Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2065567	02/27/2018
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the Complete Blood Count (CBC) Proficiency Testing (PT) records for 2016 and 2017 and upon interview with the primary testing person, determined the PT samples were not tested by twelve of thirteen testing personnel as listed on the Laboratory Personnel Report Form 209. The findings include: 1. A review of the CBC PT records for 2016 and 2017 revealed only one of thirteen testing personnel's signature on the attestation sheets. 2. An interview with the CBC primary testing person at approximately 9:30 a.m. on February 27, 2018 confirmed she was the only person of thirteen, listed on the Laboratory Personnel Report Form, who tested the proficiency testing samples for 2016 and 2017.
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 review of the complete blood count (cbc) proficiency testing (PT) attestation records in 2016-17 and an interview with the primary testing person determined the laboratory director failed to ensure that all PT attestation statements are signed during 2016 and 2017. The findings include: 1. Review of the 2016 1st-3rd events and 2017 1st-3rd events PT records for cbc for the specialty of hematology revealed the laboratory director did not sign the attestation statements for testing persons during the 2016 2nd event and 2017 1st & 3rd events. 2. Interview with the primary testing person on February 27, 2018, at approximately 9:50 AM confirmed that the director failed to attest/sign attestation statements during the 2016 2nd event and 2017 1st & 3rd events.
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 review of laboratory refrigerator temperature logs, and interview with the primary testing person determined the laboratory failed to document laboratory refrigerator temperature, have an acceptable temperature criteria listed on log sheets and were not reviewed for 2016, 2017 and 2018. Findings include: 1. Review of laboratory refrigerator temperature log for 2016 revealed no documentation for temperature in March 4,10,15,16,23,24,31, April 1,7,12,21,22,23,25,28,29,30, May 1-3,5,6,9,11,13,20,21,25,26,31, June "Biohazard frig" 1-14,23, "Vaccine frig" 4,10,18-31, July 23, August 14,19,28-30, September 4,6,10-13,16-19,23-25, October 1-4,6,10,17,20-22, November 3,8,11, and December 18,20-22,25-30 2016. 2 .Review of lab refrigerator temperature log for 2017 revealed no documentation for temperature in January 1-4,10,22-26,30-31, March 17,26-30, April 4-6,10-12,19,20,26-28, May 1,11,12,27,28, June 2,26,31, August 10,11, September 17,19-22,26-28, October 5,6,14,15,18-20,31, November 1,19,20,24-26, December 7,8. 2017. 3. Review of lab refrigerator temperature log for 2018 revealed no documentation for temperature in February 22, 23 2018. 4. Review of laboratory refrigerator temperature log for 2016 revealed no acceptable temperature criteria listed on log sheets for January-April and December, and April-July in 2017. 5. Review of the laboratory refrigerator temperature logs for 2016, 2017 and 2018 revealed the laboratory refrigerator temperature logs were not signed off indicating no review was done 2016, 2017 and 2018. 6. Interview with the primary testing person on February 27th at 11:00AM confirmed the laboratory failed to consistently document the laboratory refrigerator temperatures, have acceptable temperature criteria listed and were not reviewed in 2016, 2017 and 2018.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 review of the complete blood count (cbc) proficiency testing (PT) performace summary records and interview with testing personnel number one determined the laboratory director failed to ensure the PT performance summary records were reviewed in 2016 and 2017. The findings include: 1) Review of the CBC PT performace summary records for 1st-3rd events of 2016-2017 revealed the laboratory director's missing signature on all event's performace summary records in 2016 and 2017. 2) Interview on February 27, 2018 at 11:00 a.m. with testing personnel number one confirmed the CBC PT performace summary records for 1st-3rd events of 2016-2017 revealed the laboratory director's missing signature on all event's performace summary records in 2016 and 2017.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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. This STANDARD is not met as evidenced by: Based on the lack of 13 of 13 testing personnel competency documents for performing Complete Blood Counts (CBC) and upon interview with the primary testing person, determined the technical consultant failed to ensure documented annual competency evaluations of testing personnel for 2016-2017. The findings include: 1. There were no competency evaluations reviewed/signed for 13 of 13 testing personnel in 2016-17 for performance of CBC testing. 2. Upon interview with the primary testing person at approximately 10:30 a.m. on February 27, 2018, confirmed the Technical Consultant failed to document/sign competency assessments for 13 of 13 testing persons in 2016-17 for CBC testing.