

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D1003229	(X3) Date Survey Completed 03/23/2022
Name of Provider or Supplier Community Family Healthcare	Street Address, City, State 285 Ivie Lane, Mantachie, MS	
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS (Centers for Medicare and Medicaid Services) 209 personnel form, lack of qualifying documentation and interview with testing personnel (TP) #2 at 2:00 p.m. on 3/23/22, the laboratory did not have a technical consultant who meets the qualification requirements of 493.1411 of this subpart.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the</p>

technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
 Based on review of the CMS 209 personnel form, lack of qualifying documentation available for review, and interview with TP #2 at 2:00 p.m. on 3/23/22, the laboratory did not have an individual designated as technical consultant who meets the qualification requirements of 493.1411 of this subpart from 1/14/20 through 3/23/22.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
 Based on surveyor review of laboratory testing records from 1/14/20 through 3/23/22 and interview with TP #2 at 2:30 p.m. on 3/23/22, the following records had not been documented as reviewed by a qualified technical consultant (TC): Findings Include: 1. The surveyor reviewed laboratory records from 1/14/22 through 3/23/22. The following records had not been documented as reviewed by the technical consultant:
 a. Temperature logs (room and refrigerator) from 1/14/20 through 3/23/22
 b. AcT Diff 2 quality control (QC) from 1/14/20 through 3/21/22
 c. Proficiency Testing results for the 1st, 2nd and 3rd events of 2020 and 2021
 d. Monthly Quality Assessment checklists for 2020, 2021 and 2022
 2. Interview with TP #2 at 2:00 p.m. on 3/23/22 confirmed there was no documented review of these records by a qualified TC.

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 surveyor review of laboratory testing personnel (TP) records including the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and interview with TP2 at 2:00 p.m. on 3/23/22, a qualified technical consultant failed to evaluate annually and document the performance of testing personnel TP1 and TP2 who are responsible for performing moderate laboratory testing. Findings include: 1. The surveyor reviewed laboratory personnel records including the CMS-209 available on 3/23/22. 2. There were no annual evaluations/competencies performed by a TC included with the personnel records since 10/9/2019. 3. The evaluations available for review on TP1 and TP2 were signed as performed by non-lab personnel. 4. Interview with TP2 at 2:30 p.m. on 3/23/22 confirmed that TP1 and TP2 had not been documented as evaluated for competency by a qualified TC for the years 2020 and 2021.