Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	49D0861146	10/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
South Hill Family Medicine	514 W Atlantic Street, South Hill, VA	

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
D0000	An announced CLIA Recertification survey was conducted at South Hill Family Medicine on 10/13-14/21 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5400 - 42 C.F. R. 493-1250 Condition: Analytic Systems ***REPEAT DEFICIENCY*** D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity Laboratory Director ***REPEAT DEFICIENCY*** The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
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 review of manufacturer's operator manual, lack of documentation and interviews, the lab failed to retain documentation of the daily, weekly and monthly maintenance procedures for six of six months from November 2019 and up to April 2020. Findings include: 1. Review of the Abbott Architect 4100 chemistry analyzer revealed required maintenance procedures to include but not limited to: Daily- check 1 ml syringes and check DI water purity. Weekly- clean probe, clean mixers, pipettorWZ probe cleaning. Monthly- check dispense components, clean cuvette washer nozzles, check syringe and valves and clean ICT drain tip. 2. Review of instrument maintenance records and interview with the technical consultant on 10/14 /21 at 11 AM revealed there was a failure with the backup of instrument data and the maintenance records could not be retrieved for review. The technical consultant stated that the lab was not using paper logs to document the instrument maintenance

	procedures during the specified six month timeframe. 3. An exit interview with the technical consultant on 10/14/21 at approximately 2:00 PM confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), policy and procedures (P&P), performance verification records, operator's manual, instrument maintenance records, lack of documentation, and interviews, the laboratory failed to: 1. have a written policy for reporting patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency (Refer to D5403) REPEAT DEFICIENCY, 2. verify the reference (normal) ranges for Complete Blood Cell counts (CBC) (Refer to D5421), 3. perform the quarterly maintenance for the Abbott Emerald 22 AL hematology analyzer (Refer to D5429 part A), 4. document the Abbott Architect 4100 monthly maintenance procedures 10 of 16 months reviewed (Refer to D5429 part B), 5. follow the established P&P for performing the pipette calibration procedure annually (Refer to D5433) REPEAT DEFICIENCY, and 6. follow the established P&P for performing calibration verification procedures twice yearly for 24 of 24 months reviewed in the subspecialty of chemistry (Refer to D5439).
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: **REPEAT DEFICIENCY*** Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), policy and procedures (P&P), lack of documentation, and interviews, the laboratory failed to have a written policy for reporting patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency from 10/20/20 and up to the date of survey on 10/14/21, 12 months and four days. Findings include: 1. Review of the CMS 116 application revealed the laboratory performs COVID-19 testing. An interview with the technical consultant on 10/14/21 at approximately 11 AM revealed the lab began patient testing with the BD Veritor Rapid Detection of SARs-CoV-2 Antigen kits and the Abbott Binax Now Antigen COVID-19 kits on 10/20/20. 2. Review of the manufacturer's IFU's revealed the following statements: Abbott Binax Now Antigen COVID-19 - "Conditions of Authorization for Laboratory and Patient Care Setting", "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." BD Veritor Rapid Detection of SARs-CoV-2 Antigen- "Conditions of Authorization for the Laboratory", "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. Review of the P&P revealed lack of documentation of policy or procedure for reporting patient COVID- 19 positive and negative test results to the local health department. 4. An exit interview with the technical consultant on 10/14/21 at approximately 2:00 PM confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification records, lack of documentation, and interview, the laboratory failed to verify the reference (normal) ranges for Complete Blood Cell counts (CBC) performed on the hematology analyzer prior to reporting patient results from 05/26/21 and up to 10/14/21. Findings include: 1. Review of the Abbott Emerald 22 AL (serial number 000258, installed 05/26/21) hematology analyzer's performance verification documentation revealed lack of documentation of verification of the reference (normal) ranges for CBCs during or after the instrument was installed. The surveyor requested to review documentation that the laboratory evaluated and verified the reference (normal) ranges for the above-specified instrument prior to patient testing. The laboratory provided no documentation for review. 2. An exit interview with technical consultant on 10/14/21 at approximately 2: 30 PM confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on the review of operator's manual, instrument maintenance records and interviews, the lab failed to perform the quarterly maintenance for the Abbott Emerald 22 AL hematology analyzer at the date of survey on 10/14/21. Findings include: 1. Review of the operator's manual revealed instructions for performing quarterly maintenance of lubricating the syringe pistons (Section 9 Quarterly Maintenance). The instrument was installed on 05/26/21 and in use on 05/27/21. 