

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0669583	(X3) Date Survey Completed 06/28/2021
Name of Provider or Supplier Rogers Family Practice	Street Address, City, State 1615 B West Persimmon, Rogers, AR	
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 209 form, personnel records for the two current laboratory testing personnel, API proficiency testing results for 2019, 2020 and 2021, corrective action reports and interviews with laboratory staff, it was determined the facility failed to meet the Condition of Technical Consultant in that: D6043 - the Technical Consultant failed to ensure remedial actions were effective when laboratory performance in proficiency testing failed to meet acceptable performance. D6046 - the Technical Consultant failed to evaluate the competency of laboratory testing personnel. D6053 - the Technical Consultant failed to assess the competency of testing personnel at least semiannually during the first year of employment. D6054 - the Technical Consultant failed to evaluate and document competency of personnel who performed moderate complexity testing on an annual basis.</p>
D6043	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5)</p> <p>(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;</p> <p>This STANDARD is not met as evidenced by: Through a review of proficiency testing events of 2019, 2020, and 2021, performance</p>

review and corrective action, lack of documentation, as well as interview with staff, it was determined the corrective actions identified failed to prevent the recurrence of the deficient practice in five of six proficiency testing events reviewed. Findings follow: A) Review of the American Proficiency Institute (API) reports for 2019 revealed that the laboratory scored 50% for the identification of fungal elements in the API 2nd proficiency testing event of 2019. B) Review of the American Proficiency Institute (API) reports for 2019 revealed that the laboratory scored 0% for the identification of fungal elements in the API 3rd proficiency testing event of 2019. C) Review of the American Proficiency Institute (API) reports for 2020 revealed that the laboratory scored 50% for the identification of fungal elements in the API 1st proficiency testing event of 2020 and corrective action stated that techs were re-educated on the identification of fungal elements. D) Review of the American Proficiency Institute (API) reports for 2020 revealed that the laboratory was not scored for the identification of fungal elements in the API 2nd proficiency testing event of 2020 with a comment "instrument down". E) Review of the American Proficiency Institute (API) reports for 2020 revealed that the laboratory scored 100% for the identification of fungal elements in the API 3rd proficiency testing event of 2020. F) Review of the American Proficiency Institute (API) reports for 2021 revealed that the laboratory scored 0% for the identification of fungal elements in the API 1st proficiency testing event of 2021 and corrective action stated that techs were re-educated on the identification of fungal elements. G.) In an interview on 6/28/21 at 4:22, the laboratory manager identified as number 2 on the employee identified list confirmed the corrective action taken did not prevent the recurrence of the deficient practice.

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:
 Through review of personnel competency evaluations, the completed CMS 209 form and interview it was determined that the technical consultant failed to evaluate the competency of two of two testing personnel listed on the CMS 209 form. Findings follow: A) Review of testing personnel competency evaluations of the two testing personnel listed on the CMS 209 form revealed that three of five of the competency evaluations reviewed were completed by a person identified as number one on a separate personnel identification list. Personnel identified as number one on the personnel identification list, is not listed on the CMS 209 form submitted by the laboratory and the laboratory did not have documentation that personnel number one met the qualification requirements to function as a technical consultant. B) Review of the CMS 209 form submitted by the laboratory does not identify a technical consultant. C) In an interview on 6/28/21 at 02:25 PM, the laboratory manager, identified as number two on the separate personnel identification list, stated that the personnel, identified as number one on the separate personnel identification list, was not on the CMS 209 form but was a "super tech" from another laboratory and is performing the duties of technical consultant.

D6053

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 semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Through review of personnel competency records for two testing personnel listed on the CMS 209 form, authorizations to perform tests, and interview it was determined that the laboratory did not assess the competency of one of two testing personnel semi-annually during the first year of employment. Findings follow: A) Review of personnel records of testing personnel, identified as number 2 on the CMS 209 form, indicated that the employee was hired on 7/15/19 and authorized by the laboratory director to perform moderately complex testing without direct supervision. B) Upon review of personnel records of testing personnel, identified as number 2 on the CMS 209 form, competency evaluations were dated as performed in February 2020 and December 2020 which do not document competencies performed semi-annually during the first year of employment which was 7/15/19 to 7/15/20 for this personnel. C) In an interview on 6/28/21 at 2:25 PM, the laboratory manager, identified as number two on the separate personnel identification list verified that competency evaluations were not performed semi-annually during the first year of employment for the testing personnel identified as number two on the CMS 209 form..

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:

Through a review of the form CMS-209, a review of competency assessments, lack of documentation and interview it was determined the technical consultant failed to evaluate the competency of testing personnel on an annual basis. Survey findings follow: A) Review of personnel competency evaluations revealed that competency evaluations of the testing personnel identified as number one on the CMS 209 form were performed and documented on October 2017, November 2018 and June 2021.. B) Upon request, the laboratory could not produce documentation of the evaluation of competency of the testing personnel identified as number one on the CMS 209 form performed in 2019 or 2020. C) In an interview on 6/28/21 at 2:25 PM, the laboratory manager, identified as number two on the separate personnel identification list, confirmed that there was no documentation of a competency evaluation for the testing personnel identified as number one on the CMS 209 form between November 2018 and June of 2021.