Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0985184	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Davidson Family Medicine/Avance Care	104 Knox Court Ste 100, Davidson, NC	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of the manufacturer's IFU(instructions for use), and interview with the COVID nurse 1/27/22, the laboratory failed to follow manufacturer's instructions for the SARS-CoV-2 testing performed to ensure authorized Fact Sheets for patients and providers were included with the SARS-Cov2 test result reports. Findings: Review of laboratory records revealed the laboratory began testing for SARS-CoV-2 using BD Veritor System in September 2020 and Cepheid Gene Xpert in March 2021. 1. The laboratory failed to ensure authorized Fact Sheets for patients and providers were included with SARS CoV-2 test result reports. Review of the IFU for the BD Veritor System for Rapid detection of SARS CoV-2 revealed on page 13 and the IFU for the Cepheid Xpert Xpress SARS CoV-2 test revealed on page 33. "Conditions of Authorization for Laboratories....Authorized laboratories using your product must include with test result reports all authorized fact sheets..." During interview at approximately 11:50 a.m., the COVID nurse confirmed the laboratory does not provide the fact sheets with the test result reports for the BD Veritor or the Cepheid SARS CoV-2 tests.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on the review of laboratory records and absence of documentation 1/27/22, the laboratory failed to retain manufacturer's QC (quality control) assay sheets for chemistry and hematology testing for 2 years. Findings: Random review of 2019, 2020, and 2021 laboratory QC records for the Medica Easy RA analyzer revealed the laboratory failed to retain the Medica Easy QC Chemistry assay sheets with the quality control material acceptable ranges for the following lot numbers: 1. Easy QC Chemistry level A lot # 17270/ level B lot #17271, unknown expiration date; 2. Easy QC Chemistry level B lot# 18276, unknown expiration date; 3. Easy QC Chemistry level A lot#20266/level B lot #20267, expiration date 8/31/23. Random review of 2019, 2020, and 2021 laboratory QC records for the Medonic M series hematology analyzer revealed the laboratory failed to retain assay sheets for the following lot numbers of control material: 1. Boule lot #21811, expiration date 3/28/19; 2. Boule lot #21902, expiration date 6/25/19; 3. Boule lot #22011, expiration date 3/23/21; 4. Boule lot #22101, expiration date 6/16/21.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the off-site manager 1/27/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The laboratory's "Hematology QC" procedure states "Policy: Three (3) levels of controls, low, normal and a high control will be run daily. ... Procedure: 1. Run all 3 controls each day a patient sample is to be tested. ..." The procedure failed to include the name of the control material used by the laboratory. During interview at approximately 2:15 p.m., the off-site manager stated he did not realize the name of the control material was not included in the procedure. 2. The laboratory's "Verification of Performance/Method Validation Policy" states "Policy: Each analyzer or testing method categorized as moderately complex will be tested and evaluated to verify that it can perform to the manufacturer's specifications. ..." The policy describes the steps used by the laboratory to validate the performance

	specifications (accuracy, precision, reportable range) of new test methods, but the policy failed to state that it is not used to validate hematology analyzers. During interview at approximately 12:20 p.m., the off-site manager stated that the "Verification of Performance/Method Validation Policy" is only used for chemistry analyzers.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and interview with the off-site manager 1/27/22, the laboratory failed to follow manufacturer's instructions for storage of control material used on the Medica Easy RA analyzer for Total Bilirubin. Findings: The Medica Easy QC Chemistry Level A and Level B product inserts state, "After reconstitution, store QC material closed at 2-8 degrees C(celsius). The components of QC are stable for: .... Total Bilirubin: 3 days stored in the dark at 2-8 degrees C...." During interview at approximately 1:50 p.m., the off-site manager confirmed the laboratory reconstitutes Easy QC Chemistry controls every Monday and they are not following the 3 day open stability for Total Bilirubin.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: Based on random review of 2019, 2020, and 2021 hematology quality control records and interview with the off-site manager 1/27/22, the laboratory used expired quality control material on 14 days of testing from 6/26/19-7/19/19. Approximately 171 patients were tested during this time. Findings: Review of hematology quality control records, the laboratory used Boule control material lot #21902 with expiration date 6 /25/19 and continued to test patients for 14 days after the control material expired: a. 6 /26/19 - 14 patients tested; b. 6/27/19 - 9 patients tested; c. 6/28/19 - 10 patients tested; d. 7/1/19 - 6 patients tested; e. 7/3/19 - 12 patients tested; f. 7/8/19 - 14 patients tested; g. 7/10/19 - 18 patients tested; h. 7/11/19 - 11 patients tested; i. 7/12/19 - 13 patients tested; j. 7/15/19 - 14 patients tested; k. 7/16/19 - 8 patients tested; l. 7/17/19 - 20 patients tested; m. 7/18/19 - 10 patients tested; n. 7/19/19 - 12 patients tested. During interview at approximately 3:00 p.m., the off-site manager stated that the testing personnel who used expired control material left in July. He stated a new testing personnel was hired in August and she started a new lot number of quality control material 8/13/19. He verified the laboratory did not perform patient hematology testing from 7/20/19-8/12/19.
D5439	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedures and Chemistry installation records, review of 2019, 2020, and 2021 calibration and calibration verification records, and interview with the off-site manager 1/27/22, the laboratory failed to perform calibration verifications every 6 months for the Medica Easy RA chemistry testing and the Tosoh 360 PSA(prostrate specific antigen) as required. Findings: Review of the laboratory's "General Chemistry testing/ EasyRA Analyzer" policy and procedure states, "Calibration verification is required every 6 months for all analytes on the EasyRA Analyzer."The laboratory's Calibration Verification policy states, "Calibration verification will be performed for each analyzer testing system according to the manufacturer's instructions and/or CLIA requirements. Cal Verif is to be performed at least every 6 months. Cal verif is not necessary for test using 3 or more calibrators." Review of the Chemistry installation records revealed the laboratory began testing on the Medica Easy RA Chemistry analyzer in November 2018 and the Tosoh 360 analyzer in October 2019. 1. Review of 2019, 2020, and 2021 calibration verification records revealed the laboratory failed to perform the 6 month calibration verification that was due in June 2019 for the Medica Easy RA, and the calibration verification was not completed until 12/17/19, a period of more than 12 months since the laboratory began testing. During interview at approximately 2:30 p.m., the off-site manager confirmed the June 2019 calibration verification on the Medica Easy RA was missed. 2. Random review of 2019, 2020, and 2021 Tosoh 360 calibration records revealed the laboratory performs a 2-point calibration for PSA. Review of calibration verification records revealed the laboratory failed to perform a calibration verification for PSA from time of installation until 2/15/21, a period of more than 16 months. During interview at approximately 2:30 p.m, the off-site manager stated the calibration verification that was due for PSA in April 2020 was delayed due to the pandemic, and the laboratory had noted it was completed when they resumed testing in July 2020. He confirmed the calibration verification for PSA was not performed in July 2020 when testing resumed and was not completed until 2/15/21.