Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1092620	10/28/2024
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to attest that proficiency testing samples were tested in the same manner as patient specimens for one (2024 Chemistry Miscellaneous 1st Event) of four proficiency testing events reviewed. Findings include: 1. A review of the laboratory's proficiency testing records revealed 2024 Chemistry Miscellaneous 1st Event's attestation page had not been signed by the testing personnel and the laboratory director documenting that proficiency testing samples were tested in the same manner as patient specimens. 2. An interview on 10/28/24 at 12:06 pm with the technical consultant confirmed an attestation statement had not been completed for the proficiency testing event listed above.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents,

	materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to have an operating analyzer to perform its volume of testing for two (February 2024 to April 2024) months the EasyRA urine toxicology analyzer was not in operation. Findings include: 1. A review of 12 patient test records revealed three patients with the following turnaround timeframes for qualitative urine toxicology testing: a. Patient 7 had a specimen collected 3/12/24, was tested and reported on 4/16 /24. b. Patient 11 had a specimen collected 2/27/24, was tested and reported on 4/17 /24. c. Patient 12 had a specimen collected 2/28/24, was tested and reported on 4/17 /24. 2. An interview on 10/18/24 at 10:29 am with the technical consultant revealed the laboratory's the EasyRA urine toxicology analyzer was down from 2/22/24 to 4/16 /24. Patient specimens were held to be performed once the instrumentation was repaired.
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory failed to verify its qualitative urine toxicology testing at least twice annually (refer to D5217), failed to follow its specimen labeling policies (refer to D5311 A), failed to follow its specimen storage and preservation policies (refer to D5311 B), failed to follow its specimen processing procedures (refer to D5311 C), failed to monitor laboratory, refrigerator and freezer temperatures to ensure proper storage of reagents, specimens, and reliable analyzer operations (refer to D5413), failed to perform control procedures at least each day of patient testing (refer to D5445), failed to perform corrective actions for patients tested when controls failed (refer to D5783), and failed to perform corrective action when the temperatures were out of range (refer to D5785).
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 record review and interview with the technical consultant, the laboratory failed to verify its qualitative urine toxicology testing at least twice annually for one (2023) of two years reviewed. Findings include: 1. A review of the laboratory's test menu revealed it performs urine qualitative testing for the detection of amphetamines, barbiturates, benzodiazepines, cocaine metabolites, methadone, opiates, and oxycodone. 2. A review of the laboratory's proficiency testing records revealed 2023 Chemistry- Miscellaneous 2nd Event for its urine qualitative toxicology testing had not been performed. Only one event was performed in 2023. 3. An interview on 10/28

