Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2065567	06/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Anycare 24	702 South Cumberland St, Lebanon, TN	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of the laboratory records, and interview with the office manager, the laboratory failed to retain the complete blood count (CBC) quality control (QC) manufacturer assay sheets and sysmex maintenance records in 2021 (12 of 12 months) and 2022 (10 of 12 months). The findings include: 1) Observation of the laboratory on 6/14/23 at 8:15 am revealed three levels of Eightcheck-3WP Xtra (Lot: 3080) stabilized human erythrocytes in use for quality control of a Sysmex XP-300 analyzer (SN: A2587). 2) Review of laboratory records revealed the following: -Quality control (QC) manufacturer assay sheets for Eightcheck-3WP Xtra could not be provided for 2021 and 2022. -Sysmex XP-300 Maintenance Logs for analyzer SN: A2587 could not be provided by the laboratory for all of 2021 and 10 of 12 months for 2022. 3) Interview with the office manager on 6/14/23 at 12:30 pm confirmed the following: -The laboratory failed to retain the manufacturer assay sheets for historical CBC control lots used in 2021 and 2022. -The laboratory failed to retain the Sysmex XP-300 maintenance logs for all of 2021 and January through October of 2022.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231

	through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance plan, review of the laboratory's quality assurance records, and interview with the office manager, the laboratory failed to follow their quality assurance policy for monthly chart reviews of complete blood count (CBC) testing in 2023. The findings include: 1. Review of the laboratory's quality assessment plan states the laboratory will complete monthly chart reviews for CBC errors and discrepancies. 2. Review of the laboratory's monthly chart review log revealed no documentation of completed chart reviews for CBC errors and discrepancies for January through May of 2023. 3. Interview on 06/14/23 at 12:30 pm with the office manager confirmed the laboratory failed to complete chart reviews for CBC errors and discrepancies from the beginning of 2023 to the date of the survey.
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 observation of the laboratory, review of manufacturer's user manual, reagent package instructions, lack of documentation and interviews with the office manager, the laboratory failed to monitor the ambient temperature and relative humidity in the areas where the complete blood count (CBC) instrument and reagents were being used and stored for patient testing and refrigerator temperature for quality control (QC) material in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 6/14/23 at 8:15 am revealed the following: - Sysmex XP-300 CBC instrument (SN: A2587) in use for patient CBC testing. - Sysmex Stromatolyser-WH reagent (Lot: Y2006) used by the Sysmex XP-300 stored in ambient conditions in a storage room. - Three levels of Eightcheck-3WP Xtra QC (Lot: 3080) material stored in a Frigidaire refrigerator. 2. Review of the XP-300 Instructions for Use section titled "14.1 Specifications" revealed an operating ambient temperature range of 15 - 30 degrees Celsius (C) and a relative humidity range of 30% to 85%. 3. Review of reagent package instructions revealed the following: - Storage range for Sysmex Stromatolyser-WH reagent is between 2 - 35 degrees Celsius (C). - Storage range for Eightcheck-3WP Xtra QC material is 2 - 8 degrees Celsius (C). 4. There were no records for monitoring of refrigerator temperature, ambient temperature, or relative humidity for surveyor review. 5. Interview with the office manager on 06/14/23 at 12: 30 pm confirmed the laboratory failed to monitor refrigerator temperature, ambient temperature, or relative humidity in the areas where the Sysmex XP- 300 CBC instrument and reagents were stored and used for patient testing in 2021, 2022, and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer instructions for use, and interview with the office manager, the laboratory failed to label three of three controls observed on the date of the survey (6/14/23) with corrected expiration date after the controls were opened for use. The findings include: 1. Observation of the laboratory on 6/14/23 at 8:15 am revealed three levels of Eightcheck-3WP (Lot: 3080) in use for performing quality control on the Sysmex XP-300 complete blood count (CBC) instrument. The controls were not labeled with an open date or corrected expiration date. 2. Review of the Sysmex XP-300 instructions for use in Section 9.2 "Quality Control" revealed Eightcheck-3WP controls are to be stored at 2-8 degrees Celsius (C) and states "After opening, the product is stable for 7 days if returned to the refrigerator promptly after use". 3. Interview with with the office manager on 6/14/23 at 12:30 pm confirmed the laboratory controls in use had expiration dates that changed after opening and the laboratory failed to label the controls with the corrected expiration dates for three of three controls observed.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 review of instrument quality control (QC) printouts, review of patient test reports, and interview with the office manager, the laboratory failed to ensure controls were not used past their expiration date from 4/6/23 to 4/9/23 with a total of eight patient's results reported during the period the expired controls were in use. The findings include: 1. Review of the Sysmex XP-300 instrument (SN: A2587) QC printouts revealed three levels of Eightcheck-3WP Xtra (Lot: 2361) controls with an expiration date of 4/5/23 were used for daily QC from 4/6/23 to 4/9/23. 2. Review of patient test reports revealed a total of 8 patient complete blood counts (CBC's) were reported 4/6/23 to 4/9/23. 3. Interview with the office manager on 6/14/23 at 12:30 pm confirmed the laboratory failed to ensure controls were not used past their expiration date from 4/6/23 to 4/9/23 with patient testing performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of the Sysmex XP-300 instructions for use, review of maintenance records, and interview with the office manager, the laboratory failed to perform and document maintenance per manufacturer's requirements in 2022 and 2023. The findings include: 1. A review of the Sysmex XP-300 instructions for use in section 12.1 "Maintenance schedule" revealed the following: - Weekly: Clean SRV tray. - Every month: Clean TD and Clean waste chamber. 2. A review of the XP-300 Maintenance Logs revealed weekly maintenance was not recorded for 21 of 28 weeks reviewed and monthly maintenance was not recorded for 1 of 7 months reviewed. 3. An interview on 6/14/23 at 12:30 pm with the office manager confirmed the laboratory failed to perform and document maintenance checks for the Sysmex XP-300 System as required by the manufacturer for 2022 and 2023.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel report (CMS form 209), testing personnel competency assessments, and interview with the office manager, the technical consultant failed to evaluate annual competency for one of three testing personnel performing complete blood count (CBC) patient testing in 2022. The findings include: 1. Review of CMS form 209 revealed three testing personnel (TP1, TP2, and TP3). 2. Review of the laboratory's testing personnel competency assessments revealed one of three annual competencies(for TP3) were not performed in 2022. 3. Interview with the office manager on 6/14/23 at 12:30 pm confirmed TP3 was performing CBC patient testing in 2022 and the technical consultant failed to document competency assessment for TP3 in 2022.