Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0861025	10/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Sodhi Medical Services	1010 W Clay St, Danville, IL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory director (LD) failed to attest to the routine integration of proficiency testing samples into the patient workload using the laboratory's routine methods for microscopic urinalysis testing. Findings include: 1. Review of the 2021 Hematology /Coagulation Proficiency testing (PT) event two failed to identify the testing personnel which performed urine sediment testing. 2. Review of the 2020 Hematology /Coagulation Proficiency testing (PT) event three failed to identify the testing personnel which performed urine sediment testing. 3. Review of the 2020 Hematology /Coagulation PT event two revealed that the LD failed to sign the attestation statement under the header "Lab Director or designee" to attest to the routine integration of samples into the patient workload using the laboratory's routine methods. 4. During survey date of 10-6-2021 at 10:37 A.M., TP #1 confirmed that the LD ran the urine sediment test, but the LD did not sign the attestation statement under the header "Person(s) Performing the Test.". 5. Interview with TP#1 on 10-6-2021 at 2:57 pm confirmed the above findings.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with testing personnel (TP) #1; the laboratory failed to attain a score of at least 80 percent of acceptable responses for the analyte glucose from the second proficiency testing (PT) event of 2019, resulting in unsatisfactory analyte performance for the testing event. Findings include: 1. Review of the 2019 routine chemistry PT event two identified a score of 20% for analyte, glucose. 2. Review of PT documentation found no corrective action documented for the unsatisfactory analyte performance for glucose. 3. Interview with TP#1 on 10-6-21 at 2:57pm, confirmed the laboratory failed to document a corrective action of the glucose analyte failure for PT event 2 of 2019.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP #1); the laboratory failed to evaluate ungraded alanine aminotransferase (ALT) samples (See D5213), document all proficiency testing evaluation and verification activities for albumin proficiency testing (PT) sample failures (See D5221), outline all control procedures for chemistry testing on the Alfa Wassermann Ace Axcel (See D5403), perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for chemistry testing performed on the ACE Axcel analyzer (See D5429), and establish and verify the criteria for acceptability of control materials for chemistry testing on the ACE Axcel analyzer (See D5469).
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with testing personnel (TP #1); the laboratory failed to document all proficiency testing evaluations for microscopic urinalysis proficiency testing (PT) samples that were not evaluated by the PT provider for event three of 2020. Findings include: 1. Review of laboratory PT records identified that one of two microscopic urine sediment samples (US-06) for PT event three of 2020 was not graded by the PT provider. 2. Review of the laboratory's PT records found no self-evaluation for the urine sediment sample US-06 that was not graded by the PT provider. 3. Interview with TP#1 on 10-6-21 at 2:57pm confirmed the non-graded sample was not evaluated by the laboratory. B. Based on review of laboratory records and interview with testing personnel (TP #1); the laboratory failed to document all proficiency testing evaluations for the chemistry analyte alanine aminotransferase (ALT) when a proficiency testing (PT) sample was not evaluated by

	the PT provider for event one of 2021. Findings include: 1. Review of the laboratory's PT records identified that one of five ALT samples (CH-02) for PT event one of 2021 was not graded by the PT provider. 2. Review of the laboratory's PT records found no self-evaluation for ALT CH-02 sample that was not graded by the PT provider. 3. Interview with TP#1 on 10-6-21 at 2:57 pm confirmed the non-graded sample was not evaluated by the laboratory.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: A. Based on review of laboratory records and interview with testing personnel (TP #1); the laboratory failed to document all proficiency testing evaluation and verification activities for microscopic urinalysis proficiency testing (PT) failure during event one of 2020. Findings include: 1. Review of laboratory PT records identified an unacceptable grade (50%) for microscopic urinalysis PT during event one of 2020. a. Sample B - Unacceptable 2. Review of the laboratory's PT records found no corrective action was documented for the microscopic urinalysis failure for this PT event. 3. Interview with TP#1 on 10-6-21 at 2:57 pm confirmed the above findings. B. Based on review of laboratory records and interview with testing personnel (TP #1); the laboratory failed to document all proficiency testing evaluation and verification activities for albumin proficiency testing (PT) sample failure during event one of 2021. Findings include: 1. Review of laboratory PT records identified an unacceptable grade for the sample CH-02 for albumin during PT event one of 2021. a. Albumin Sample CH-02 - Unacceptable 2. Review of the laboratory's PT records found no corrective action was documented for the sample failure for albumin for this PT event. 3. Interview with TP#1 on 10-6-21 at 2:57 pm confirmed the above findings.
