Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2071163	10/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sullivan Medical Clinic	6040 W Lisbon Ave, Ste 200, Milwaukee, WI	

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 surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory director has not attested to the routine integration of the PT samples into the patient workload using the laboratory's routine methods for four of four reviewed PT events in 2017 and 2018 and has not delegated the responsibility in writing to the technical consultant. Findings include: 1. Review of PT records show the laboratory director has not signed the attestation statements for the last two events in 2017 and the first two events in 2018. 2. Interview with the technical consultant on October 16, 2018 at 10:30 AM confirms the director has not signed the attestation statements for four PT events in 2017 and 2018 and has not delegated the responsibility in writing to the technical consultant. This is a repeat deficiency previously cited on June 30, 2014.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with the technical consultant, the laboratory did not verify the accuracy of a Benzodiazepine result that was not scored by the PT program in the Urine Drug Screen (UDS) event UDS-B 2018. Findings include: 1. Review of PT records from event UDS-B in 2018 showed the PT program did not score the Benzodiazepine result for sample UDS-10. No evidence of evaluation by the laboratory is present. 2. Interview with the technical consultant on October 16, 2018 at 10:30 AM confirmed the accuracy of the unscored result had not been verified.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Item one: Based on surveyor observation of control and calibration materials and interview with the technical consultant, the laboratory used materials after the expiration date had passed. Findings include: 1. Observation of supplies in the refrigerator on October 16, 2018 at 10:00 AM revealed a tray that held individual containers of controls and calibrators. Three containers showed expiration dates that had passed. Cedia Buprenorphine high control Lot number 72781885 Expiration Date 2018 09 Cedia Buprenorphine Calibrator 50 Lot number 72629887 Expiration Date 2018 09 DRI Negative Urine Calibrator Lot number 604111151 Expiration Date 2015 06 2. Interview with the technical consultant on October 16, 2018 at 10:30 AM confirmed the tray held supplies in current use. Further interview confirmed the Buprenorphine Control and Calibrator expired September 30, 2018 and the Negative Urine Calibrator expired June 30, 2015. Item two: Based on surveyor observation of control materials, review of the manufacturer's instructions and laboratory records, and interview with the technical consultant, the laboratory used Drug of Abuse Total (DOAT) controls without ensuring the material was not past the open expiration date of the control. Findings include: 1. Observation of DOAT control materials in the refrigerator on October 16, 2018 at 10:00 AM revealed controls that had been opened but were not dated. 2. The manufacturer's instructions for the DOAT control material includes the following statement, "Once opened, vials of control are stable for 30 days when stored tightly capped at 2-8C" (Celsius). 3. Review of laboratory records showed no documentation of dates DOAT control vials were opened. 4. Interview with the technical consultant on October 16, 2018 at 10:30 AM confirmed open expiration dates had not been monitored or documented for DOAT controls.
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 surveyor review of maintenance records for the Indiko Plus analyzer and

	email correspondence with the technical consultant, the laboratory has not documented maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. Findings include: 1. Review of maintenance logs for the Indiko Plus analyzer showed the laboratory discontinued use of the manufacturer's maintenance log in June 2017. The log used since June 2017 does not include monthly or occasional maintenance and does not include the following weekly maintenance tasks: *Clean and check probes and mixing paddle, clean the wash wells. *Clean reagent and sample racks. *Wash liquid and solid waste reservoirs. * Back up database on USB flash drive. The following end of day daily task is not documented: *Empty and disinfect (5% bleach) solid waste and waste water reservoirs. 2. Email correspondence on October 16, 2018 at 3:12 PM with the technical consultant confirmed some of the maintenance on the Indiko Plus analyzer had not been documented with the frequency specified by the manufacturer since June 2017.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with the technical consultant, the procedures do not identify the number and type of control materials required for the seven tests performed on the Indiko Plus Analyzer. Findings include: 1. Review of laboratory procedures showed no reference to the number or type or controls required for the following seven tests performed on the Indiko Plus Analyzer: Amphetamines Benzodiazepines Buprenorphine Cannabinoids (THC) (tetrahydrocannabinol) Cocaine metabolites Opiates Oxycodone 2. Interview with the technical consultant on October 16, 2018 at 10:30 AM confirms the procedures do not define the number and type of controls required for the seven tests performed on the Indiko Plus Analyzer.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on surveyor review of maintenance records and email correspondence with the technical consultant, the consultant did not document oversight of maintenance of the Indiko Plus analyzer. Findings include: 1. Review of maintenance records from 2017 through 2018 show no documented review by the technical consultant. 2. Email correspondence on October 16, 2018 at 3:12 PM with the technical consultant

	confirmed oversight of the maintenance of the Indiko Plus analyzer had not been documented.