Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641691	09/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Adph-Bureau Of Clinical Laboratories	204 Legends Court, Prattville, 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
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory general supervisor (GS), the laboratory failed to enroll in Proficiency Testing (PT) for FT4II performed in chemistry section on the Roche Cobas e601 in 2022 and 2023. Findings includes: 1. A review revealed the laboratory College of American Pathologists (CAP) PT test report did not include FT4II analyte in 2022 or 2023. The laboratory failed to include the FT4II test as one of PT assays performed in chemistry section. The laboratory procedure and service manual included the FT4II on the test list offered by the laboratory. The laboratory service manual listed the Free T4 test under their Thyroid Panel. 2. A review revealed the laboratory performs quality control for FT4II daily. The laboratory performs approximately 112 tests annually. 3. During the interview with the GS revealed the laboratory used a calculation based on the package insert titled, "Elecys T-Uptake Cobas", to determine FT4II results and did not use the values generated directly from the Roche Cobas e601 analyzer . The laboratory chemistry procedure manual failed to include documentation pertaining to the FT4II proficiency testing or calculation information for the FT4II test results. 4. Interview with the laboratory general supervisor on September 7, 2023 at 09:00 am confirmed the laboratory did not enroll in PT for the FT4II analyte.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)

	(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) 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 record review and interview with the laboratory general supervisor, the technical supervisor failed to sign the College of American Pathologists proficiency testing (PT) attestation statements for 5 of 30 PT events between 2022 and 2023. Findings includes: 1. A review revealed the laboratory technical supervisor (TS) failed to sign the attestation statements for the College of American Pathologists PT events C-C 2022-A, C-A 2023-A, HIV-A 2023, HCV-A 2023, and VM-A 2023. 2. Interview with the laboratory general supervisor on September 6, 2023 at 1:00 pm confirmed the laboratory TS did not sign all attestation documents listed above.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview, the laboratory failed to verify accuracy of the Hologic Aptima HIV-RNA Qualitative Assay twice annually for 2022. Findings included: a. A review of the laboratory's STD section proficiency testing records for 2022 revealed the laboratory had not completed twice annual verification of accuracy for the Hologic Aptima HIV-1 RNA Qualitative Assay. b. During an interview 9/06/23 at 12:30 PM in the conference room, the Quality Manager stated a PT company could not be sourced to provide samples for this assay, and the twice annual accuracy verification study had been done on the HIV quantitative assay run on plasma, but not on the Hologic Aptima HIV-1 RNA Qualitative assay run on serum which was brought to their active test menu in March 2022. The interview corroborated the findings. Word Key: STD - Sexually Transmitted Diseases PT - Proficiency Testing
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: I. Based on record review and interview with the general supervisor, the laboratory failed to include the specimen collection temperature range for the storage of samples for the Chemical Threat (CT) procedure manual for Abrine and Ricinine (ABRC) in Urine by Tandem Mass Spectrometry. Findings included: 1. A review revealed the ABRC procedure manual did not include the temperature range documented in the laboratory service manual under "Storage and Shipment Temperatrue Requirements". The laboratory service manual listed the temperature range for the specimen storage at -20C. The procedure manual titled, Abrine and Ricinine (ABRC) in Urine by Tandem Mass Spectrometry on page 1 of 14, states " 4.3 Samples should be frozen as soon as possible and stored on dry ice for shipping ...All samples should be stored -70C or colder". 2. Interview with the laboratory general supervisor on September 6, 2023 at 1: 00 pm confirmed the laboratory did not ensure the specimen collection temperature range in the laboratory service manual was consistent with the ABRC procedure manual. 