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: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to outline all control procedures for chemistry testing on the Alfa Wassermann Ace Axcel. Findings include: 1. Review of the policy and procedure manual identified the policy, "Test Procedures", which stated to refer to the operator's manual for all testing on the Alfa Wassermann Ace Axcel. 2. Review of the operator's manual for the Alfa Wassermann Ace Axcel (Revision C, 12/15) failed to outline quality control procedures for quality control acceptability for chemistry testing. 3. Review of the Quality control check parameters for the Ace Axcel Clinical Chemistry analyzer found no defined standard deviation rules were in place for the following analytes: creatinine, carbon dioxide (CO2), creatine kinase (CK), aspartate aminotransferase (AST), and alanine transaminase (ALT). See D5469. 4. On survey date 10/6/21 at 12:36 P.M., TP #1 confirmed that the 2 Standard Deviation (SD) range was being used on the instrument although this was not listed in the procedure and how to proceed when chemistry controls fall outside the 2SD range of acceptability. 5. On date of survey 10-6-21 at 2:57 P.M., TP #1 confirmed the laboratory failed to outline quality control acceptability criteria for all chemistry analytes tested on the Alfa Wassermann Ace Axcel chemistry analyzer.
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: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer for chemistry testing performed on the ACE Axcel in 2020 through 2021. Findings include: 1. Review of the manufacturer's operator's manual for the ACE Axcel chapter 10 defines the maintenance procedures and states "periodic maintenance procedures must be performed on the ACE Axcel Clinical Chemistry System in order to assure consistent efficient performance or to repair or replace user-serviceable components. Certain procedures are to be performed at a specified scheduled frequency whereas unscheduled maintenance procedures are performed on an as-needed basis. All maintenance procedures performed on the instrument must be documented in a maintenance log in order to comply with CLIA 88 requirements." 2. Review of the Ace Axcel Clinical Chemistry System Maintenance Logs found the laboratory failed to document the following maintenance items: Daily Shut Down maintenance was not documented 42 of 87 days for 4 of 4 months reviewed. 9-2-2021 9-9-2021 9-13-2021 9-15-2021 9-21-2021 9-22-2021 9-29-2021 4-08-2021 4-14-2021 4-21-2021 4-26-2021 4-27-2021 4-29-2021 12-01-2020 12-03-2020 12-08-2020 12-16-2020 12-21-2020 12-22-2020 12-23-2020 4-1-2020 4-2-2020 4-3-2020 4-6-2020 4-7-2020 4-8-2020 4-9-2020 4-10-2020 4-13-2020 4-14-2020 4-15-2020 4-16-2020 4-17-2020 4-20-2020 4-21-2020 4-22-2020 4-23-2020 4-24-2020 4-27-2020 4-28-2020 4-29-2020 4-30-2020 Weekly Maintenance was not documented for 1 of 39 weeks reviewed in 2021 -Week of July 26-30, 2021 Bi-annual replacement of ISE pump tubing and ISE electrode inspection from September 2019 through September 2021 - No ISE Electrode inspection documented from September 2021 through September of 2019 -

