Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0861146	08/01/2023
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 the South Hill Family Medicine on July 21, 2023 and August 1, 2023 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** and D6033- 42 C.F.R. 493-1409 Condition: Technical Consultant.
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 policy and procedures (P&P), the plan of corrections (POC) submitted on 11/22/21, manufacturer's operator manual, maintenance records, the Center for Medicare and Medicaid Services Laboratory 116 application form (CMS-116), manufacturer package inserts, lack of documentation, and interview, the lab failed to: 1) Document and monitor the relative humidity percentage (RH%) in the lab testing area for 18 or 18 months reviewed. Refer to 5413. 2) Document the Abbott Architect 4100 quarterly maintenance procedures as defined by the manufacturer. Refer to D5429 **REPEAT DEFICIENCY 3) Follow the established P&P for performing the pipette calibration procedure annually. Refer to D5433 **REPEAT DEFICIENCY 4) Follow the established P&P for performing calibration verification procedures twice yearly for calendar year of 2022 in the subspecialty of chemistry for

	17 or 17 analytes. Refer to D5439 **REPEAT DEFICIENCY and 5) Follow the quality assurance plan as defined in the P&P and the POC submitted on 11/22/21 for 18 of 18 months reviewed. Refer to D5791.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of hematology and chemistry analyzers operator's guide, lack of documentation and interview, the lab failed to document and monitor the relative humidity percentage (RH%) in the lab testing area for 18 or 18 months reviewed. Dates of record review include 01/01/22 up to date of survey 08/01/23. Findings include: 1. Review of the Abbott Cell Dyn 22 hematology and the Abbott Architect 4100 chemistry analyzer operator's guide revealed the following, "environmental requirements for RH% are maximum of 80% and 10-85% ", respectively. 2. Review of daily laboratory temperature logs revealed a lack of documentation of the RH% readings for the lab testing area from 01/01/22 up to date of survey 08/01/23. The lab was unable to provide documentation of the monitoring of the RH% upon request. 3. An exit interview with the technical consultant on 08/01/23 at approximately 1230 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: **REPEAT DEFICIENCY** 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 quarterly maintenance procedures as defined by the manufacturer for 18 of 18 months reviewed from January 2022 and up to dates of survey on 07/31/23 and 08/01/23. Findings include: 1. Review of the Abbott Architect 4100 chemistry analyzer operators manual revealed required quarterly maintenance procedures to include but not limited to lamp change, sample syringe maintenance, wash syringe maintenance, reagent syringe maintenance, change 1 microliter (mL) syringes, change ICT ASP check valve and check ICT reference check valve. 2. Review of available instrument maintenance records revealed a lack of documentation of the above-specified maintenance performed on the defined quarterly basis. Records showed the quarterly maintenance performed on 05/02/22 and 01/11/23. The inspector

	requested to review additional documentation. The documentation was not available for review. 3. An exit interview with the technical consultant on 08/01/23 at approximately 1230 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 in calendar year 2022. 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 Diamond 100-1,000 l pipette to reconstitute the BioRad Lyphochek Diabetes Control materials. The inspector requested to review calibration verification documents from January 2022 up to the dates of survey on 07/31/23 and 08/01/23 (18 months). The documents were not available for review. 3. An exit interview with the technical consultant on 08/01 /23 at approximately 1230 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: **REPEAT DEFICIENCY** 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, calibration verification records, lack of documentation and interview, the lab failed to follow the established P&P for performing calibration verification procedures twice yearly for calendar year of 2022 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, 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. 3. Review of available calibration verification records revealed the lab performed the procedures on 12/29/21 and again on 07/31/23. The inspector requested to review additional calibration verification documents according to the established policy between the specified timeframe. The records were not available for review. Review of the CMS 116 application revealed the annual test volume for the subspecialty of chemistry is 241,076. 4. An exit interview with the technical consultant on 08/01/23 at approximately 1230 confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), the plan of corrections (POC) submitted on 11/22/21, lack of documentation, and interview, the lab failed to follow the quality assurance plan as defined in the P&P and the POC submitted on 11/22/21 for 18 of 18 months reviewed. Dates of review include 01/01/22 up to the dates of survey on 07/31/23 and 08/01/23. Findings include: 1. Review of the P&P, "Quality Assurance Plan", signed by the lab director on 07/29/19, outlined systems that were to be reviewed monthly to include "patient test management, quality control assessment, proficiency testing, relationship of test results to patient information, personnel assessment, communication, complaint investigation, quality assurance review, and quality assurance records." 2. Review of the POC submitted on 11/22/21 stated "the changes that have been made to ensure deficient practice will not reoccur include: 1) Development and implementation of a quality assurance duty planner incorporating printing and reviewing all quality control, temperature and maintenance logs by the lab manager, 2) development and implementation of an annual quality assurance calendar, and 3) putting into practice a lab monthly quality assurance checklist." See attached documents. 3. The inspector requested to review the quality assurance

