

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D0861146	<b>(X3) Date Survey Completed</b>  07/31/2025
<b>Name of Provider or Supplier</b>  South Hill Family Medicine	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at South Hill Family Medicine July 29-30, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations and included a follow up off-site interview with the laboratory manager on 7/31/25. South Hill Family Medicine was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions: D2016 - 42 CFR. 493.803 Condition: Successful Participation D5400 - 42 CFR 493.1250 Condition: Analytic Systems **REPEAT DEFICIENCY D6000 - 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p>

This CONDITION is not met as evidenced by:  
Based on a review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing records and interviews, the laboratory failed to successfully participate within the Chemistry specialty for the Carbon Dioxide analyte. The laboratory had unsatisfactory scores for the first and third event of 2024 and the first event in 2025. Refer to D2096.

**D2096**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
A. Based on review of the laboratory's proficiency testing (PT) records, and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Carbon Dioxide (CO<sub>2</sub>) for two (2) out of three (3) consecutive chemistry events in calendar year 2024 resulting in unsuccessful PT performance as reviewed on the dates of the inspection July 29-31, 2025 (review timeframe August 2023 through July 2025). Findings include: 1. A review of the American Proficiency Institute (API) PT records (2023 Event 3, 2024 Events 1-3, 2025 Event 1), a total of five events, revealed CO<sub>2</sub> scores of less than 80% for the following 2 out of 3 consecutive chemistry events: 2024 API Event 1: CO<sub>2</sub> scored 60% (challenge sample 2 reported as 24 with acceptable range 14-22, challenge sample 5 reported as 26 with acceptable range 16-25); 2024 API Event 3: CO<sub>2</sub> scored 60% (challenge sample 14 reported as 23 with acceptable range 23-38, challenge sample 15 reported as 17 with acceptable range 20-30); resulting in an unsuccessful PT performance noted by API. 2. Interviews with the Technical Consultant on 7/29/25 at 3:00 PM and an off-site follow up exit interview on 7/31/25 at 2:00 PM with the lab manager confirmed the above findings. B. Based on a pre-survey review of the Center for Medicaid and Medicare Services CASPER 0155 report (CMS 0155), PT records, and interviews, the laboratory failed to attain a score of at least 80% for CO<sub>2</sub> for 2 consecutive chemistry module testing events resulting in a non-initial unsuccessful PT performance as reviewed on the dates of the inspection July 29-31, 2025 (review timeframe August 2023 through July 2025). Findings include: 1. A pre-survey review of the CMS 0155 report revealed the laboratory received an unsatisfactory score of 60% for the regulated analyte #0351, CO<sub>2</sub>, in the Chemistry 2025-1st Event. 2. A review of American Proficiency Institute (API) PT records (2023 Event 3, 2024 Events 1-3, 2025 Event 1), a total of five events, revealed the following unsatisfactory scores: 2024 API Event 1: CO<sub>2</sub> scored 60%; 2024 API Event 3: CO<sub>2</sub> scored 60%; 2025 API Event 1: CO<sub>2</sub> scored 60% (challenge sample CH 02 reported as 24 with acceptable range 14-22, challenge sample CH 05 reported as 26 with acceptable range 16-25); resulting in a non-initial unsuccessful PT performance noted by API. 3. Interviews with the Technical Consultant on 7/29/25 at 3:00 PM and an off-site follow up exit interview on 7/31/25 at 2:00 PM with the lab manager confirmed the above findings.

**D2127**

**HEMATOLOGY**  
CFR(s): 493.851(d)

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on a review of the Centers of Medicaid and Medicare Services CLIA Survey Summary Report (CMS CASPER Report 0096D), proficiency testing (PT) records, and interviews, the laboratory failed to submit hematology PT results receiving unsatisfactory scores for one (1) of five (5) events reviewed (timeframe of review: August 2023 through July 2025). Findings include: 1. During a pre-survey review, the CMS CASPER Report 0096D revealed zero percent (0%) scores were reported on 2023 Event 3 for the following speciality and six (6) analytes: 0760 HEMATOLOGY 0765 CELL ID- Automated Diff 0775 RBC - Red Blood Cell Count 0785 HCT - Hematocrit 0795 HGB - Hemoglobin 0805 WBC - White Blood Cell Count 0815 PLT - Platelets 2. Review of the laboratory's American Proficiency Institute (API) PT hematology module event results (2023 Event 3, 2024 Events 1-3, 2025 Event 1), a total of 5 events, revealed unsatisfactory scores for the following event: API 2023 Event 3: PT samples ABT 11, ABT 12, ABT 13, ABT 14, and ABT 15 received 0% scores for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count, White Blood Cell Count, Platelet Count, Hemoglobin, and Hematocrit. API reported "results not reported to API resulting in score of zero". 3. The inspector inquired regarding corrective action for the event outlined above. The Technical Consultant (TC) stated on 7/30/25 at 2 PM, "I did not submit and received the zero scores from API. We did run the samples. I just failed to get them submitted by the deadline". The inspector requested to review the self grading for the event. No documentation was available for review. 4. Interviews with the TC on 7/30/25 at 2 PM and with the lab manager on 7/31/25 at 2:00 PM confirmed the above 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 a review of procedures, maintenance logs, manufacturer's package insert, Centers for Medicare and Medicaid Services Clinical Laboratory CLIA Certification form (CMS 116), calibration verification records, manufacturer's operation guide, a tour, lack of documentation and interviews, the laboratory failed to: 1. follow their protocol to perform annual calibration procedures for one pipette utilized for chemistry quality control preparations in calendar years 2024 and 2025 \*\*REPEAT DEFICIENCY, Cross Reference D5433; and 2. perform calibration verification studies every six months in calendar year 2025 for twenty-one chemistry /endocrinology test analytes according to their policy \*\*REPEAT DEFICIENCY, Cross Reference D5439.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

