

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D1092620	<b>(X3) Date Survey Completed</b>  03/22/2022
<b>Name of Provider or Supplier</b>  Physical Medicine Rehabilitation And Consultant	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The purpose of this unannounced survey was for complaint #MI00126842. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003) for the following Condition: 493.1213 Condition: Toxicology 493.1409 Condition: Laboratories performing moderate complexity testing; Technical Consultant
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:                      . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to retain proficiency testing records for at least 2 years for 1 (2020 Event 2 Chemistry Miscellaneous) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed a lack of documentation of the results from the proficiency testing provider for Chemistry Miscellaneous Event 2 in 2020 performed on 5/7/20. 2. The surveyor requested the proficiency testing results for the Chemistry Miscellaneous Event 2 in 2020 on 3/22/22 at 4:27 pm and they were not made available. 3. An interview on 3/22/22 at 4:27 pm with the LD confirmed the laboratory did not retain proficiency testing results for at least 2 years.</p>
<b>D5022</b>	<p><b>TOXICOLOGY</b> CFR(s): 493.1213</p> <p>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.</p>

This CONDITION is not met as evidenced by:  
. Based on record review and interviews, the laboratory failed to meet the requirements for the specialty Toxicology as specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to follow its policy for patient specimen storage and preservation. Refer to D5311. 2. The laboratory failed to ensure results of control materials met established criteria for acceptability before reporting patient test results. Refer to D5481.

**D5213**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of its toxicology analytes not scored by the American Proficiency Institute (API) proficiency testing program for 1 (2021 Chemistry Miscellaneous Event 2) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's API proficiency testing records revealed the laboratory did not participate in the Chemistry Miscellaneous Event 2 in 2021, receiving a score of 0% for Amphetamines, Barbiturates, Benzodiazapines, Cocaine Metabolites, Methadone, Opiates, and Oxycodone. 2. A review of the laboratory's "Proficiency Testing " procedure revealed a section stating, "When PT results are unsatisfactory, we will evaluate the results and take appropriate corrective action as specified in Corrective Action Checklist (see Checklist form)." and "PT results that are not graded will be self-graded by comparing the results to the expected results of the PT agency or peer results." 3. A review of the laboratory's Chemistry Miscellaneous Event 2 in 2021 documentation revealed a lack of evaluation of the results the laboratory's testing of the proficiency testing samples or documentation the laboratory verified the accuracy of its toxicology analytes. 4. The surveyor requested the verification of accuracy documentation for the Chemistry Miscellaneous Event 2 in 2021 on 3/22/22 at 4:26 pm and it was not made available. 5. An interview on 3/22 /22 at 4:26 pm with the LD confirmed the laboratory did not verify the accuracy of its toxicology testing for the Chemistry Miscellaneous Event 2 in 2021 not scored by API.

**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:

. Based on observation, record review, and interview with the Testing Personnel (TP), the laboratory failed to follow its policy for patient specimen storage and preservation for 24 of 28 specimens observed in the laboratory refrigerator. Findings include: 1. The surveyor observed a plastic bin in the laboratory's refrigerator with 24 patient urine specimens dated 3/14/22, 3/15/22, 3/16/22, and 3/17/22 on 3/22/22 at 12:39 pm. 2. A review of the laboratory's "Specimen Processing, Result Review and Send Out Procedures" revealed a section titled "Specimen Processing Steps" stating, "Once organized the specimens can be stored in refrigerator until testing." 3. A review of the laboratory's "Barbiturate (BARB)" procedure revealed a section titled "Specimen Storage and Stability" stating, "If a sample cannot be analyzed immediately, it can be stored refrigerated for up to 3 days." 4. A review of the laboratory's "Cocaine (COCM)" procedure revealed a section titled "Specimen" stating, "COCM specimens may be stored at 2-8 degrees C for up to 3 days or frozen for longer storage per reagent package insert." 5. A review of the laboratory's "Methadone (METD)" procedure revealed a section titled "Specimen" stating, "Methadone specimens may be stored at 2-8 degrees C for up to 3 days or -20 degrees C for longer storage per reagent package insert." 6. A review of the laboratory's "Opiate (OP)" procedure revealed a section titled "Specimen" stating, "Opiate specimens may be stored at 2-8 degrees C for up to 3 days or -20 degrees C for up to 12 months per reagent package insert." 7. A phone interview on 3/22/22 at 1:21 pm with the Testing Personnel revealed the specimens in the refrigerator were to be tested and confirmed the dates listed on the urine cups were the dates of collection.