	checklist as described in the POC from 01/01/22 up to the date of survey on 08/01/23. The documentation was not available for review. 4. An exit interview with the technical consultant on 08/01/23 at approximately 1230 confirmed the findings.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), delegation of duties, policy and procedures (P&P), the plan of corrections (POC) submitted on 11/22/21, manufacturer's operator manual, maintenance records, the Center for Medicare and Medicaid Services Laboratory 116 application form (CMS-116), manufacturer package inserts, lack of documentation, and interview, the lab director failed to ensure the technical consultant performed duties as assigned on 07/29/21 at the dates of survey on 07/31/23 and 08/01/23. Findings include: 1. Review of the CLIA CMS-209 Form revealed one technical consultant. 2. The delegation of "Technical Consultant Responsibilities" document, signed by the lab director on 07/29 /19, included the following statement, "The technical consultant is responsible for the technical and scientific oversight of the laboratory." 3. The POC submitted on 11/22 /21 included the following statements, "In addition, the implementation of the 2022 Quality Assurance Calendar, Duty Planner and monthly checklists will provide a more proactive review of our test systems and personnel." 4. Refer to D6036 for detailed findings. 5. In an exit interview with the technical consultant on 08/01/23 at approximately 1230, the technical consultant confirmed that the quality assurance plan stated in the POC in 11/22/21 was not followed and confirmed the findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on the review of policy and procedures (P&P), the plan of corrections (POC) submitted on 11/22/21, manufacturer's operator manual, maintenance records, the Center for Medicare and Medicaid Services Laboratory 116 application form (CMS-116), manufacturer package inserts, lack of documentation, and interview, the technical consultant (TC) failed to provide technical oversight of the laboratory. Refer to D6036.

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 policy and procedures (P&P), the plan of corrections (POC) submitted on 11/22/21, manufacturer's operator manual, calibration verification, maintenance records, the Center for Medicare and Medicaid Services Laboratory 116 application form (CMS-116), manufacturer package inserts, lack of documentation, and interview, the technical consultant (TC) failed to: 1) Document and monitor the relative humidity percentage (RH%) in the lab testing area for 18 or 18 months reviewed. Refer to 5413. 2) Document the Abbott Architect 4100 quarterly maintenance procedures as defined by the manufacturer. Refer to D5429 **REPEAT DEFICIENCY 3) Follow the established P&P for performing the pipette calibration procedure annually. Refer to D5433 **REPEAT DEFICIENCY 4) Follow the established P&P for performing calibration verification procedures twice yearly for calendar year of 2022 in the subspecialty of chemistry for 17 or 17 analytes. Refer to D5439 **REPEAT DEFICIENCY and 5) Follow the quality assurance plan as defined in the P&P and the POC submitted on 11/22/21 for 18 of 18 months reviewed. Refer to D5791.