(b)(1)(i) 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. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of procedures, maintenance logs, manufacturer's package insert, tour, lack of documentation, and interviews, the laboratory failed to follow their protocol to perform annual calibration procedures for one (1) of 1 pipette utilized for chemistry quality control (QC) preparations in calendar year 2024. \*\*REPEAT DEFICIENCY Findings include: 1. Review of the laboratory's procedures revealed a protocol (title: Pipette Calibration Verification) that stated, "All pipettes used for critical measurements and dilutions should be calibrated annually." 2. During a tour of the chemistry room with the technical consultant (TC) on 7/29/25 at 1 PM revealed a Diamond variable volume pipette (Serial Number QA342924) utilized for chemistry QC preparation. 3. Review of the available laboratory equipment maintenance logs revealed no pipette calibration records for the pipette outlined above in calendar year 2024. The inspector noted a pipette calibration was performed using Streck Pipette Verification Service dated 7/28/25 with a coefficient of variation reported as 2.45% (outside of the Streck acceptable range of less than 2.0%). The calibration report noted, "If the coefficient of variation value is above 2.0% there may be question. It is the responsibility of the laboratory director to establish acceptable performance limits." 4. Review of the Diamond Pipette package insert revealed the following instructions, "Frequency of calibration: general recommendation -at a minimum calibrate your Diamond pipette at least once a year. Consider calibrating every six months if pipettes are used frequently and/or require high precision. Maintain a detailed record of all calibration events, results, and adjustments for quality control and audits." 5. Interviews with the TC on 7/29/25 at 3:30 PM and an off-site follow up exit interview on 7/31/25 at 2:00 PM with the lab manager confirmed the above findings.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(b)

(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 a review of the Centers for Medicare and Medicaid Services Clinical Laboratory CLIA Application for Certification form (CMS 116), calibration verification records, manufacturer's operation guide, lack of documentation, and interviews, the laboratory failed to perform one of three six month calibration verifications for twenty-one (21) of 21 chemistry/endocrinology Abbott Alinity ci Series analyzer test analytes according to policy as noted on the dates of the inspection, July 29-31, 2025. \*REPEAT DEFICIENCY Findings include: 1. A pre-survey review of the CMS 116 form revealed that the laboratory director (LD) identified non-waived chemistry testing performed on an Abbott Alinity ci Series analyzer (Serial Numbers AC06235, AI26254) with annual test volumes of ninety-one thousand six hundred thirty-three (91,633) patient chemistry results. 2. Review of the laboratory's Alinity analyzer records revealed that the analyzer was installed in December 2023 and that calibration verification was completed for the following 21 chemistry analytes on 6/12/24 and 12/17/24: Albumin Alkaline Phosphatase Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Blood Urea Nitrogen (BUN) Calcium Cholesterol Chloride Carbon Dioxide (CO2) Creatinine Direct Bilirubin Glucose Cholesterol, High Density Lipoprotein (HDL) Potassium Sodium Total Bilirubin Total Protein Triglyceride Prostate Specific Antigen (PSA) Thyroid Stimulating Hormone (TSH) Hemoglobin A1c The inspector noted the routine calibrators for the 21 analytes outlined above as two point and requested to review documentation of calibration verification with three or more calibrators at the expected six month June 2025 due date. No documentation was available for review. 3. Review of the manufacturer's online operations manual revealed instructions, "linearity studies are performed every 6 months to verify calibration for all assays that have a calibration curve of less than 3 points". 4. The inspector inquired regarding the laboratory's policy for calibration verification studies for the Abbott Alinity ci Series chemistry testing. The laboratory Technical Consultant (TC) stated on 7/29/25 at 3:30 PM, "the protocol is to run calibration verification studies every six months. I ordered the cal verifiers and have them in the refrigerator but have not had time to assay and evaluate them yet." 5. Interviews with the TC on 7/29/25 at 3:30 PM and an off-site follow up exit interview on 7/31/25 at 2:00 PM with the lab manager confirmed the above 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.

