Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1102656	05/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
C S Sewell Md Pc	341 West Central Ave, Jamestown, TN	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), personnel records, American Proficiency Institute (API) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that one of two testing personnel (TP) who routinely performed patient Complete Blood Count (CBC) testing also participated in proficiency testing in 2022 and 2023. The findings include: 1. Observation of the laboratory on 05/20/24 at 8:30 a.m. revealed a Beckman Coulter DxH 520 analyzer (ID: 83354869) for patient CBC testing. 2. A review of the FORM CMS-209 revealed two persons (TP-1 and TP-2) who perform moderately complex patient testing. 3. A review of the laboratory's personnel records revealed that TP-1 and TP-2 both perform patient testing for CBC. TP-1 is an established testing person. The laboratory completed TP-2's initial competency for CBC testing on 03/24/22. 4. A review of the laboratory's API PT attestation statements revealed that TP-2 did not participate in any CBC PT events. 5. An interview with TP-1 on 05/20/24 at 1:30 p.m. confirmed that TP-2 routinely performed patient CBC testing and did not participate in any PT events in 2022 and 2023.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on laboratory observation, review of the Clinical Laboratory Improvement Amendments Application for Certification (Form CMS-116), review of American Proficiency Institute (API) proficiency testing (PT) records, review of the laboratory's Quality Assurance (QA) plan, lack of records, and staff interviews, the laboratory failed to verify the accuracy of urine microscopic sediment exam testing twice a year in 2022 and 2023, with an average of 1224 tests performed annually. The findings include: 1. Observation of the laboratory on 05/20/24 at 8:30 a.m. revealed laboratory personnel performing manual microscopic exams on concentrated urine sediment (patient IDs: 12968, 14499, and 12023). 2. A review of the laboratory's Form CMS-116 revealed the laboratory performed approximately 1224 urine microscopic exams annually. 3. A review of the laboratory's 2022 and 2023 API records revealed that the laboratory did not enroll in external PT to evaluate urine microscopic exam testing accuracy. 4. A review of the section "4. Comparision of Test Results" in the laboratory's QA plan revealed the following statement: -"Our lab will verify the accuracy of backup instruments or any test that are not enrolled in a proficiency testing program." 5. No records for twice-yearly verification of the accuracy of urine microscopic exams were available for review. 6. An interview with TP-1 on 05/20/24 at 1:30 p.m. confirmed that the laboratory failed to verify the accuracy of urine microscopic sediment exam testing twice yearly in 2022 and 2023.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the Clinical Laboratory Improvement Amendments Application for Certification (Form CMS-116), review of the laboratory's policy and procedure manual, and staff interview, the laboratory failed to establish a written policy for urine sediment exam testing, with an average of 1224 tests performed annually. The findings include: 1. Observation of the laboratory on 05 /20/24 at 8:30 a.m. revealed laboratory personnel performing manual microscopic exams on concentrated urine sediment (patient IDs: 12968, 14499, and 12023). 2. A review of the laboratory's Form CMS-116 revealed the laboratory performed approximately 1224 urine microscopic exams annually. 3. A review of the laboratory's policy and procedure manual revealed that no written procedure for performing urine microscopic exam testing was available for reference. 4. An interview with TP-1 on 05 /20/24 at 1:30 p.m. confirmed that the laboratory did not have a written policy for urine microscopic sediment exams.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assurance (QA) plan, QA records, and staff interviews, the laboratory director failed to ensure the maintenance of the QA plan in 2022, 2023, and 2024 (a total of 28 months reviewed). The findings include: 1. A review of section "10. Quality Assurance Review" in the laboratory's QA plan revealed the following statements: -"We will perform a quality review at least monthly and review the results with the laboratory director or technical consultant for their approval." -"The laboratory director or consultant will initial and date our written reviews and actions." 2. A review of the laboratory's "Annual Quality Assurance Summary" logs revealed no initials or dates listed in the "Reviewed by Director" spaces from January 2022 to April 2024. 3. An interview with TP-1 on 05/20/24 at 1: 30 p.m. confirmed no records of the laboratory director's review and approval of the quality assurance activities were available for 2022, 2023, and 2024.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), the laboratory's Quality Assurance (QA) plan, testing personnel (TP) records, and staff interviews, the technical consultant failed to evaluate the annual competency of one of two testing personnel in 2022 and two of two testing personnel in 2023 performing complete blood count (CBC) patient testing. The findings include: 1. A review of the FORM CMS-209 revealed two persons (TP-1 and TP-2) who perform moderately complex patient testing. 2. A review of the section "6. Personnel Assessment" in the laboratory's QA plan revealed the following statement: -"At least annually, the laboratory director and /or technical consultant will review the performance of each employee working in the laboratory to assure employee competency." 3. A review of the laboratory's testing personnel records revealed that TP-1 and TP-2 both perform patient CBC testing. There was no documented 2022 or 2023 competency for TP-1 and no 2023 competency for TP-2. 4. An interview with TP-1 on 05/20/24 at 1:30 p.m. confirmed that TP-1 did not have an annual competency assessment in 2022 and that both TP-1 and TP-2 did not have a yearly competency assessment in 2023.