2. Review of instrument maintenance records revealed lack of documentation of the quarterly maintenance of lubricating the syringe pistons. Based on the date of install, the quarterly maintenance would have been due in the month of August 2021. The inspector requested to review documentation of the quarterly maintenance. The documentation was not available for review. 3. An exit interview with the technical consultant on 10/14/21 at approximately 2:30 PM confirmed the findings. The technical consultant stated they were not aware of the required quarterly maintenance. B. Based on review of the manufacturer's operator manual, maintenance records, lack of documentation and interview, the lab failed to document the Abbott Architect 4100 monthly maintenance procedures 10 of 16 months reviewed from May 2020 and up to September 2021. Findings include: 1. Review of the Abbott Architect 4100 chemistry analyzer operators manual revealed required monthly maintenance procedures to include but not limited to check dispense components, clean cuvette washer nozzles, check syringe and valves and clean ICT drain tip. 2. Review of available instrument maintenance records revealed lack of documentation for the following months: November and December 2020, January-August 2021. Maintenance records were not available for review from October 2019 up to April 2020 (See D3031). 3. An exit interview with the technical consultant on 10/14/21 at approximately 2:00 PM confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on the review of policy and procedures (P&P), lack of documentation and interview, the lab failed to follow the established P&P for performing the pipette calibration procedure annually for 24 of 24 months reviewed. Findings include: 1. Review of P&P revealed the following, "Laboratory Policy Pipette Calibration Verification (signed by the lab director on 7/30/19)", "1. All pipettes used in the SHFM [South Hill Family Medicine] laboratory for critical measurements and dilutions should be calibrated annually." 2. The laboratory utilizes the Fisherbrand 100-1,000 l Finnpipette (serial number DH20688) to reconstitute the

	BioRad Lyphochek Diabetes Control materials. The inspector requested to review calibration verification documents from September 2019 and September 2021 (24 months). The documents were not available for review. 3. An exit interview with the technical consultant on 10/14/21 at approximately 2:30 PM confirmed the findings.
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 the review of Center for Medicare and Medicaid Services Laboratory 116 application form (CMS-116) , policy and procedures (P&P), manufacturer package inserts, lack of documentation and interview, the lab failed to follow the established P&P for performing calibration verification procedures twice yearly for 24 of 24 months reviewed in the subspecialty of chemistry for 17 or 17 analytes. Findings include: 1. Review of P&P revealed the following statements, "Laboratory Procedure Calibration Verification (signed by the lab director on 1/27/10)", "1. Twice yearly or after major instrument maintenance, calibration verification studies will be performed on the Architect on tests with less than 3 calibrators. 2. Run calibration verification material according to manufacturer's guidelines. 3. Cal. Verification values will be assessed for accuracy and will be signed by the lab manager and the lab director." 2. Review of manufacturer package inserts revealed the following analytes with less than three calibrators: albumin, alanine aminotransferase, alkaline phosphatase, and aspartate aminotransferase, blood urea nitrogen, calcium, carbon dioxide, chloride, cholesterol, creatinine, glucose, potassium, sodium, total bilirubin, total protein, thyroid stimulating hormone and prostate specific antigen. Total of 17 analytes. The inspector requested to review the calibration verification documents according to the established policy for the above-specified analytes from September 2019 up to September 2021 (24 months). The records were not available for review. Review of the CMS 116 application revealed the annual test volume for the subspecialty of chemistry is 229,990. 3. An exit interview with the technical consultant on 10/14/21 at approximately 2:30 PM confirmed the findings.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on the review of performance verification documents, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures (P&P), quality assurance (QA) policy, lack of documentation, and interview, the lab director failed to: 1. review and approve the accuracy, precision, reportable range documentation for the hematology analyzer (Refer to D6013), 2. follow the established policy and ensure that two of two new TP had documented training and competency assessments prior to performing patient testing procedures (Refer to D6029), and 3. ensure a P&P was approved and available for testing personnel for the hematology analyzer installed on 05/26/21 (Refer to D6031).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on the review of performance verification documents, lack of documentation, and interview, the lab director failed to review and approve the accuracy, precision, reportable range documentation for the hematology analyzer installed on 05/26/21 and up to the date of survey on 10/14/21. Findings include: 1. Review of the performance verification documents for the Abbott Emerald 22 AL (serial number 000258) hematology analyzer revealed instrument installation on 05/26/21 and patient use on 05/27/21. The documents lacked the lab director signature of review and approval of the accuracy, precision and reportable range studies. The reference range (normal value) verification was not available for review (See D5421). 2. An exit interview with the technical consultant on 10/14/21 at approximately 2:30 PM confirmed the findings.