	/24 at 12:06 pm with the technical consultant confirmed the laboratory had not verified the accuracy of its qualitative urine toxicology testing at least twice annually in 2023.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with the technical consultant, the laboratory failed to follow its specimen labeling policies for 10 of 53 specimens present in the refrigerator. Findings include: 1. The surveyor observed 10 patient urine specimens with only first initial and last names on the urine cups on 10/28/24 at 9:05 am. 2. A review of the laboratory's "Patient Report Forms and ID" policy revealed a section stating, "The patient name and DOB will also be placed on the specimen." 3. An interview on 10/28/24 at 9:23 am with the technical consultant confirmed the laboratory had not followed its specimen labeling policies. B. Based on observation, record review, and interview with the technical consultant, the laboratory failed to follow its specimen storage and preservation policies for of 53 patient urine specimens present in the laboratory's refrigerator. Findings include: 1. The surveyor observed the laboratory's urine specimens in the refrigerator revealed specimens with the following dates of collection: a. 8/21/24, two specimens. b. 8/22/24, 10 specimens. c. 8/26/24, eight specimens. d. 8/27/24, one specimen. e. 8/28/24, two specimens. f. 9/16/24, one specimen. g. 10/7/24, three specimens. h. 10/8/24, eight specimens. i. 10/9/24, three specimens. j. 10/14/24, seven specimens. k. 10/15/24, four specimens. l. 10/16/24, two specimens. m. 10/17/24, one specimen. n. 10/18/24, one specimen. 2. A review of the laboratory's "Amphetamins (AMPH)" test procedure revealed a section titled "Specimen" stating, "Due to the additional drugs tested within the panel, 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." 3. An interview on 10/28/24 at 9:24 am with the technical consultant confirmed the specimens present in the refrigerator were awaiting testing and the specimens listed above had exceeded stability requirements and were not stored frozen. C. Based on observation, record review and interview with the technical consultant, the laboratory failed to follow its specimen processing procedures for two (October 2022 to October 2024) of two years reviewed. Findings include: 1. The surveyor observed turbid and cloudy specimens stored in the laboratory's refrigerator and an unplugged centrifuge on 10/28/24 at 9:05 am. 2. A review of the laboratory's "Amphetamines (AMPH)" revealed a section titled "Patient Testing" stating, "Samples with high turbidity should be centrifuged prior to analysis." 3. An interview on 10/28/24 at 9:24 am with the technical consultant revealed the centrifuge was not in use by the laboratory and urine specimens had not been centrifuged prior to analysis.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to monitor laboratory, refrigerator and freezer temperatures to ensure proper storage of reagents, specimens, and reliable analyzer operations for two (October 2022 to October 2024) two years reviewed. Findings include: 1. A review of the laboratory temperature monitoring logs revealed a lack of documentation for temperature readings between 2/27/24 and 4/16/24 when specimens and reagents were stored in the laboratory's freezer and refrigerator. 2. A review of the laboratory's temperature monitoring logs between October 2022 and October 2024 revealed dates with temperatures out of range. Refer to D5785. 3. A review of the laboratory's "Amphetamines (AMPH)" test procedure revealed a section titled "Specimen" stating, "Due to the additional drugs tested within the panel, 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 days limit." 4. An interview on 10/28/24 at 11: 13 am with the technical consultant revealed temperatures are monitored only on patient testing dates.
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 at least each day of patient testing for one (9/18 /24) of 11 patient testing dates reviewed. Findings include: 1. A review of quality control records from 11 patient testing dates revealed a lack of controls performed for its benzodiazepines, oxycodone, and methadone assays on 9/18/2024. 2. A review of patient test requests and test reports from 9/18/24 revealed patients had orders for the drug screen panel. Test reports had crossed out the patient's reports for benzodiazepines, oxycodone, and methadone assays with a black marker. The only result on the patient test reports was opiates. No indication on the test report as to why the results were crossed out. A total of 48 patients were tested. 3. An interview on 10 /28/24 at 11:23 am with the technical consultant revealed controls during this period

	were reviewed on 10/15/24. They had noticed controls were not performed and crossed out results on the test reports with black marker. Test reports were available for the provider to review prior to 10/15/24.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to perform corrective actions for patients tested when controls failed for two (6 /16/23 and 7/11/24) of 11 patient testing dates reviewed. Findings include: 1. A review of the laboratory's quality control records revealed controls failed for the following patient testing dates: a. 6/16/23 included failed positive control with the result of "Neg-" for amphetamines, methadone, and barbiturates. b. 7/11/24 included failed positive, with the result of "Neg-," and negative controls, with the result of "Pos+," for amphetamines, barbiturates, methadone, opiates, oxycodone, and cocaine. 2. A review of patient test reports revealed the following: a. On 6/16/23 results for amphetamines, methadone, and barbiturates were present on patient test reports. A total of 97 patients had testing reported. b. On 7/11/24 results for amphetamines, barbiturates, methadone, opiates, oxycodone, and cocaine were present on patient test reports. A total of 38 patients had testing reported. 3. A review of the laboratory's "Amphetamines (AMPH", "Barbiturate (BARB)", "Cocaine (COCM)", "Methadone (MTD)", and "Opiate (OP)" procedures revealed a section stating, "Good laboratory practices recommend the use of at least two levels of control specimens (one positive and one negative near the cutoff) daily to ensure proper assay performance" and "Test a positive and negative control each day of testing. Both controls levels must be within acceptable limits prior to patient testing." 4. An interview on 10/28/24 at 11:39 am with the technical consultant confirmed controls for the analytes and dates listed above had not passed and corrective action for patients was not performed.
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 corrective action when the temperatures were out of range for 13 dates reviewed in 2023. Findings include: 1. A review of the laboratory's "Freezer Temperature Log" records, used to monitor specimen storage in the freezer, revealed the following dates when temperatures were out of range: a. 10/18/23, -10 degrees F.

