

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  25D2085360	<b>(X3) Date Survey Completed</b>  04/09/2019
<b>Name of Provider or Supplier</b>  Elite Care Family Medicine	<b>Street Address, City, State</b>  571 Mitchell Street, Ste C, Guntown, MS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing event records from 2018 and 2019 and confirmation with TP (testing personnel) #1 and technical consultant (TC) at 3:00 PM the day of survey, the laboratory failed to retain all proficiency records to include but not limited to results, attestation statements and analyzer printouts. Findings include: 1. Observation of 1st, 2nd and 3rd events of 2018 proficiency testing records revealed the laboratory did not retain the following: a. Analyzer printouts for 1st, 2nd and 3rd events of 2018. b. Report sheet/submitted result sheets for 1st, 2nd and 3rd events of 2018. c. Attestation statement for 3rd event of 2018 2. Interview with TP #1 and the TC at 3:00 pm on 4/9/19 indicated that the previous listed proficiency records were not retained after completion of the proficiency event.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory personnel annual evaluations/competencies and interview with the Technical Consultant (TC) at 4:00 pm on 4/9/19, the laboratory failed to follow written policies to assess competency of the TC competency at least annually since employed in December 2017. On the day of survey, there was no</p>

annual competency for the TC of the laboratory for the year 2018 performed by the laboratory director. Findings include: 1. Interview with clinic owner and TC listed on the Centers for Medical & Medicaid Services (CMS) 209 form indicated that no evaluation/competency had been performed by the laboratory director on the TC since the hire date of December 2017. 2. Based on review of the personnel records the day of survey, 4/9/19, the laboratory director failed to follow policies and evaluate the TC at least annually.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:  
Based on testing personnel (TP) records available the day of survey and interview with TP #1 and the Technical Consultant (TC) at 2:30 pm on 4/9/19, TP #2, as listed on the CMS-209 (Centers For Medicare & Medicaid Services) personnel form, the laboratory director failed to ensure TP #2 received appropriate training for performing thyroid stimulating hormone (TSH) testing with the Nano-Tek Frend analyzer prior to testing patients. Findings include: 1. The TC and TP #1 at 2:30 pm on day of survey confirmed waived tests and TSH training was performed by TP #1 for TP #2, but TSH training was not documented. 2. Review of TP #2 personnel records revealed only waived testing was documented at training. There was no documentation of TSH training on the Nano-Tek Frend on the day of survey, 4/9/19. 3. According to personnel records, TP #1 and TP #2 did not have the following training before they were allowed to collect, perform and report patient testing: a. Skills required for proper specimen collection, including patient preparation b. Skills required for implementing all standard laboratory procedures c. A working knowledge of reagent stability and storage d. The skills required to implement the quality control policies and procedures of the laboratory e. The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values to prior to reporting patient test results d. Knowledge of how to report patient results (charting, electronically, etc.) e. AcT Diff training (testing quality controls, troubleshooting, maintenance, calibrating, etc.) .

**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 review of laboratory records (including quality control, calibrations,

temperatures, proficiency records and maintenance) from 10/19/17 through the day of survey 4/9/19, and confirmation with Technical Consultant (TC) at 3:30 pm, the TC failed to document as reviewed the following laboratory records: Proficiency Records for 2018-2019 and Maintenance records for the Nano-Tek Frend. Finding include: 1. Interview with the TC at 3:30 pm on 4/9/19 confirmed there was no documented review by the TC of proficiency results for the 1st, 2nd and 3rd events of 2018 and 1st event of 2019. 2. Observation of Nano-Tek Frend analyzer maintenance records revealed no evidence of TC review.

**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:  
Based on review of laboratory personnel records from 10/19/17 through day of survey 4/9/19, the CMS-209 (Centers for Medicare and Medicaid) personnel form and interview with the technical consultant (TC) at 2:30 pm on 4/9/19, the TC failed to evaluate and document the performance of testing personnel (TP) #2 responsible for performing moderate complexity testing at least semiannually during the first year of employment. The hire date for TP #2 was 4/1/18. A semiannual evaluation must be performed during the first year of employment by the laboratory's technical consultant. Findings include: 1. Review of the personnel records for TP #2 revealed a hire date of 4/1/18. 2. There was no documentation of an evaluation/competency available for TP #2 through the date of survey. 3. Interview with the laboratory's TC at 2:30 pm on the day of survey confirmed that no 6 month evaluation/competency had been performed for TP#2.

**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 review of testing personnel (TP) records since the initial survey (10/19/17) and confirmation with the technical consultant (TC) at 2:30 pm on 4/9/19, the TC listed on the CMS-209 (Centers for Medicare and Medicaid) form failed to evaluate and document the performance competency of TP #1 and #2 at least annually. Findings include: 1. Observation of the personnel records for TP #1 revealed no annual evaluation/competency for 2018 performed by the TC. This annual evaluation was due 5/3/18. 2. Observation of the personnel records for TP #2 revealed no annual evaluation/competency for 2019 performed by the TC. This annual evaluation was due 4/1/19.