Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1047507	04/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Western Slope Laboratory	1197 Rochester Road Suite K, Troy, MI	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on procedure manual review and interview with the Quality Assurance Supervisor (QAS), the laboratory director failed to approve, sign, and date each procedure biennially for 2 of 2 years. Findings include: 1. A review of "Laboratory SOPs and Guidelines" and the"Quality Systems Management" procedure revealed the laboratory director failed to approve, sign, and date procedures biennially for 2017 and 2018. Procedures include: a. Instrument Cleaning #27, last approved March 2015. b. Laboratory Receiving #31, last approved June 2015. c. Calibrating Centrifuges #41, no approval dates between July 2013 and October 2018. d. Glassware Cleaning #50, last approved November 2015. e. Creating a Validation Plan #1020, last approved August 2016. 2. An interview on 4/22/19 at 10:35 am with the QAS confirmed the procedures listed above were not approved, signed or dated biennially according to the laboratory's "Quality Systems Management" procedure.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 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. The laboratory must 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 record review and interview with the Quality Assurance Supervisor (QAS), the laboratory failed to perform and document weekly and monthly maintenance for 3 of 5 Ab Sciex Qtrap 5500 instruments according to the manufacturer. Findings include: 1. Review of the weekly, monthly, and quarterly maintenance logs revealed a lack of documentation and performance of the following Ab Sciex Qtrap 5500 instruments in 2017 and 2018: a. Ab Sciex Qtrap 5500 (MSG) 1. Weekly maintenance was not performed as follows: a. 1 of 4 weeks in October, November, and December of 2017. b. 1 of 4 weeks in January and February of 2018. c. 3 of 4 weeks in June 2018. 2. Monthly maintenance was not performed during the following months: a. November 2017. b. January, June, July, August, September, October, November, and December of 2018. b. Ab Sciex Qtrap 5500 (MSB) 1. Weekly maintenance was not performed as follows: a. 1 of 4 weeks in August, October, November, and December of 2017. b. 2 of 4 weeks in September 2017. c. 2 of 4 weeks in May and September of 2018. d. 3 of 4 weeks in June and August of 2018. e. 4 of 4 weeks in July, October, November, and December of 2018. 2. Monthly maintenance was not performed during the following months: a. September and October 2017. b. July, August, October, November, and December 2018. c. Ab Sciex Qtrap 5500 (MSF) 1. Weekly maintenance was not performed as follows: a. 1 of 4 weeks in October and December of 2017. b. 2 of 4 weeks in May and June of 2018. c. 3 of 4 weeks in September 2018. d. 4 of 4 weeks in July, August, October, November, and December of 2018. 2. Monthly maintenance was not performed for the following months: a. November 2017. b. May, June, July, August, September, October, November, and December of 2018. 2. Interview on 4/22/19 at 2:25 pm with the QAS confirmed the lack of documentation and performance of weekly and monthly maintenance for 3 of 5 Ab Sciex Qtrap 5500 analyzers.
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 record review and interview with the Quality Assurance Supervisor (QAS), the laboratory failed to perform chemistry calibration verification (linearity) at least once every 6 months as required for 4 (1 event in 2017, 2 events in 2018, and 1 event in 2019) out of 5 events required. Findings include: 1. A record review revealed a lack of documentation showing linearity was not completed at least every 6 months for the Carolina Liquid Chemistries CLC 6410 analyzer since it was installed 2/28/17. One event in 2017, two events in 2018, and one event in 2019 of linearity testing were not completed for the following tests: a. Specific Gravity b. Oxidants c. pH d. Urine Creatinine 2. An interview with the QAS on 4/22/19 at 1:18 pm confirmed linearity for the tests listed above was not completed at least every 6 months in 2017, 2018, and 2019.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Assurance Supervisor (QAS), the laboratory failed to ensure 28 (9 events in 2017, 19 events in 2018) of 29 proficiency testing final reports were reviewed by the testing personnel. Findings include: 1. A record review of proficiency testing events from 2017 and 2018 revealed a lack of documentation of testing personnel review of proficiency testing final reports for the following testing events: a. 2017 1. OFD - B-D 2. ETB - B 3. Pennsylvania Department of Health II and III 4. UT - B 5. TMU - B 6. SCDD - B 7. DMPM - B b. 2018 1. DMPM - A and B 2. UT - A-C 3. Pennsylvania Department of Health I - III 4. DAI - A and B 5. ETB - A and B 6. DFC - A 7. OFD - A-D 8. TMU - A and B 2. An interview on 4/22/19 at 12:03 pm with the QAS confirmed the testing personnel did not review the final graded proficiency testing reports.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on record review and interview with the Quality Assurance Supervisor (QAS), the laboratory director failed to ensure an approved corrective action plan was established and followed during unsatisfactory proficiency testing for 22 (8 events in

	2017 and 14 events in 2018) of 29 testing events. Findings include: 1. A record review revealed the laboratory did not establish and follow a proficiency testing policy that included a corrective action plan for unsatisfactory results for the following testing events and errors: a. 2017 1. OFD-B and DMPM-B a. Educational Challenge (26). b. Response qualified with a greater than or less than sign; unable to quantitate (28). 2. OFD-C and OFD-D a. (26) b. (28) c. No credit assigned due to absence of response (42). 3. ETB-B and TMU-B a. Result is outside the method/instrument reportable range (22) b. (26) 4. SCDD-B a. (26) b. This drug is not included in our test menu. Use of this code counts as a correct response (44). 5. Pennsylvania Department of Health II a. Unsatisfactory b. 2018 1. DMPM-A and B a. (26) b. (28) 2. UT-B a. Results for this kit were not received (40). 3. DAI-A and B, DFC-A, TMU-A a. 26 4. ETB-A a. 22 5. ETB-B a. 22 b. No credit assigned due to absence of response (42). 6. TMU-B a. 22 b. 26 7. OFD-A-D a. 26 b. 28 c. 44 2. An interview on 4/22/19 at 12:03 pm with the QAS confirmed corrective action had not been completed for the unsatisfactory proficiency testing results listed above.