This STANDARD is not met as evidenced by:  
 Based on a review of quality control (QC) monthly statistical reports, policies, lack of documentation, and interviews, the laboratory failed to follow policy to document monthly chemistry/endocrinology QC statistical review and failed to identify the lapse in review during eight (8) of twenty-four (24) months (timeframe August 2023 through July 2025). Findings include: 1. During a review of the monthly Abbott Alinity chemistry QC files for the 24 month survey timeframe of August 2023 through July 2025, the inspector noted no monthly Levey Jennings (LJ) statistical reports for the following twenty-five (25) analytes in months of March, April, May 1

through May 19, August, September, October, November, and December of calendar year 2024: Albumin Alkaline Phosphatase Alanine Aminotransferase (ALT) Aspartate Aminotransferase (AST) Blood Urea Nitrogen (BUN) Calcium Cholesterol Chloride Carbon Dioxide (CO2) Creatinine Direct Bilirubin Glucose Cholesterol, High Density Lipoprotein (HDL) Potassium Sodium Total Bilirubin Total Protein Triglyceride Prostate Specific Antigen (PSA) Thyroid Stimulating Hormone (TSH), Thyroxine (T4), Free T4 Vitamin B12 25-OH Vitamin D Hemoglobin A1c The inspector requested the LJ review documentation for the 25 analytes during the 8 months outlined above. The records were not available for review. 2. Review of the laboratory's policies revealed a quality assurance (QA) plan that outlined that hematology and chemistry analyzers' LJ reports to be "reviewed on a monthly basis in order to assess and correct analytic problems". The inspector inquired regarding corrective action records for the lapses in monthly QC review. No corrective documentation records were available. 3. Interviews with the Technical Consultant on 7/29/25 at 3:30 PM and an off-site follow up exit interview on 7/31/25 at 2:00 PM with the lab manager confirmed the above 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 a review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records, quality control (QC) monthly statistical reports, policies, lack of documentation, and interviews, the laboratory director (LD) failed to provide overall direction and management of the laboratory services. The LD failed to: 1. ensure the overall quality of the laboratory services provided. Refer to D6016; 2. ensure corrective action was documented for unsuccessful PT performance noted on two of five chemistry and unsatisfactory performance for one of five hematology PT events reviewed during the recertification inspection on July 29-31, 2025. Refer to D6019; 3. ensure that monthly chemistry /endocrinology QC statistical review was performed per policy and failed to identify the lapse in review during eight (8) of twenty-four (24) months reviewed (timeframe August 2023 through July 2025). Refer to D6023.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on a review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interview, the laboratory director (LD) failed to ensure the overall quality of the laboratory services provided. The LD failed to ensure successful participation in their Health and Human Services (HHS) approved PT program. Refer to D2096 A, B.

<p><b>D6019</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;</p> <p>This STANDARD is not met as evidenced by:  Based on a review of the Center for Medicaid and Medicare Services (CMS) CASPER 0155 and CMS Survey Summary 0096D reports, the laboratory's proficiency testing (PT) records and interviews, the laboratory director failed ensure corrective action was documented when unsuccessful PT performance was reported by American Proficiency Institute on two of five chemistry events and unsatisfactory scores on one of five hematology events as reviewed during the recertification inspection July 29-31, 2025 (survey timeframe August 2023 through July 2025). Refer to D2096 A,B and D2127.</p>
<p><b>D6023</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1407(e)(6)</p> <p>(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;</p> <p>This STANDARD is not met as evidenced by:  Based on a review of quality control (QC) monthly statistical reports, policies, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that monthly chemistry/endocrinology QC statistical review was performed per policy and failed to identify the lapse in review during eight (8) of twenty-four (24) months reviewed (timeframe August 2023 through July 2025). Refer to D5791.</p>
<p><b>D6055</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(9)</p> <p>(b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by:  Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedures, new analyzer installation validation records, manufacturer's users guide, laboratory personnel files, and interviews, the technical consultant (TC) failed to document training and competency evaluations for one (1) of four (4) testing personnel (TP) after a chemistry analyzer change occurred in the laboratory in December 2023. Findings include: 1. Review of the CMS 209 form with the laboratory manager on 7/29/25 revealed that the laboratory director identified one TC and 4 TP responsible for non-waived chemistry patient testing during the review timeframe of August 2023 through the dates of the inspection July 29-31, 2025. 2. Review of chemistry procedures revealed the laboratory moved in December 2023 from an Abbott Architect Series to the Abbott Alinity ci Series for all chemistry, endocrinology, and immunoassay patient testing. 3. Review of the laboratory's instrument validation records revealed the new analyzer installation</p>

(Alinity ci Series Serial Number AC06235, AI26254) was performed by a field service technical specialist in November 2023 with a go live date of 12/5/23. 4. Review of the Alinity ci Series online user's guide revealed that the manufacturer required "Training Checklist to be completed prior to patient testing". 5. Review of the laboratory personnel files and installation records revealed that TP Number 1 (TP #1) lacked an Alinity ci Series Training checklist and competency assessment (See Personnel Code Sheet). The inspector requested to review the training/competency evaluations for TP #1 for operating the Alinity ci Series. No documentation was available for review. The TC stated on 7/30/25 at 11:30 AM, "We sent two techs to Texas for training and Abbott field service trained the remaining staff onsite. I will have to reach out to our representative to ask for the missing training record." (See Personnel Code Sheet.) 6. An off-site follow up exit interview on 7/31/25 at 2:00 PM with the lab manager confirmed the above findings