47107 II. Based on review of the laboratory's procedure, direct observation, and interview with the Technical Supervisor of the STD section, the laboratory failed to follow their own written policy in preparing a 3% concentration sodium hypochlorite solution for preparation of equipment and testing materials, for 4 of 4 Hologic Panther System Analyzers. Findings included: a. A review of the laboratory's procedure titled, "ADPH-BCL-Prattville and Mobile - Serology Aptima Combo 2 Assay Panther System" revealed on page 6 of 14 the following: "Preparation of Equipment and Testing Materials: Prior to starting assay, wipe down work surfaces with 3% bleach solution. Allow bleach to remain on surfaces for at least 1 minute (do not bleach solution dry) then rinse with DI water. Cover bench surfaces with clean absorbent lab towels." b. In direct observation, on 9/07/23 at 10:06 AM, in the STD section of the laboratory, two bleach cleaning solution bottles were observed for use on the four Hologic Panther System Analyzers at 4.125% (50% of commercial 8.25% Clorox Germicidal Bleach bottle) and 10% concentrations. c. An interview with the Technical Supervisor of the STD section on 9/07/23 at 10:06 AM in the laboratory corroborated these findings. Word Key: STD - Sexually Transmitted Diseases
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on a review of the Analyte List, manufacturer's instructions, laboratory's procedure, and interview with the Quality Manager the laboratory failed to provide processing staff with accurate specimen storage information for one of two tests reviewed. a. A review of the "Analyte List" (05/2023) stated "Syphilis Testing, (Syphilis Screen, RPR, TP-PA) An RPR will be performed on all reactive Syphilis screens. TPPA will be performed on all nonreactive RPR specimens ...Storage and Shipment Temperature Requirements ...Specimens must be received by the lab within 5 days from date of collection." b. A review of "SERODIA-TP-PA" (Rev 001) stated "SPECIMEN COLLECTION AND PREPARATION ...Store patient serum samples in a refrigerator at 2-8 [degrees Celsius] if testing is done within 5 days." c. A review of the laboratory's procedure "T. pallidum Particle Agglutination" (Revision Date: 10 /26/2022) stated on page 2, "Criteria for Specimen Acceptability/Rejection ... Specimen too old ([greater than] 5 days from date of collection date)." d. A review of "Specimen Processing" (Revision Date: 04/28/2021) stated on page 6, "SPECIMEN STORAGE: ...Syphilis Screen: ambient temperature for [less than or equal to] 72 hours; 2 [degrees Celsius] to 8 [degrees Celsius] for [less than or equal to 7 days] ... SPECIMEN PRESERVATION ...Syphilis Screen: ambient temperature for [less than] 72 hours, 2 [degrees] Celsius to 8 [degrees] Celsius for [less than or equal to] 7 days ... Specimen Transportation...Syphilis Screen: ambient temperature is specimen received by BCL within 48 hours of collection; shipped cold to maintain a temperature of 2 [degrees Celsius] to 8 [degree Celsius] if received by BCL [greater than] 3 days and [less than or equal to] 7 days of collection". The 7-day timeframe exceeds the laboratory's and manufacturer's allowable limit (5 days). Specimens received after 5 days would be too old for testing. e. In an interview conducted on 09/07/2023 at 11:00 AM in the conference room, the Quality Manager confirmed the processing procedure does not match the syphilis testing procedures or the analyte list.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: I. Based on review of manufacturer's instructions, laboratory's policy, the laboratory's incubator chart, and interview with the microbiology manager, the laboratory failed to follow manufacturer's instructions with setting the C78 bacteriology incubator at the manufacturer's specific required temperature range for July 2023 to date of the survey as evidence by: 1. In review of the manufacturer's instructions for the Blood and McConkey's agar from Remel state, "incubate plates aerobically, or in 5-10% Co2 for 18-24 hours at 33 to 37 degrees C. " 2. In review of the laboratory policy titled, "Reference bacteriology Reference Manual" origin date 12/06/2016 states, "incubators (aerobic, CO2) (33-35 degrees C, 42 degrees C, 25 degrees C, 28-33 degrees C." 3. In review of the laboratory's incubator chart, C78 ISOtempincubator, from July 2023 to date of the survey, the chart indicated the temperature range as 35 +/- 5 degrees C. 4. In interview with the microbiology manager at 1128 on 9/7/2023, she stated that traditionally through the years, the bacteriology incubators have always been set at 35 +/- 5 degrees C. 41090 II. Based on the manufacturer's instructions, the laboratory's policy and procedures, direct observation, and interview with Technical Supervisor

