

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2144466	(X3) Date Survey Completed 08/02/2022
Name of Provider or Supplier Holtville Family Practice, Llc	Street Address, City, State 213 Lightwood Road, Suite 1, Deatsville, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Hematology proficiency testing (PT) records, a review of the policy and procedure manual, and an interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director and Testing Personnel signed the attestation statement for four of seven 2020-2022 PT surveys. The findings include: 1. A review of the attestation statements for the 2020-2022 API Hematology PT records revealed the following: A) 2020-Event #3 and 2022-Event #1: No signature by the Laboratory Director B) 2021-Event #2: No signature by Testing Personnel #3 C) 2021-Event #3: No signature by Testing Personnel #1 2. A review of the policy and procedure manual revealed under "Guidelines for Proficiency Testing" which specified the laboratory should retain "copies of the attestation form signed by the testing personnel and the laboratory director...". 3. During an interview on August 4, 2022, at 10:45 AM, surveyor reviewed the instructions on the attestation statement requiring the Laboratory Director (or designee) and testing personnel to sign the document; Testing Personnel #1 confirmed the Laboratory Director and Testing Personnel had failed to sign the attestations for the above surveys. .</p>
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p>

semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on a review of the personnel records, the policy and procedure manual, and an interview with Testing Personnel #1, the Technical Consultant (also the Laboratory Director) failed to evaluate and approve the semi-annual competency assessment for one of one new testing personnel performing moderate-complexity patient testing. The findings include: 1. A review of the testing personnel records revealed Testing Personnel #2 was trained to perform CBC's (Complete Blood Counts, a moderate-complexity test) in June 2021. The semi-annual competency assessment was performed in October 2021 and signed by the CRNP (Certified Registered Nurse Practitioner), however there was no documentation of the Technical Consultant's review and approval (as indicated by a signature and date). 2. A review of the policy and procedure manual under Quality Assessment on page 3 revealed, "...D. Since competency assessment is the responsibility of the Technical Consultant, the reviews will only be personnel who meet the regulatory qualification requirements for the technical consultant.". 3. During an interview on August 4, 2022, at 10:45 AM, Testing Personnel #1 confirmed the CRNP, who is not qualified to perform the duties as the Technical Consultant, reviewed and signed the semi-annual competency. .

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 a review of the 2020-2022 personnel records, the policy and procedure manual, and an interview with Testing Personnel #1, the Technical Consultant (also the Laboratory Director) failed to evaluate and approve the annual competency assessment for three of three testing personnel performing moderate-complexity patient testing. The findings include: 1. A review of the testing personnel records revealed the annual competency assessments performed from October 2020 through April 2022 for Testing Personnel #1, #2, and #3 were performed and signed by the CRNP (Certified Registered Nurse Practitioner). There was no documentation of the Technical Consultant's review and approval (as indicated by a signature and date). 2. A review of the policy and procedure manual under Quality Assessment on page 3 revealed, "...D. Since competency assessment is the responsibility of the Technical Consultant, the reviews will only be personnel who meet the regulatory qualification requirements for the technical consultant.". 3. During an interview on August 4, 2022, at 10:45 AM, Testing Personnel #1 confirmed the CRNP, who is not qualified to perform the duties as the Technical Consultant, reviewed and signed the annual competencies. SURVEYOR ID #s 32558 and 46291 Licensure and Certification Surveyors