| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>11D2171780 | **(X3) Date Survey Completed**<br><br>09/10/2026 |
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| **Name of Provider or Supplier**<br><br>Southern Primary Care | **Street Address, City, State**<br><br>101 Willie Lee Parkway, Suite 400, Warner Robins, GA | |

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 |
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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) Initial survey was completed on September 10, 2026. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview, facility document review, and facility policy review, the laboratory failed to obtain the required signatures on proficiency testing attestation statements/forms for 7 of 10 events reviewed. Findings included: A laboratory policy titled, "Proficiency Testing Policy," implemented 03/01/2025, revealed, "C. The testing person and laboratory director must attest to the routine integration of the samples into the patient workload." Per the policy, "5. The testing person must sign /date the attestation statement. 6. Have the attestation statement signed by the laboratory director or delegated designee." The "Attestation Statement" for the "2025 Hematology / Coagulation - 2nd Event" electronically submitted 07/26/2025, revealed no evidence to indicate the Attestation Statement was signed by the Laboratory Director (LD). The "Attestation Statement" for the "2025 Chemistry - Core - 3rd Event" electronically submitted 09/10/2025, revealed no evidence to indicate the Attestation Statement was signed by the LD. The "Attestation Statement" for the "2025 Hematology / Coagulation - 3rd Event" electronically submitted 11/11/2025, revealed no evidence to indicate the Attestation Statement was signed by the LD or the person(s) who performed the test. The "Attestation Statement" for the "2026 |

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| | Hematology / Coagulation - 1st Event" electronically submitted 03/26/2026, revealed no evidence to indicate the Attestation Statement was signed by the LD. The "Attestation Statement" for the "2026 Chemistry - Core - 2nd Event" electronically submitted 06/10/2026, revealed no evidence to indicate the Attestation Statement was signed by the LD or the person(s) who performed the test. The "Attestation Statement" for the "2026 Hematology / Coagulation - 2nd Event" electronically submitted 07/14/2026, revealed no evidence to indicate the Attestation Statement was signed by the person(s) who performed the test. The "Attestation Statement" for the "2026 Chemistry - Core - 3rd Event" electronically submitted 09/08/2026, revealed no evidence to indicate the Attestation Statement was signed by the LD or the person(s) who performed the test. During an interview on 09/10/2026 at 11:40 AM, the Technical Consultant stated it was an oversight as to why the attestation statements were not signed. During an interview on 09/10/2026 at 3:15 PM, the LD stated he did not realize the attestation statements had to be signed. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview, facility document review, and facility policy review, the laboratory failed to follow ensure competency evaluation/assessments were completed and signed per the laboratory policy for 2 of 2 personnel files reviewed. Findings included: A laboratory policy titled, "Competency Assessment - Testing Personnel," implemented 03/01/2025, revealed, "B. Evaluating and documenting the performance of testing personnel must be conducted initially at post training and prior to testing and reporting test results, semiannually during the first year the individual tests patient specimens, and annually thereafter." A laboratory policy titled, "Technical Consultant Job Description/Personnel Records Checklist/Competency Evaluation," implemented 03/01/2025, revealed, "A. It is the responsibility of the laboratory director to review and approve the duties and responsibilities described below for CLIA [Clinical Laboratory Improvement Amendments] personnel Moderate complexity testing." Review of Testing Personnel (TP) #2's personnel file with a hire date of 12/16/2024 revealed evidence of only an annual "Testing Personnel Competency Assessment Form" dated 01/29/2026 and signed by TP #2, the Technical Consultant (TC), and the Laboratory Director (LD). The "Technical Consultant Competency Evaluation Form" dated 12/01/2025 and signed by the TC revealed no evidence to indicate the form was signed by the LD. During an interview on 09/10/2026 at 11:30 AM, the TC was asked to provide documentation of initial and semi-annual competency for the testing personnel. The TC stated those competencies were not performed. The TC was asked to provide a copy of her competency signed by the LD and she stated the LD did not sign her competency assessment. During an interview on 09/10/2026 at 3:15 PM, the LD stated he did not realize the competency forms had to be signed. |
| **D5293** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(b)(c)<br><br>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and |