	ISE pump tubing replaced only documented 1 time (8-2021) from 9-2019 though 9-2021. Annual - Replace All ISE Tubing - Not documented from September of 2019 through September of 2021 3. Interview with TP#1 on 10-6-21 at 2:57 pm confirmed the laboratory failed to document/perform all maintenance activities as required by the manufacturer for the ACE Axcel analyzer.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to establish and verify the criteria for acceptability of control materials for chemistry testing performed on the Ace Axcel analyzer in 2021. Findings include: 1. Review of Operator's Manual for the Ace Axcel Clinical Chemistry System identified a procedure for defining a new control. a. Instructions state that the expected values for mean and standard deviation must be entered manually and to consult the package insert for expected values. 2. Interview with TP#1 at 12:36pm on 10-06-21 confirmed the laboratory uses two standard deviations as acceptability criteria for chemistry controls based on the information provided in the package insert. 3. Review of the Quality control check parameters for the Ace Axcel Clinical Chemistry analyzer found no defined standard deviation rules were in place for the following analytes: creatinine, carbon dioxide (CO2), creatine kinase (CK), aspartate aminotransferase (AST), and alanine transaminase (ALT). 4. Review of the Ace Axcel Clinical Chemistry System setup control values, found that the quality control acceptability ranges were not in line with the manufacturer's product inserts for level one (1501UNCM) and level two (1166UECM) that were put into use on 4-22-2021 and 5-3-2021, respectively. 5. Review of the manufacturer's inserts for the chemistry controls and the setup values for the controls found programmed in the Ace Axcel analyzer found the laboratory failed to enter the new standard deviations (SD) for the assayed control materials currently in use for 12 of 18 level 1 (1501UNCM) analytes and 16 of 18 level two (1166UECM) analytes. Level 1 - 1501UNCM Analyte Product Insert SD SD in Instrument Albumin 0.14 0.15 ALP* 4.4 4.6 ALT 3.5 2.8 AST 3.3 2.9 Total bilirubin 0.13 0.13 BUN* 0.8 0.9 Calcium 0.32 0.32 Cholesterol 3.7 3.6 CK 8.5 8.5 CO2 0.99 1.18 Creatinine 0.1 0.1 Glucose 3.3 3.3 HDL* 1.9 1.5 Total Protein 0.15 0.16 Triglycerides 5.1 5.6 Sodium 4.59 5.00 Potassium 0.167 0.167 Chloride 3.56 3.62 Level 2 - 1166UECM Analyte Product Insert SD SD in Instrument Albumin 0.23 0.22 ALP* 26.7 28.8 ALT 9.2 7.4 AST 14.3 13.6 Total bilirubin 0.35 0.39 BUN* 3.3 3.1 Calcium 0.40 0.39 Cholesterol 6.6 6.8 CK 26.4 28.4 CO2 2.03 2.03 Creatinine 0.372 0.362 Glucose 10.3 10.1 HDL* 3.4

	3.5 Total Protein 0.26 0.25 Triglycerides 9.8 8.8 Sodium 4.09 4.21 Potassium 0.167 0.167 Chloride 2.69 2.73 6. On date of survey 10-6-21 at 2:57 P.M., TP #1 confirmed the laboratory failed to enter the new standard deviation values from the manufacturer's insert for the level one and level two quality control lots in use and define the acceptability criteria in the analyzer for all chemistry analytes. **ALP - alkaline phosphatase, BUN - Blood Urea Nitrogen, HDL - High Density Lipoprotein
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP #1); the technical consultant failed to evaluate and document the performance of one of one new TP at least semiannually during the first year the individual tests patient specimens. Findings include: 1. Review of testing personnel competency records identified new testing personnel, TP #4. 2. Review of Sodhi Medical Services Laboratory Competency Skills Checklist indicated that TP #4 had a start date of 8-5-2020 and a competency assessment for TP #4 was documented on 2-17-2021. 3. Interview with TP#1 on 10-6-2021 at 2:57pm confirmed the laboratory failed to perform a second semi-annual competency assessment for TP #4 from 8-5-2020 to 8-4-2021.