Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641691	06/05/2025
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
D0000	A recertification survey was performed on 06/03/25 through 06/05/25. Standard-level deficiencies were cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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: Based on laboratory's written policy and procedure, record review, and interview with technical supervisor# 19 (TS# 19), the laboratory failed to follow a written laboratory procedure for monthly quality control (QC) checks for one of three months. Findings include: 1. Review of the laboratory's written policy and procedure titled, "ADPH BCL Prattville Mycotics Quality Control" section, "3. BACKGROUND INFORMATION:" stated, "The Mycotics Section of the Bureau of Clinical Laboratories (BCL) performs quality control (QC) procedures with each test; each new lot of media, stains, or test kits; and monthly (or as needed to ensure valid results are reported)". 2. Review of QC record for Sabourad Dextrose Agar Plates and Mycosel media from 06/10/2024 through 08/08/24 revealed monthly QC not performed as follows: a. Sabourad Dextrose Agar Plates Monthly QC not performed in July 2024. b. Mycosel Media Monthly QC not performed in July 2024. 3. Interview on 06/04/25 at 10:50 am with TS# 19 confirmed the laboratory findings above.
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:
I. Based on direct observation, review of the manufacturer's operator's manual, and interview with Technical Supervisor (TS) #8, the laboratory failed to monitor and document temperature and humidity conditions in Room C44 for 2024 and 2025, where newborn screening testing is performed using Revvity GSP analyzers. Findings: 1. During a laboratory tour conducted on June 4, 2025, at approximately 2: 00 PM, three Revvity GSP analyzers were observed in operation for newborn screening testing in Room C44. No devices for monitoring temperature or humidity (e. g., hygrometers or thermohygrometers) were observed in the workspace. 2. Review of the Revvity GSP manufacturer's operator's manual revealed the following required environmental conditions for instrument operation: Temperature: 18 - 27 C; Relative Humidity: 10 - 80% Temperature: 28 - 30 C; Relative Humidity: 10 - 65% 3. During an interview on June 4, 2025, at approximately 2:15 PM, the TS #8 confirmed that the laboratory did not monitor or document temperature and humidity levels in Room C44 where the GSP analyzers are located. II. Based on direct observation, review of temperature records, and interview with the Laboratory Director (LD), the laboratory failed to defined criteria for proper storage of reagents, and failed to review temperature conditions in Warehouse Room B62B for 2024 and 2025, where temperature-sensitive materials were stored, including nine of nine boxes of Remel Cary Blair w/Indicator Fecal Transport System. Findings: 1. During a tour of Warehouse Room B62B on June 3, 2025, at approximately 10:00 AM, 9 boxes (containing 120 units each) of Remel Cary Blair w/Indicator Fecal Transport System were observed in storage. The product label specified a required storage temperature of 15 - 25 C. The laboratory did not have a define temperature range for proper storage of reagents. The folllowing reagents were also observed: a. Hologic Aptima Assay Fluid containing: Wash Solution, Lot # 915165, Oil, Lot # 894898, and Buffer for Deactivation Buffer, Lot # 914551, with a required storage temperature of 15 - 30 C. b. Aptima Urine Specimen Collection Kit, Lot # 916819, with a required storage temperature of 15 - 30 C. c. Puritan UniTranz-RT Transport System, Lot # 240523, with a required storage temperature of 2 - 25 C. 2. A review of warehouse temperature records identified instances where temperatures exceeded the acceptable limit of 25 C on the following dates: -August 3, 2024 - 25.4 C -August 4, 2024 - 25.6 C -August 10, 2024 - 26.0 C -August 11, 2024 - 26.0 C -August 17, 2024 - 26.1 C -August 18, 2024 - 26.1 C No documentation of corrective actions taken in response to these out of range temperatures was found. 