	(TS) #18 the laboratory failed to follow manufacturers instructions for specimen storage and transport for one of five tests performed. a. A review of "Xpert MTB/RIF" (Rev. G July 2020) stated on page 6, "Storage and Transport ...Raw sputum: Transport and store specimens at 2-8 [degrees Celsius] before processing whenever possible. If necessary, sputum specimens can be stored at a maximum of 35 [degrees Celsius] for up to three days and then at 2-8 [degrees Celsius] for an additional seven days." b. A review of the "GeneXpert Real Time Polymerase Chain Reaction GeneXpert MTB /RIF Assay" (Revision Date: 11/30/2018) stated on page 1, "SPECIMEN REQUIREMENTS ...Specimen Storage: Raw sputum/bronchial wash: Store specimens at 2-8 [degrees Celsius] before processing whenever possible. If necessary, specimens can be stored at a maximum of 35 [degrees Celsius] for up to three days and then at 2-8 [degrees Celsius] for an additional seven days ...Specimen Transportation: N/A-procedure does not require specimen transportation." c. A review of "Analyte List" (05/2023) stated on page 18, "Mycobacteria ...Storage and Shipment Temperature Requirements ...Other shipmen: [less than or equal to] 24 hours, ambient." d. A review of "Standard Operating Procedure (SOP) for Monitoring Temperature of Specimens Received for Clinical Testing at the Bureau of Clinical Laboratories (BCL)" (Revision 2, 02/10/2023) stated on page 1, "Scope ...This procedure should be used by personnel who receive specimens that have a defined temperature range ...ambient (equal to surrounding environment)." e. On 09/07/2023 at 6:33 AM in the processing room the surveyor observed tuberculosis specimens received in specimen canisters packaged in manila envelopes. The laboratory did not ensure specimens were maintained at 2-35 degrees Celsius per manufacturer's instructions. f. An interview conducted on 09/07/2023 at 6:33 AM with processing staff confirmed tuberculosis specimens are received at ambient temperatures (as defined by the laboratory). 47107 III. Based on review of the manufacturer's instructions, direct observation and confirmed in interview, the laboratory failed to follow manufacturer's instructions for avoiding cross-contamination during specimen processing of 90 of 90 Hologic Aptima Combo 2 Assay Tubes on September 6, 2023. Findings included: a. A review of manufacturers instruction for the Aptima Combo 2 Assay Panther System (502446 Rev. 009) stated on page 5 the following: "Avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen contains do not contact one another, and discard used materials without passing over open containers." b. In direct observation, on 9/06/23 at 8:55 AM, in the Specimen Processing area of the facility, 90 Hologic Aptima Combo 2 Assay Tubes for GC, CT and TV were placed horizontally, physically touching one another by the specimen handler during intake, once removed from bags, for counting and accessioning purposes. c. An interview with staff on 9/06/23 at 8:55 AM, in the Specimen Processing area of the facility, corroborated these findings. Word Key: GC - Gonorrhea CT - Chlamydia Trachomatis TV - Trichomonas vaginalis
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 the laboratory's temperature records, direct observation and interview with Technical Supervisor (TS) #18, the laboratory failed to define the room temperature storage range according to the manufacturer's instructions for two of three rooms where reagents were stored. a. A review of the laboratory forms "Temperature /Humidity Chart" revealed "Section: Mycobacteriology; Year: 2023; Equipment Name: Room Temperature; Equipment Location: C51; Temperature Range: 20-30 [degrees] Celsius" and "Section: Mycobacteriology; Year: 2023; Equipment Name: Room Temperature; Equipment Location: C56; Temperature Range: 15-30 [degree] Celsius". b. A sampling of reagents observed at room temperature included: Room C51 09/06/2023 at 12:54 PM: Two cartridges; Xpert MTB/RIF; Lot # 1001010541; Storage 2 to 28 [degrees] Celsius Room C56 09/06/2023 at 12:54 PM: 10 boxes; Xpert MTB/RIF; Lot # 1001010547; Storage 2 to 28 [degrees] Celsius 30 boxes; Xpert MTB/RIF; Lot # 100105736; Storage 2 to 28 [degrees] Celsius 7 boxes; BD BBL MGIT; Lot # 3032616; Storage 2 to 25 [degrees] Celsius 22 boxes; BD BBL MGIT; Lot # 3159812; Storage 2 to 25 [degrees] Celsius The laboratory's defined range exceeded the stored reagents requirements as listed above. c. In an interview conducted on 09/06/2023 at 12:58 PM, TS #18 confirmed the range needed to be redefined.
