

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 34D2020801	<b>(X3) Date Survey Completed</b> 08/16/2024
<b>Name of Provider or Supplier</b> Desantis Family Practice	<b>Street Address, City, State</b> 10 3rd Avenue Ne, Suite 500, Hickory, NC	
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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and testing personnel (TP) #1 interview 8/16/24, the laboratory failed to ensure expired reagents were not in use for patient testing of Cholesterol (CHOL) and Triglycerides (TRIG). Findings: At approximately 10:15 a. m. surveyor observed 4 bottles of ACE CHOL reagent, Lot # F4745, in the bottom right hand side drawer of the laboratory refrigerator with an expiration date of 07/31 /24. At approximately 10:15 a.m. surveyor observed 4 bottles of ACE TRIG reagent, Lot # F4731, in the bottom right hand side drawer of the laboratory refrigerator with an expiration date of 06/30/24. During interview at approximately 10:15 a.m., TP #1 confirmed the reagent was expired, pulled the expired reagent off the analyzer, and disposed of the expired bottles of reagent in the laboratory refrigerator. TP #1 stated they had removed the top of the boxes of reagent when they began using them and did not realize they were expired because they normally note the expiration date of reagents from the box top and not the reagent bottle itself.</p>
<b>D6029</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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</p>

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 review of personnel records and interview with the TC (technical consultant) 8/16/24, the laboratory director failed to ensure that prior to testing patient specimens, 4 of 5 testing personnel (TP #2, #3, #4, #5) had received appropriate training for the hematology testing performed on the DxH 520 and could perform all testing operations reliably to report accurate patient test results. Findings: Review of personnel records revealed TP #1 had documentation of training for the new DxH 520 hematology analyzer which was installed in March 2022. Review of personnel records revealed TP #2, TP #3, TP #4, and TP #5 had competency evaluations in October 2022, April 2023, and May 2024 which included the DxH 520, but there was no documentation of training. During interview at approximately 11:40 a.m., the TC stated that TP #2, TP #3, TP #4, and TP #5 were trained on the DxH 520 by TP #1 and a former testing personnel, but the training was not documented.