3. During an interview on June 3, 2025, at approximately 11:15 AM, the LD confirmed that the laboratory did not monitor or document temperature conditions or had taken corrective actions for the temperature in the Warehouse Room B62B. 47272 III. Based on observation, review of manufacturer's instructions, record review, and interview with the media manager, the laboratory failed to store media supplies according to manufacturer's instructions for 14 of 84 days. Findings include: 1. Observation on 06/03/25 at 01:55 pm of the media refrigerator (Ref #2 - tagged 31692) revealed the following: a. 1 bottle of BBL Urea Agar Base lot# 4288566 with a manufacturer's storage requirement of 2-8C b. 1 bottle of Defco Phenylalanine Agar lot# 1208850 with a manufacturer's storage requirement

	of 2-25C c. 1 bottle of BBL Moeller DeCarboxylase Broth Base lot# 3040506 with a manufacturer's storage requirement of 2-8C d. 5 boxes of Remel OADC Enrichment lot# 181587 with a manufacturer's storage requirement of 2-8C 2. Record review of Ref #2 temperature records from 01/02/25 through 04/30/25 revealed the laboratory failed to store media supplies according to manufacturer's instructions for 14 of 84 days a. 01/15/25 temperature documented at 1.7C b. 01/17/25 temperature documented at 1.7C c. 01/27/25 temperature documented at 1.8C d. 01/28/25 temperature documented at 1.8C e. 02/25/25 temperature documented at 1.9C f. 02/28 /25 temperature documented at 1.8C g. 03/12/25 temperature documented at 1.9C h. 03/14/25 temperature documented at 1.9C i. 03/17/25 temperature documented at 1.9 C j. 03/19/25 temperature documented at 1.9C k. 04/16/25 temperature documented at 1.8C l. 04/25/25 temperature documented at 1.8C m. 04/29/25 temperature documented at 1.8C n. 04/30/25 temperature documented at 1.8C 3. Interview with the media manager on 06/03/25 at 02:10 pm confirmed the findings above. IV. Based on laboratory written policy and procedure, record review, and interview with technical supervisor# 15 (TS# 15), the laboratory failed to store Escherichia Coli quality control (QC) organisms according to laboratory QC policy and procedure for 18 of 18 days. Findings include: 1. Review of the laboratory's written policy and procedure titled, "ASPH BCL Prattville/Mobile Enterics Escherichia Coli" section "11. QUALITY CONTROL PROCEDURES" stated, "11.2.2. The Escherichia coli Quality Control organisms will be kept frozen in TSB w/Glycerin at -80C." 2. Record review of freezer (serial# 2311941) for January 2025 revealed temperatures warmer than -80C for 18 of 18 days: a. 01/02/25 temperature documented at -77C b. 01/03/25 temperature documented at -77C c. 01/06/25 temperature documented at -77C d. 01/07 /25 temperature documented at -73C e. 01/08/25 temperature documented at -73C f. 01 /09/25 temperature documented at -72C g. 01/13/25 temperature documented at -73C h. 01/14/25 temperature documented at -72C i. 01/15/25 temperature documented at -73C j. 01/16/25 temperature documented at -72C k. 01/17/25 temperature documented at -72C l. 01/23/25 temperature documented at -72C m. 01/24/25 temperature documented at -73C n. 01/27/25 temperature documented at -73C o. 01/28 /25 temperature documented at -73C p. 01/29/25 temperature documented at -74C q. 01/30/25 temperature documented at -73C r. 01/31/25 temperature documented at -73 C 3. Interview on 06/04/25 at 03:11 pm with TS# 15 confirmed the findings above.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on laboratory Mycology Media Master List, direct observation, and interview with technical supervisor# 19 (TS# 19), the laboratory failed to label one of one bottle of Lactophenol Cotton Blue Stain with the specified expiration date. Findings include: 1. Record review of the laboratory's, "Mycology Media Master List" stated, "Lactophenol Cotton Blue Stain" has a shelf life of "1 Year". 2. Observation on 06/04 /25 at 10:45 am revealed one bottle of Lactophenol Cotton Blue Stain lot# 6-10-24.