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: I. Based on direct observation and interview with staff, the laboratory failed to perform and document function checks on two of two timers used to perform rapid plasma reagin (RPR) card test. a. On 09/06/2023 at 3:08 PM, the surveyor observed two Durac timers: #3; SN L194792; Calibrated 1/21/22 Post 7; SN 2194791; Calibrated 1/11/22 b. In interview conducted on 09/07/2023 at 8:29 AM in the conference room, the Quality Manager stated there is no other calibrations and they are out of compliance; the new person did not know they had to do it [calibrate the timers]. II. Based on direct observation, a review of the manufacturer's instructions, the laboratory's quality control records, and interview with Technical Supervisor (TS) #15 the laboratory failed to perform and document the speed of one of two mechanical rotators used to perform rapid plasma reagin (RPR) card test. a. On 09/06/2023 at 3:08 in the laboratory the surveyor observed two mechanical rotors in use for patient testing of RPR. b. A review of "BD Macro-Vue RPR Card Tests" stated "18mm Circle Quantitative Card Test ...6. Rotate for 8 min ([plus or minus] 30 s[econds]) under humidifying cover, on mechanical rotator at 100 [plus or minus] 2 rpm." c. A review of "RPR Quality Control Worksheet" revealed "Month/Year September 2023 ... Daily Maintenance ...2.) Rotator (100 [plus or minus] 2 RPMs)." Only the speed is documented. No documentation identifying the specific rotor checked. d. In an

	interview conducted on 09/07/2023 at 1:15 PM, TS #15 stated only one rotor is checked per day and there is no way to tell which rotor was checked.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory failed to perform 1 of 2 calibrations for the Beckman Coulter DxH800 in 2023. Findings includes: 1. A review of the procedure for Beckman Coulter DxH800 Hematology analyzer, revealed the laboratory failed to provide documentation for 1 of 2 calibrations required in 2023. The laboratory provided documentation for the calibration performed on September 5, 2023. 2. The laboratory procedure " Beckman Coulter DxH800 Hematology Analyzer" states, " 8.7.2. The laboratory procedure dictates that we perform every 6 months." 3. Interview with the laboratory general supervisor on September 7, 2023 at 11:00 am confirmed the laboratory performed only one calibration for the DxH800 in 2023.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, the laboratory procedure, quality control records, direct observation, and interview with staff the laboratory failed to

	titer positive control material for quantitative rapid plasma reagin (RPR) card test for 8 of 8 patient samples. a. A review of "BD Macro-Vue PRP Card Tests" (0212013JAA, 2010/02) stated "Quality Control ...Quality control requirements must be performed in accordance with applicable local, state/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures." b. A review of "BioPlex 2200 Syphilis Total [and] RPR Assay (Revision 10/11/2022) stated on page 4, "PERFORMANCE OF PROCEDURE ...If the dilution is [less than] 1:4 or [greater than] 1:64, perform a manual dilution following the RPR manual dilution procedure. The procedure does not provide instructions for titering positive controls when performing titers on patient samples. c. A review of the "RPR Quality Control Worksheet" revealed "Month/Year September 2023 ...Daily Maintenance ...10.) RPR Reactive Control Result ...11.) RPR Min Reactive Control Result ...12.) RPR Non-reactive Control Result". Qualitative results are performed and recorded but quantitative positive control titers are not performed or documented. d. On 09/06/2023 at 3:08 PM the surveyor observed the following RPR patient samples titered without a titered positive control: Lab ID: M2309002178-01; Date Reported: 09 /07/2023; Dilution Result: 128 Lab ID: M2309002205-01; Date Reported: 09/07 /2023; Dilution Result: 4 Lab ID: M2309002185-01; Date Reported: 09/07/2023; Dilution Result: 4 Lab ID: M2309002174-01; Date Reported: 09/07/2023; Dilution Result: 32 Lab ID: M2309002156-01; Date Reported: 09/07/2023; Dilution Result: 2 Lab ID: M2309001735-01; Date Reported: 09/07/2023; Dilution Result: 32 Lab ID: M2309002211-01; Date Reported: 09/07/2023; Dilution Result: 128 Lab ID: M2309002217-01; Date Reported: 09/07/2023; Dilution Result: 64 e. In an interview conducted on 09/06/2023 at 1:40 PM in the laboratory, TS#14 stated quality controls are performed in the morning. In an interview conducted on 09/06/2023 at 3:08 PM in the laboratory, TS#15 stated quality controls are not titered.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview with the general supervisor, the laboratory director failed to document their review of the College of American Pathologists proficiency testing (PT) evaluation reports for 3 of 30 PT events between 2022 and 2023. Findings includes: 1. A review revealed the laboratory director failed to document their review of the evaluation reports from the College of American Pathologists PT events: HIV-A 2022, HCV-A 2023, and VM-A 2023. 2. Interview with the laboratory general supervisor on September 6, 2023 at 1:00 pm confirmed the laboratory director did not document their review of all evaluation reports listed above.