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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, quality assurance (QA) policy, and interviews, the laboratory director failed to follow the established policy and ensure that two of two new TP had documented training and competency assessments prior to performing patient testing procedures for hematology at the date of survey on 10/14/21. Findings include: 1. Review of CLIA CMS-209 form revealed that TP E and F as new TP as of 01/20/21 and 06/29/21 respectively(See attached TP Code Sheet). 2. The inspector requested to review training documentation and competency assessments on the above-mentioned TP on 10/13/21 at approximately 2 PM. The documentation was not available for review. 3. Review of the QA policy (signed by the lab director on 06/22/15) revealed the following statement, "Laboratory personnel are initially trained in the correct performance of the testing they are authorized to perform. A training checklist will be used to note acceptable training." 4. An exit interview with the technical consultant on 10/14/21 at approximately 2:00 PM confirmed the findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the review of performance verification documents, policy and procedures (P&P), lack of documentation, and interviews, the lab director failed to ensure a P&P was approved and available for testing personnel for the hematology analyzer installed on 05/26/21 and up to the date of survey on 10/14/21. Findings include: 1. Review the performance verification documents for the Abbott Emerald 22 AL (serial number 000258) hematology analyzer revealed instrument installation on 05/26/21 and patient use on 05/27/21. 2. Review of the P&P revealed lack of documentation of an approved manual or procedure for operation and maintaining the hematology analyzer. During an interview with the technical consultant on 10/13/21 at approximately 1 PM, the inspector requested to review an approved procedure manual or operator's manual from the manufacturer for the hematology analyzer. The technical consultant stated that the lab did not receive an operator's manual when the instrument was installed. Purchase and installation conducted by a second party (Peak Services) and not Abbott Diagnostics. The inspector was presented with a "Customer Training Guide" for the specified analyzer. The review of the training guide revealed minimal instructions for use and maintenance of the analyzer and repeated, "refer to operator's manual" for more detailed instructions. The instrument at the time of interview was not functioning properly and the testing personnel could not analyze patient samples. 3. A telephone interview with a Peak Services technical specialist on 10/14/21 at 9:18 AM revealed that Peak Services would send the lab an electronic

	copy of the Abbott Emerald 22 AL operator's manual upon request and subsequently emailed the manual. 4. An exit interview with the technical consultant on 10/14/21 at approximately 2:30 PM confirmed the findings.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), policy and procedures (P&P), performance verification records, operator's manual, instrument maintenance records, lack of documentation, and interviews, the technical consultant (TC) failed to ensure 1) a written policy available for reporting patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency (Refer to D5403) REPEAT DEFICIENCY; 2) verify the reference (normal) ranges for Complete Blood Cell counts (CBC) (Refer to D5421); 3) perform the quarterly maintenance for the Abbott Emerald 22 AL hematology analyzer (Refer to D5429 part A); 4) documentation of the Abbott Architect 4100 monthly maintenance procedures 10 of 16 months reviewed (Refer to D5429 part B); 5) follow the established P&P for performing the pipette calibration procedure annually (Refer to D5433) REPEAT DEFICIENCY; and 6) follow the established P&P for performing calibration verification procedures twice yearly for 24 of 24 months reviewed in the subspecialty of chemistry (Refer to D5439). The deficient practice was confirmed during the Exit interview with the TC on 10/14/21 at 2:00 PM.
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: ***REPEAT DEFICIENCY*** Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, the quality assurance (QA) policy and interviews, the technical consultant failed to perform and document annual competency assessments for three of three TP in 2020. Findings include: 1. Review of the CMS-209 form revealed there were 3 TP (B-D) performing patient testing in 2020. See attached list. 2. Review of the 3 TP records revealed lack of documentation of annual competency assessments performed in 2020. The inspector requested the annual competency assessments for the 3 TP on 10/13/21 at approximately 2 PM. The documentation was not available for review. 3. Review of the QA policy (signed by the lab director on 06/22/15) revealed the following statement: "Personnel Assessment- The competency and performance of all laboratory personnel will be evaluated yearly. The results will be recorded on a laboratory personnel competency assessment form and kept for review." 4. An exit interview with the technical consultant on 10/14/21 at approximately 2:30 PM confirmed the findings.