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| | procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview, facility document review, and facility policy review, the laboratory failed to document all general laboratory systems quality assessment activities for 4 of 8 months reviewed. Findings included: A laboratory policy titled, "Quality Management and Assessment Plan," implemented 03/01/2025, revealed, "C. An assessment checklist is used as a tool to document the audits performed of all the quality systems. D. The review or assessment is performed monthly, quarterly, semi-annually, and annually initially, and will be reviewed in the future by the laboratory director if more reviews are deemed necessary." The "Quality Systems Assessment Checklist QM001A" revealed there was no evidence of assessment forms for 05/2026, 06/2026, 07/2026, or 08/2026. The assessment forms for 01/2026, 02/2026, 03/2026, and 04/2026 were not signed by the Laboratory Director (LD). During an interview on 09/10/2026 at 2:20 PM, the Technical Consultant stated the assessment forms for 05 /2026, 06/2026, 07/2026, and 08/2026 were not done because she was out on sick leave. During an interview on 09/10/2026 at 3:15 PM, the LD stated he did not realize the assessment forms had to be signed. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and<br><br>This STANDARD is not met as evidenced by:<br>Based on interview, facility document review, and facility policy review, the Laboratory Director (LD) failed to ensure performance on 2 of 10 proficiency testing (PT) events reviewed was evaluated. Findings included: A laboratory policy titled, "Proficiency Testing: Results Evaluation and Documentation of Corrective Action," implemented 03/01/2025, revealed, "Procedure A. Evaluation of Result Summary Report 1. Upon receipt of the evaluation report from the PT provider, the laboratory director or designee must review all results reported. 2. Any discrepancies in results must be investigated and corrective action(s) must be taken and documented for the following instances: a. A score of 80% or less regardless of the SDI [standard deviation interval]. b. Any unacceptable result for a specimen or sample. c. Any unsuccessful performance. d. Any consecutive unsuccessful performance. e. When the result received is 'ungraded' or 'educational challenge', evaluate the result against the participant summary report to determine the laboratory's performance and document corrective action if the result failed to agree with the majority of the participants." The policy specified, "B. Documentation of the Evaluation and Corrective Action for Failures 1. The evaluation and corrective action must be taken and documented on the PT Result Failure and Corrective Action form." The American Proficiency Institute "Comparative Evaluation" for the "2025 Hematology / Coagulation - 3rd Event" revealed the laboratory obtained an unacceptable result for hematocrit DXH-14 sample and the red cell count DXH-14 sample. The American Proficiency Institute "Comparative Evaluation" for the "2026 Chemistry - Core - 1st Event" revealed the bilirubin CH-05 was not graded. During an interview on 09/10/2026 at 11:40 AM, the |

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| | Technical Consultant (TC) stated she did not realize unacceptable results on individual PT samples had to be evaluated. The TC explained that the failure to document the evaluation of the ungraded bilirubin sample was an oversight. During an interview on 09/10/2026 at 3:15 PM, the LD stated he was not made aware of the unacceptable and ungraded results that needed to be reviewed. |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<br><br>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on interview and facility policy review, the Laboratory Director (LD) failed to ensure a Declaration of Delegation of Duties was completed for 1 of 1 Technical Consultant (TC) employed by the laboratory. Findings included: A laboratory policy, "Laboratory Director Job Description/Personnel Records Checklist," implemented 03 /01/2025 revealed, "A. It is the responsibility of the laboratory director to review and approve the duties and responsibilities described below for CLIA [Clinical Laboratory Improvement Amendments] personnel Moderate complexity testing." Per the policy, "C. The laboratory director may delegate his/her duties to his/her qualified subordinates in writing. A Declaration of Delegation of Duties (Form #QM003A) is utilized for this purpose." Review of the TC's personnel file revealed no evidence to indicate the Delegation of Duties form had been completed or signed by the LD. During an interview on 09/10/2026 at 3:15 PM, the LD stated he did not realize the Delegation of Duties form had to be completed. |