Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0668923	11/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Jcdh Central Health Center Disease Control	1400 Sixth Avenue South, Birmingham, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a lack of review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiency Testing (PT) records and an interview with the Laboratory Director (LD) also qualified as the Technical Consultant (TC), the laboratory failed to ensure proficiency (PT) testing records were complete and retained for at least two years. This was noted for five of seven PT events reviewed in 2023 through 2024. The findings include: 1. A lack of review of the AAB-MLE PT records revealed no evidence of PT documentation, during the survey, of review and attestation pages from the Laboratory Director,or designee, and TP for the following surveys: a) 2023 Chemistry M3, b) 2024 Chemistry M1-M3, c) 2025 Chemistry M1. 2. During the laboratory tour on 11/12/2025, at 9:15 AM, the Laboratory Director told the surveyor the PT documentation could not be located prior to the survey.
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 the environmental records, policy and procedures, and an interview with the Laboratory Director, the Laboratory failed to ensure the room temperature for RPR (Rapid Plasma Reagin) patient testing stayed within the limits specified by the laboratories policy and procedures. The surveyor noted the room temperature was below acceptable ranges for 15 days of 31 days in October 2025. The findings include: 1. A review of environmental records revealed the room temperature was below the specified performance parameters for RPR patient testing for 15 days in October 2025. 2. A further review of the Reagents/Media/Equipment Policy 5.3.1 Performance parameters revealed, "Before testing ensure that the RPR suspension is at room temperature 22-30 degrees Celsius." 3. During an interview on 11/12/2025, at 2:26 PM, the Laboratory Director confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the environmental records, policy and procedures, and an interview with the Laboratory Director, the Laboratory failed to document corrective actions when the room temperature was outside the manufacturers' performance parameters. The surveyor noted the room temperature was below acceptable ranges for 15 days of 31 days in October 2025 with no documentation of corrective action. The findings include: 1. A review of environmental records revealed the room temperature was below the specified performance parameters for RPR (Rapid Plasma Reagin) patient testing for 15 days in October 2025 (Refer to D5413) with no evidence of corrective active. 2. A further review of the Reagents/Media/Equipment Policy 5.3.1 Performance parameters revealed, "Before testing ensure that the RPR suspension is at room temperature 22-30 degrees Celsius." 3. During an interview on 11/12/2025, at 2:26 PM, the Laboratory Director confirmed the above findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by:

	Based on reviews of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records, room temperature records, and testing personnel semi annual and annual competencies, the Technical Consultant (TC) and the Laboratory Director who is also qualified as a TC failed to provide adequate technical and scientific oversight of the laboratory. The findings include: 1. A review of the laboratory records revealed the TC and LD failed to: a) Ensure proficiency (PT) testing records were complete and retained for at least two years (Refer to D2015). b) Ensure the room temperature for RPR (Rapid Plasma Reagin) patient testing stays within the limits specified by the laboratories policy and procedures (Refer to D5413). c) Document corrective actions when the room temperature was outside the specified performance parameters (Refer to D5781). d) Ensure testing personnel had competency assessments that included all six minimal regulatory requirements (Refer to D6046). e) Failed to evaluate semi-annual competencies for testing personnel (TP) performing moderate complexity testing (Refer to D6053). f) Failed to evaluate annual competencies for testing personnel (TP) performing moderate complexity testing (Refer to D6054).
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 and an interview with the Laboratory Director (LD), the Technical Consultant (TC) who is also the LD, failed to ensure testing personnel had competency assessments that included all six minimal regulatory requirements. The surveyor noted the 6 elements were missing on 9 of 11 TP 2024 annual competencies and 1 of 11 TP 2024 semi-annual competency. The findings include: 1. A review of the personnel records revealed annual and semi-annual competency was assessed on RPR (Rapid Plasma Reagin) and Gram Stain testing by taking a quiz. The surveyor noted no documentation of the six minimal requirements for assessment of competency required by CLIA, as follows: 1. Monitoring the recording and reporting of test results. 2. Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive maintenance results. 3. Direct observation of performance of instrument maintenance and function checks. 4. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 5. Assessment of problem solving skills. 2. During an interview on 11 /21/2025, at 3:05 PM, the LD confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by:

	Based on a review of the personnel records and an interview with the Laboratory Director (LD), the Technical Consultant (TC) who is also qualified as the LD failed to evaluate semi-annual competencies for testing personnel (TP) performing moderate complexity testing. This was noted for one of two new TP listed on the CMS-209 (Laboratory Personnel Report) for 2024. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by either TC or the LD for the semi-annual competency of TP#8. 2. During an interview on 11/12/2025, at 3:12 PM, the surveyor gave the LD until 11/21/25 to email the missing documentation. The semi-annual competency on TP#8 was never received.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the Laboratory Director (LD), the Technical Consultant (TC) who is also qualified as the LD failed to evaluate annual competencies for testing personnel (TP) performing moderate complexity testing. This was noted for 9 of 9 previously qualified TP listed on the CMS-209 (Laboratory Personnel Report) for 2024 and 11 of 11 TP listed on the CMS-209 for 2025. The findings include: 1. A review of the personnel records revealed no evidence of evaluation by either TC or the LD for the annual competencies of the following: a) 2024: TP#1-5,7,8,10,11 b) 2025: TP#1-11 2. During an interview on 11 /12/2025, at 3:12 PM, the surveyor gave the LD until 11/21/25 to email the missing documentation. The surveyor received the 2024 quizzes which did not include the proper criteria and the 2025 competencies were not performed.