Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0861025	05/30/2019
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
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: A. Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to outline all required components of test procedure 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 the following required components of a test procedure: a. Preparation of reagents used in testing. b. Control procedures. c.

	Calibration and Calibration Verification procedures. d. Corrective action to take when control or calibration results fail to meet the laboratory's criteria for acceptability. e. Description of the course of action to take if a test system becomes inoperable. 3. During survey date 05-30-2019, at 1:00 pm, the above findings were confirmed by TP #1. B. Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to outline all required components of the microscopic urinalysis test procedure. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Urine Microscopy", which failed to outline the following required components: a. Microscopic examination, including the detection of inadequately prepared slides. b. Step-by-step performance including interpretation of results. c. Control procedures. d. Corrective action to take when controls fail to meet the laboratory's criteria for acceptability. e. The laboratory's system for entering results in the patient record. f. Description of the course of action to take if a test system becomes inoperable. g. Reference intervals (normal values). h. Pertinent literature references. 2. During survey date 05-30-2019, at 1:00 pm, the above findings were confirmed by TP #1.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. 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 perform and document centrifuge preventative maintenance for microscopic urinalysis testing. Findings Include: 1. Direct observation during tour of the laboratory facility on 5-30-2019 at 9:15am identified a PSS 602L centrifuge. 2. Interview with TP#1 on survey date 5-30-2019, at 9:15 am, confirmed the PSS 602L centrifuge is used to spin down urine samples for microscopic urinalysis testing. 3. Review of the operation manual for the PSS 602L centrifuge on page 4, under the heading of calibration, recommends the centrifuge's RPM be calibrated at least every 6 months. 4. Review of preventive maintenance records failed to document RPM calibrations at 6 month intervals for 2017 through the date of survey (5-30-2019) in 2019. 5. On survey date 5-30-2019, at 1:00 pm, the surveyor findings were confirmed by TP#1.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	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 establish and perform functional checks for the centrifuge timer used when performing microscopic urinalysis testing. Findings Include: 1. Direct observation during tour of the laboratory facility on 5-30-2019, at 9: 15am, identified the PSS 602L centrifuge. 2. Interview with TP#1 on survey date 5-30-2019, at 9:15 am, confirmed the PSS 602L centrifuge is used to spin down urine samples for microscopic urinalysis testing. 3. Review of the operation manual for the PSS 602L centrifuge failed to define criteria for functional checks of the centrifuge timer. 4. Review of the laboratory procedure, "Urine Microscopy", indicates, in step 6, that samples should be spun for 5 minutes. 5. Review of preventive maintenance records failed to identify a protocol to check the centrifuge timer and no timer checks were documented in 2017 through the date of survey (5-30-2019) in 2019. 6. On survey date 5-30-2019, at 1:00 pm, the surveyor findings were confirmed by TP#1.
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: Based on review of laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory failed to conduct 6 month calibration verifications as required for chemistry analytes on the Alfa Wassermann Ace Axcel in 2018 through the date of survey (5-30-19) in 2019. Findings include: 1. Review of the laboratory's policy and procedure manual found the laboratory failed to outline the calibration verification procedure for chemistry testing on the Alfa Wassermann Ace Axcel chemistry analyzer. See D5403. 2. Review of the calibration verification records found the laboratory documented calibration verifications in March of 2017, November of 2017, and June of 2018 for all analytes tested on the Alfa Wassermann Ace Axcel. 3. Interview on 5-30-2019, at 1:00 pm, with laboratory TP#1 confirmed no calibration verification had been performed for chemistry analytes tested on the Alfa Wassermann Ace Axcel afer the June 2018 calibration verification.

D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review laboratory records and interview with testing personnel (TP) #1; the laboratory failed to indicate all the required components of a test report for 3 of 3 microscopic urinalysis patient test reports reviewed. Findings Include: 1. Review of 3 of 3 microscopic urinalysis test reports failed to indicate the test performed and the interpretation of the test results. Patient Identification Test Date P6 04-23-2019 P7 06-26-2018 P8 10-18-2017 2. On survey date 5-30-2019, at 1:00 pm, TP#1 confirmed the above findings.