Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2020484	09/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Family Care Clinic, Llc	306 N Chancery Street, Mcminnville, 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
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 Quality Assurance plan and interview with Lead testing person, the laboratory failed to have an effective Quality Assurance plan and failed to review, evaluate, document and monitor criteria as indicated in their policy for 2019, 2020 and 2021. The findings include: 1. Review of the laboratory's Quality Assurance plan revealed the laboratory's policy is to monitor and document the following quality criteria: Evaluate the effectiveness of our written policies and procedures, identify problems in our laboratory and apply corrective action, assure that accurate and reliable test results are obtained and reported in a timely manner, assure that laboratory personnel are adequately trained and that their performance is periodically evaluated and Review our laboratory policies and procedures whenever necessary. Also listed in the policy is Patient test management, Quality Control review, Proficiency Testing review, error/complaints, Personnel Assessment and Quality Assurance Records. 2. Interview with the laboratory Lead Testing person on September 30, 2021 at 11:30 a.m. confirmed the laboratory failed to review, evaluate, document and monitor criteria as indicated in the laboratory quality assurance policy for 2019, 2020 and 2021.
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: Based on review of the laboratory procedure manual and upon interview with the laboratory Lead testing person determined the laboratory failed to include procedures and policies for Complete Blood Count (CBC) and wet preps for KOH during 2019, 2020 and 2021. The findings include: 1. Based on review of laboratory procedure manual revealed no polices or procedures for specimen collection, specimen rejection, specimen storage, reference ranges, critial values for CBC and Wet preps for KOH. 2. An interview at 09:30. on September 30, 2021 with the Laboratory Lead testing person, confirmed the laboratory procedures and policies failed to include specimen collection, specimen rejection, specimen storage, reference ranges, critial values for CBC and Wet preps for KOH during 2019, 2020 and 2021.
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 review of personnel records and interview with the laboratory lead testing person, determined the Technical Consultant failed to evaluate and documented the six required criteria for assessing personnel competency for 6 out 15 testing persons listed on the Centers for Medicare and Medicaid (CMS) 209 personnel form for 2019 and 2020. The findings include: 1. Lack of competency assessments available for review for 6 out of 15 testing personnel revealed no evaluation and documented of the six required criteria of competency that include: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, assessment of problem solving skills for 2019 and 2020. 2. Interview with the Lead testing person at 1:30 pm. on September 30, 2021, confirmed the Technical Consultants failed to evaluate and documented the six required criteria for annual technical competencies for 6 out of 15 testing personnel in 2019 and 2020.