	The expiration date is one year from this date (06-10-25). The Lactophenol Cotton Blue Stain was labeled with an expiration date of 10-10-25. 3. Interview on 06/04/25 at 11:00 am with TS# 19 confirmed the findings above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: I. Based on laboratory written policy and procedure, record review of the Reference Bacteriology Daily Work Card, and interview with technical supervisor# 15 (TS #15), the laboratory failed to perform QC (Quality Control) each day of patient use for one of one patient. Findings include: 1. Review of the laboratory's written procedure titled, "Malachite Green (5%) stain-Spore Stain" section, "Quality Control:" stated, "Performed by Reference Bacteriology each time of use with known positive and negative controls." 2. Review of the laboratory's, "REFERENCE BACTERIOLOGY DAILY WORK CARD" for one patient# 5895342 revealed no QC documentation for the Malachite Green (5%) stain-Spore Stain on the day of patient testing (05/16/25). 3. Interview on 06/04/25 at 03:30 pm with TS# 15 confirmed the findings above. II. Based on record review, lack of quality control (QC) documentation, and interview with technical supervisor# 15 (TS# 15) and the laboratory director, the laboratory failed to perform QC for six of six lots of media. Findings include: 1. On 06/04/25 at 01:20 pm. TS# 15 confirmed the laboratory used Sheep Blood agar (SBA), MacConkey agar (MAC), and Campylobacter Blood agar (CBP), and Columbia Blood Agar (CS) for patient testing in microbiology. 2. Record review of microbiology "LABORATORY REPORT CARD" for three patients revealed no documentation of QC for the following media: a. SBA lot# 249558 and MAC lot# 258524 media for Patient# M2505008611 - specimen collected on 05/06/25, received into the laboratory on 05/14/25, and reported on 05/16/25 b. CBP lot# 264275 and CS lot# 263724 media for patient# M2505013639 - specimen collected on 04/27/25, received into the laboratory on 05/20/25, and reported on 05/23/25 c. SBA lot# 260534 media for patient# 5534771 - specimen collected on 05/12/25, received into the laboratory on 05 /22/25, and reported on 06/03/25 3. Interview on 06/05/25 at 10:10 am with the laboratory director confirmed the findings above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

	This STANDARD is not met as evidenced by: Based on a laboratory observation on June 4, 2025, a review of the Panther instrument comparison procedure, the laboratory quality plan, and an interview with the Technical Supervisor #2 (TS #2) on the Form CMS-209, page 1, the laboratory failed to perform twice annual instrument comparisons for two of two Panther instruments for the HIV test from September 2023 to December 2024. Findings included: 1. Laboratory observation during a tour of the Sexually Transmitted Diseases (STD) section, on June 4, 2025, at 1:55 PM, revealed two Panther instruments were used to test for HIV-1 RNA. Panther instrument (S/N: 02223) was used as the primary testing instrument and Panther (S/N: 02222) was used as a back-up instrument. 2. A review of the Panther instrument comparison procedure, page 1, revealed the statement, "Frequency: Twice a year minimum." 3. A review of the Laboratory Quality Plan, page 13, XI. H., stated "parallel (comparison) studies will be performed at least semi-annually for all analytes or tests performed on multiple instruments (ex: back-up systems) or performed by different methodologies ..." 4. In an interview on June 4, 2025, at 1:55 PM, the TS #2 confirmed that Panther instrument (S/N: 02223) served as the primary instrument for HIV-1 RNA testing and Panther instrument (S/N: 02222) served as a back-up instrument for HIV-1 RNA testing and no test results comparisons were completed between Panther instruments S/N 02223 and 02222, twice annually from September 2023 to December 2024.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the Reference Range of Analytes available on the Alabama Department of Public Health - Bureau of Clinical Laboratories website, the Lymphocyte Subset Enumeration final patient test report, and an interview with the Technical Supervisor (TS) #26, the laboratory failed to have available reference ranges or normal values for the Lymphocyte Subset Enumeration test to its clients. Findings: 1. A review of the Reference Range of Analytes listed on the Alabama Department of Public Health - Bureau of Clinical Laboratories website on June 4, 2025 at approximately 2:00 PM, indicated that for the Lymphocyte Subset Enumeration test, users are directed to refer to the final laboratory report. 2. A review of one randomly selected Lymphocyte Subset Enumeration final patient test reports (Sample ID: 15479-87380) on June 4, 2025 at approximately 1:30 PM, revealed that reference ranges or normal values were not included in the patient test report. 3. During an interview conducted on June 4, 2025, at approximately 1:30 PM, the TS #26 confirmed that the laboratory does not provide reference ranges for the Lymphocyte Subset Enumeration test in the final report or on the laboratory's website.