Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1092620	02/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Physical Medicine Rehabilitation And Consultant	21675 Coolidge Hwy Suite A, Oak Park, 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
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to have test requests for qualitative urine toxicology testing for patients for 7 (Patients 8605, 9167, 9467, 5553, 9889, 5236, and 8907) of 7 patient test records reviewed. Findings include: 1. A review of patient test records revealed the following patients had qualitative urine toxicology testing performed by the laboratory with a lack of test request available: a. Patient 8605 had testing performed on 6/15/22. b. Patient 9167 had testing performed on 7/27/22. c. Patient 9467 had testing performed on 8/25/22. d. Patient 5553 had testing performed on 10/30/22. e. Patient 9889 had testing performed on 11/17/22. f. Patient 5236 had testing performed on 12/13/22. g. Patient 8907 had testing performed on 1/29/23. 2. An interview on 2/15/23 at 9:36 am with the Technical Consultant confirmed test requests for the patients listed above were not available.
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: . Based on observation and interview with the Technical Consultant, the laboratory

	failed to ensure its EasyRa Surfactant reagent was not used past its expiration date for 3 (November 2022 to February 2023) of 3 months since the reagent had expired on 11 /9/22. Findings include: 1. The surveyor observed 6 bottles of EasyRa Surfactant reagent in the laboratory with the expiration date of 11/9/22 on 2/15/23 at 8:45 am. 2. An interview on 2/15/23 at 9:43 am with the Technical Consultant revealed the expired reagent was in use and is added to the reagent water each date of patient testing.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to perform control procedures each date of patient testing for its qualitative urine toxicology testing for 1 (8/25/22) of 7 patient testing dates reviewed. Findings include: 1. A review of patient test records and quality control records revealed on a lack of quality control performance on 8/25/22 when patients had been tested. 2. A review of the laboratory's "Barbiturate (BARB)", "Benzodiazepine (BENZ)", "Cocaine (COCM)", "Methadone (METD)", "Opiate (OP)", "Amphetamine (AMPH)", and "Oxycodone (OXYC)" procedures revealed a section stating, "Test a positive and negative control each day of testing." 3. An interview on 2/15/23 at 10:09 am with the Technical Consultant confirmed patient testing was performed when quality control had not been performed. A total of 10 patients had received testing on 8 /25/22.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory failed to perform and document corrective actions when freezer temperatures were out of range for urine specimen storage for 8 (10/14/22, 10/21/22, 10/23/22, 11/6/22, 11 /17/22, 11/27/22, 12/13/22, and 12/29/22) of 10 dates between October 2022 and January 2023. Findings include: 1. A review of the laboratory's "Oxycodone (OXYC)", "Opiate (OP)", "Methadone (METHD)", "Cocaine (COCM)", "Benzodiazepine (BENZ)", and "Amphetamines (AMPH)" procedures revealed a section titled, "Specimen" stating, "Note: This laboratory stores specimens at 2-8 degrees C for up to three days and freezes specimens at less than or equal to -20

	degrees C when not tested within the 3 day limit." 2. A review of the laboratory's "Physical Medicine and Rehabilitation Freezer Temperature Log" revealed the following dates when temperature readings were out of range: a. 10/14/22 had a reading of -18.8 degrees C. b. 10/21/22 had a reading of -17.6 degrees C. c. 10/23/22 had a reading of 19.2 degrees C. d. 11/6/22 had a reading of -1 degrees C. e. 11/17/22 had a reading of 0 degrees C. f. 11/27/22 had a reading of -10 degrees C. g. 12/13/22 had a reading of 2 degrees F (-17 degrees C). h. 12/29/22 had a reading of -1 degrees F (-18 degrees C). 3. An interview on 2/15/23 at 2/15/23 at 10:09 am with the Technical Consultant confirmed the dates above were out of the established temperature range for storage of patient urine specimens and corrective action for the specimens stored during this time had not been performed.