Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301999	06/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Drs Dabbs & Hyland P C	1513 Pediatric Drive, Jasper, AL	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on reviews of the Selective Strep Agar (SSA) and Bacitracin Differentiation Disc (BDD) Instructions for Use (IFU) and an interview with the Testing Personnel 1 (TP1), the laboratory failed to follow manufacturer's requirement for the incubator temperature on the Culture Presumptive Group A Strep by Bacitracin testing The surveyor noted the incubator temperature recordings had been outside manufacturer's specification from the date of the last survey, 05-23-2023 to the date of the current survey, 06-05-2025. The findings include: 1) A review of the Temperature Logs revealed the incubator temperatures were outside the manufacturer's required incubation temperature. The laboratory's temperature log revealed the range of 34-38 degrees Celsius from 2023-2025. 2) A review of the Hardy Diagnostics SSA IFU and the BDD IFU revealed the manufacturer's specification to incubate inoculated media for 18-24 hours at 35 degrees Celsius in 5-10 percent CO2. The manufacturer did not specify a range for the incubation temperature. 3) The TP1 confirmed the above findings during the exit conference on 06-05-2025 at 3:25 PM.
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 reviews of the Temperature Logs, Selective Strep Agar (SSA) and A disc package inserts and an interview with the Testing Personnel 1 (TP1), the laboratory failed to ensure the incubator temperature for the Culture Presumptive Group A Strep by Bacitracin testing was within the laboratory's acceptable limits. The surveyor noted the incubator temperature was out of range for 6 of the 31 days in August 2024. The findings include: 1. A review of the Temperature Logs revealed the incubator temperatures were outside the laboratory's specified ranges of 34-38 degrees Celsius for the following days in 2024: A) August 1-2, B) August 5-6, C) August 9, D) August 30. 2. During the temperature logs review at approximately 1:35 PM, the surveyor requested to see the incubator manual to confirm what range of incubator temperature was required but TP1 could not find it. She stated 34-38 degrees Celsius had been used since the last survey and she was never questioned about it. 3. At approximately 3:08 PM, TP1 notified the surveyor she confirmed the incubator temperature range via the internet because the manufacturer's manual was still unavailable.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 reviews of the Selective Strep Agar (SSA) media Quality Control (QC) logs, the patient records, and an interview with the Testing Personnel 1 (TP1), the laboratory utilized expired media for patient testing. The surveyor noted the expired materials were used for 2 of the 31 days in August 2024. The findings include: 1. A review of the SSA media QC logs revealed the laboratory had opened and utilized expired media for patient testing for the following days: A) Lot 630552, Expiration date of 08-20-2024, opened and used on 08-22-2024 B) Lot 631374, Expiration date of 08-28-2024, opened and used on 08-29-2024 2. A review of the patient records revealed a total of 13 patients were tested with the expired media, eight patients on 08-22-2024 and five patients on 08-29-2024. 3. During an interview with the TP1 on 06-05-2025 at approximately 3:25 PM, TP1 confirmed the above findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

	This STANDARD is not met as evidenced by: Based on a review of the personnel records, laboratory's competency assessment form and an interview with the Testing Personnel 1 (TP1), the Technical Consultant (TC) failed to ensure competency assessments for Testing Personnel (TP) performing moderate complexity testing included all six CLIA minimal regulatory requirements. The surveyor noted six of the six requirements were missing on the annual competencies from 2023-2025. The findings include: 1. A review of the 2023-2025 personnel records revealed TP competency assessments for Testing Personnel listed on the CMS 209 form (Laboratory Personnel Report) had no documentation on six of the six CLIA minimal regulatory requirements. The surveyor noted the six missing requirements were as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. (2) Monitoring the recording and reporting of test results. (3) Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. (4) Direct observation of performance of instrument maintenance and function checks. (5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (6) Assessment of problem-solving skills. 2. A review of the laboratory's competency assessment forms revealed the laboratory had two separate forms for evaluations, one for non-waived and the other for waived testing. Four of the six minimal CLIA requirements were only included on the annual TP waived testing evaluations. 3. The TP1 confirmed the above findings during the exit conference on 06-05-2025 at 3:25 PM.