Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2029867	06/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Vaughn Family Care Llc	9540 Wynlakes Place, Montgomery, 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**
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on reviews of Environmental Monitoring records, Policies and Procedures, and the Cell Dyn 18 Plus Hematology Control package insert and an interview with Testing Personnel #1, the laboratory failed to document corrective actions when refrigerator temperatures exceeded acceptable limits (too low). This was noted in six out of 32 months reviewed from the date of the last survey (10/17/2019) to the date of the current survey (06/29/2022). The findings include: 1. A review of the Environmental Monitoring records revealed the following months when refrigerator temperature were outside acceptable limits (too low) with no documentation of corrective action, as follows: a) In November 2020, the refrigerator temperature was out of range four out of 25 days. b) In October 2020, the refrigerator temperature was out of range one out of 24 days. c) In September 2020, the refrigerator temperature was out of range three out of 26 days. d) In April 2020, the refrigerator temperature was out of range five out of 27 days. e) In May 2021, the refrigerator temperature was out of range eight out of 26 days. f) In June 2022, the refrigerator temperature was out of range three out of 29 days. 2. A review of the Policies and Procedures under "Quality Control:...B. Temperatures" revealed , " ...1) Lab refrigerator temperatures should fall within the 2 - 8 degrees Celsius [or 35 - 46 degrees Fahrenheit] ...". 3. A review of refrigerator contents on 6/29/2022 at approximately 12:00 PM revealed the Cell Dyn 18 Plus Hematology Controls with a package insert specifying the manufacturer's storage requirements of 2 - 10 degrees Celsius [or 35 - 50 degrees

	Fahrenheit]. 4. During the exit summation on 6/29/2022 at 12:15 PM, the surveyor asked if the laboratory implemented any corrective actions when refrigerator temperatures were too low. Testing Personnel #1 stated the staff were supposed to adjust the temperature and document the actions on a "Trouble Shooting Log", however she was unable to provide any documentation on the day of the survey of any corrective actions taken. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of the post analytical report and an interview with Testing Personnel #1, the laboratory failed to ensure units of measurement (one of five required parameters on patient reports) for Complete Blood Counts (CBCs) were included on the EMR (Electronic Medical Record) report. The findings include: 1. During the post analytical review, the surveyor requested a copy of a final patient report which revealed the units of measurement for CBC parameters were not included on the eCLinical Works EMR report. 2. During an interview on June 29th, at 12:57 PM, Testing Personnel #1 confirmed the units of measurement for CBC parameters were not included on the patient's final report printed from the EMR. .
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 a review of the personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to ensure four of six testing personnel had competency assessments that included all six minimal regulatory requirements in 2020 through 2022. The surveyor noted five of six elements missing on annual and semi-annual competencies. The findings include: 1. A review of the personnel records revealed annual and semi-annual Hematology competency was assessed on Complete Blood Count (CBC) testing by running one patient CBC. The surveyor noted no documentation for five 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; and 5. Assessment of problem solving skills. 2. During an interview on June 29th, 2022, at 10:06 am, when Testing Personnel #1 was asked how she assessed the Hematology competency for the testing personnel, she stated she observed employees performing one patient CBC "to make sure they are doing it correctly." The surveyor then reviewed the CLIA requirements for competency, and Testing Personnel #1 confirmed all six minimal regulatory requirements were not performed and documented. SURVEYOR ID#32558 Licensure and Certification Surveyor