**D5481**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (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 Testing Personnel, the laboratory failed to ensure results of control materials met established criteria for acceptability before reporting patient test results for 8 (5/7/20, 7/9/20, 7/16/20, 8/6/20, 8/13/20, 9/17/20, 9/28/20, and 10/1/20) of 13 testing dates reviewed. Findings include: 1. A review of the laboratory's quality control documentation revealed the following dates when quality control was out of range: a. 5/7/20, benzodiazepine positive control had a negative result. b. 7/16/20, cocaine negative control had a positive result. c. 7/9/20, benzodiazepine negative control had a positive result. d. 8/6/20, barbiturate negative control had a positive result. e. 8/13/20, opiate and benzodiazepine negative controls had positive results. f. 9/17/20, cocaine negative control had a positive result. g. 9/28/20, cocaine negative control had a positive result. h. 10/1/20, benzodiazepine negative control had a positive result. 2. A review of the laboratory's "Quality Assessment Plan" revealed a section titled "Testing and Instrumentation Quality Control" stating, "NO PATIENT TESTING SHOULD TAKE PLACE WHEN CONTROL VALUES ARE OUTSIDE THE EXPECTED RANGES. SPECIMENS SHOULD BE HELD UNTIL CORRECTIVE ACTIONS ALLEVIATES THE PROBLEM AND CONTROLS TEST WITHIN THE EXPECTED RANGES." 3. A review of the laboratory's "Benzodiazepine (BZO)", "Cocaine (COC)", and "Opiates (OP)" procedures revealed a section titled "Quality Control" stating, "Good laboratory practices recommend the use of at least two levels of control specimens (one positive and one negative control near the cut-off) daily to ensure proper assay performance."

4. A review of the laboratory's "Barbiturate (BARB)" procedure revealed a section titled "Quality Control" stating, "Test a positive and negative control each day of testing. Both controls must be within acceptable limits prior to patient testing." 5. A review of patient test records revealed the following patients had testing performed on dates when quality control testing was not within acceptable limits: a. 5/7/20, Patient 9703 b. 7/16/20, Patient 10308 c. 7/9/20, Patient 10111 d. 8/6/20, Patient 9139 e. 8/13/20, Patient 1514 f. 9/17/20, Patient 5401 g. 9/28/20, Patient 9796 h. 10/1/20, Patient 6656 6. The surveyor requested corrective action documentation for the dates when quality control was not within acceptable limits on 3/22/22 at 3:17 pm and it was not made available. 7. A phone interview on 3/22/22 at 3:17 pm with the Testing Personnel confirmed the laboratory had quality control runs outside of acceptable limits on patient testing dates and no corrective action was documented.

**D6021**

**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 quality assessment programs are 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 Laboratory Director (LD), the Laboratory Director failed to ensure the laboratory's established quality assessment program was maintained for 1 (2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Quality Assessment Plan" revealed the following sections: a. "Testing and Instrumentation Quality Control" stating, "Review frequency: Daily and monthly review of all quality control results. Overall review done yearly. Reviewed by: Laboratory Director, or Technical Consultant, or qualified staff." b. "Patient Test Management and Test Tracking Systems" stating, "Periodic evaluation of pre-analytical, analytical, and post analytical phases of Patient Test Management and Test Tracking shall be performed to determine if the standards below are met and to ensure quality specimen collection, handling, testing, and reporting in the laboratory. Review conducted by: Laboratory Director, or Technical Consultant, or qualified staff." c. "Instrument Maintenance" stating, "The quality assessment reviews the control data, instrument calibration, and maintenance for each test method used in the lab. Performance specifications of each instrument will be evaluated to ensure operation is within acceptable limits. Evaluation of patient normal ranges will be reviewed when the patient population changes or with new methodology. Review frequency: Annually (each month instrument corrective actions are reviewed at the time of a problem and followed up to verify any problems have been solved.). Reviewed by: Laboratory Director, or Technical Consultant, or qualified staff. d. "Laboratory Incidents Management and Errors" stating, "The purpose of this plan is "to provide a process for the identification and investigation of issues, true cause analysis, development of corrective action plans, and communication of the findings and the actions for all Incidents and Errors" made by the in-house laboratory and contracted reference laboratories. Goals of this laboratory are to "provide safety in the facility for patient care and staff, reduce the risk of injury, encourage open communication regarding discovery of incidents, and the effectiveness of the corrective actions. Review frequency: As required per incident or error Reviewed by:

	<p>Laboratory Director, or Technical Consultant, or qualified staff." 2. A review of the laboratory's records revealed quality assessments were not present from 10/30/20 to 1/7/22. 3. An interview on 3/22/22 at 4:28 pm with the LD confirmed no quality assessments were performed in 2021.</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPLEXITY</b> CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:  . Based on record review and interview with the Laboratory Director, the laboratory failed to have a Technical Consultant providing technical oversight. Findings include:  1. The laboratory failed to employ an individual to perform the duties of a Technical Consultant. Refer to D6034.</p>
<p><b>D6034</b></p>	<p><b>TECHNICAL CONSULTANT QUALIFICATIONS</b> CFR(s): 493.1411</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.</p> <p>This STANDARD is not met as evidenced by:  . Based on record review and interview with the Laboratory Director (LD), the laboratory failed to employ an individual to perform the duties of a Technical Consultant for 16 (November 2020 to March 2022) months. Findings include: 1. The surveyor requested a completed Laboratory Personnel Report CMS-209 on 3/22/22 at 12:45 pm. 2. A review of the laboratory's Laboratory Personnel Report CMS-209 revealed a lack of a Technical Consultant. 3. An interview on 3/22/22 at 12:45 pm with the LD revealed the laboratory had not had a Technical Consultant or person performing the functional duties of a Technical Consultant since November 2020.</p>