced by: Based on record review and interview conducted on 2/18/2026 with the laboratory director (LD), laboratory failed verify the accuracy of their Uricult CLED/EMB testing at least twice annually in 2025. Findings include: 1. Record review of 2024 and 2025 proficiency testing records revealed no documentation that the laboratory verified the accuracy of Uricult CLED/EMB testing in all of 2025. 2. Interview with the LD on 2/18/2026 at 11:10 AM confirmed the findings above. 3. The laboratory reported performing 432 Urine cultures annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director (LD) on 2/18 /2026, the laboratory failed to review and evaluate proficiency testing (PT) a sample result failure for one of three events in 2024. Findings include: 1. Record review on of 2024 and 2025 proficiency testing (PT) records revealed the following sample failure: a. 2024 AccuTest Bacteriology PT Cycle 2 - 80% Score. Incorrect response Sample E. Laboratory response: negative for Group A Streptococcus. Acceptable result: positive for Group A Streptococcus. 2. Surveyor record review 2024 PT records revealed no evidence of an evaluation, or corrective action for incorrect sample result. 3. Interview on 02/18/2026 at 10:50 AM with the LD, confirmed the laboratory failed to evaluate or implement corrective action for the PT sample failure.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the surveyor review of laboratory records and staff interviews conducted on 2/18/2026, the laboratory failed to document the physical characteristics, verify

	sterility, and test the growth-supporting capability of each lot and shipment of UriCult CLED/EMB and SSA media prior to patient use (refer to D5477), and failed to monitor and document the temperature of the 37C incubator (D5413). The cumulative effect of these systemic deficiencies compromised the laboratory ' s ability to ensure the accuracy and reliability of patient test results.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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: Based on a review of 2025 quality control (QC) records, procedure manuals, and a laboratory staff interview, it was determined that the laboratory failed to monitor and document the temperature of the 37C incubator used for Beta Strep screening and UriCult testing from 2025 through February 18, 2026. The findings include: 1. Record review of the laboratory's Beta Strep Screen procedure manual revealed that the laboratory must monitor the 37 C Incubator temperature (36 -/+ 2 C) and when in use. 2. Record review of the Uricult CLED/EMB manufacturer's package insert states the following, "place inoculated Uricult vial upright in incubator 36 C +/- 2 C for 18 to 24 hours." 3. Record review of bacteriology quality control records revealed no documentation of temperature monitoring for the laboratory's 37C incubator from January 1, 2025, through February 18, 2026. 4. Laboratory staff interview with a staff nurse conducted on 1/18/2026 at 11 AM revealed that the temperature of the 37 C incubator was checked when in use, but the temperature was not documented on the temperature chart.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (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. This STANDARD is not met as evidenced by: A. Based on the surveyor's record review and an interview with the Laboratory Director (LD) conducted on 2/18/2026, the laboratory failed to document the physical characteristics, verify sterility, and confirm the growth-supporting capability of each lot and shipment of UriCult CLED/EMB culture paddles prior to patient use. Findings include: 1. Record review conducted of 2024 and 2025 of Uricult CLED/EMB quality control (QC) records revealed a lack of documentation indicating that the Uricult

	culture-paddles were visually inspected, checked for sterility, and tested for their ability to support growth in 2025. 2. Interview with the LD on 2/18/2026 at 11:20 AM confirmed the findings above. 3. The laboratory reported performing 432 urine cultures annually B. Based on surveyor record review and interview with the laboratory director (LD) conducted on 2/18/2026, the laboratory failed to document that the BD SSA agar used for throat cultures visually inspected, checked for sterility, and tested for their ability to support growth in 2025. Findings include: 1. Record review of the Beta-Strep Screen procedure stated under section Quality Assurance Protocol, "With each new lot of SSA or Bacitracin disks a positive and negative streptococcal A culture control will be run and a note made in the laboratory book of results". 2. Record review of SSA plate quality control logs and the laboratory result book revealed no documentation that each lot of SSA agar plates were checked for physical characteristics, sterility, and tested for their ability to support growth before patient use. 3. Interview with the LD at 11:20 AM confirmed the findings above. 4. The laboratory reported performing 215 throat cultures annually.