Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2133403	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
4m Healthcare, Llc	15110 Glenwood, Overland Park, KS	

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
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 review of Proficiency Testing (PT) and interview with the general supervisor on October 5, 2018 at 10:30 AM the laboratory failed to twice annually verify the accuracy of urine pH, creatinine, specific gravity and oxidant.
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 Olympus AU400e calibration and interview with the general supervisor on October 5, 2018 at 11:00 AM the laboratory failed to perform calibration verification of urine pH, creatinine, specific gravity and oxidant including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of range to verify the laboratory's reportable range once every six months in 2018.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 review of Proficiency Testing (PT) results for 2017, 2018 and interview with the general supervisor the laboratory director failed to ensure PT results were reviewed by appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. PT kit 1 for 2017 for the analyte 7-aminoclonazepam was unacceptable and no review of the analyte and no corrective action was documented. 2. PT kit 1 for 2018 for the analytes Nicotine qual, Nicotine quant, Anabasine qual, cotinine qual, cotinine quant, ethylone and butylone were not graded by PT provider and no self-grading by appropriate staff was documented. 3. Interview with the general supervisor on October 5, 2018 at 11:00 AM confirmed the laboratory director failed to ensure PT results were reviewed by appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.