	b. 10/25/23, -11 degrees F. c. 2/2/23, 73 degrees F. d. 2/11/23, 73 degrees F. e. 2/14 /23, 74 degrees F. f. 2/20/23, 78 degrees F. 2. A review of the laboratory's "Temperature and Humidity Log" records revealed a column for monitoring room temperature titled "Temp Degrees F (59-90 degrees F)" with the following dates with temperatures out of range: a. 2/2/23, 32 degrees F. b. 2/11/23, 32 degrees F. c. 2/14 /23, 32 degrees F. d. 2/20/23, 33 degrees F. e. 5/2/23, 9 degrees C, 48.2 degrees F. f. 5 /25/23, 10 degrees C, 50 degrees F. g. 5/29/23, 9 degrees C, 48.2 degrees F. 3. An interview on 10/28/24 at 11:13 am with the technical consultant confirmed corrective action for dates with temperatures out of range was not performed.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory failed to ensure patient dates of birth were accurate on test reports for one (Patient #9) of 12 patient test requests and test reports reviewed. Findings include: 1. A review of 12 patient test requests and test reports revealed Patient #9 had a date of birth year of 1968 listed on the test request and 1948 listed on the test report. 2. An interview on 10 /28/24 at 11:13 am with the technical consultant confirmed the date of birth on the test report was inaccurate for the patient listed above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the laboratory director failed to ensure the laboratory had an operating analyzer to perform its volume of testing (refer to D6007), failed to ensure the laboratory verified the accuracy of its qualitative urine toxicology testing at least twice annually (refer to D6017), failed ensure control procedures were performed at least each day of patient testing (refer to D6020), and failed to ensure patient test results were not reported when controls failed (refer to D6025).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory director failed to ensure the laboratory had an operating analyzer to perform its volume of testing for two (February 2024 to April 2024) months the EasyRA urine toxicology analyzer was not in operation. Refer to D3007.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) 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)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory director failed to ensure the laboratory verified the accuracy of its qualitative urine toxicology testing at least twice annually. Refer to D5217.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory director failed ensure control procedures were performed at least each day of patient testing. Refer to D5445.
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the laboratory director failed to ensure patient test results were not reported when controls failed. Refer to D5783.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: . Based on observations, record review, and interviews, the technical consultant failed to ensure the laboratory maintained its specimen labeling policies (refer to D6042 A), failed to ensure the laboratory maintained its specimen storage and preservation policies (refer to D6042 B), failed to ensure the laboratory maintained specimen processing procedures (refer to D6042 C), failed to ensure the laboratory maintained control procedures (refer to D6042 D), failed to perform corrective action when the temperatures were out of range (refer to D6043), and failed to ensure patient test results were not reported until corrective actions were made for patients tested when controls failed (refer to D6044).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with the technical consultant, the technical consultant to ensure the laboratory maintained its specimen labeling policies. Refer to D5311 A. B. Based on observation, record review, and interview with the technical consultant, the technical consultant failed to ensure the laboratory maintained its specimen storage and preservation policies. Refer to D5311 B. C. Based on observation, record review and interview with the technical consultant, the technical consultant failed to ensure the laboratory maintained specimen processing procedures. Refer to D5311 C. D. Based on record review and interview with the technical consultant, the technical consultant failed to ensure the laboratory maintained control procedures. Refer to D5445.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5)

	(b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the technical consultant failed to perform corrective action when the temperatures were out of range. Refer to D5785.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: . Based on record review and interview with the technical consultant, the technical consultant failed to ensure patient test results were not reported until corrective actions were made for patients tested when controls failed. Refer to D5783.