

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D1087498	<b>(X3) Date Survey Completed</b> 11/04/2020
<b>Name of Provider or Supplier</b> Southwest Ohio Pain Institute	<b>Street Address, City, State</b> 7760 W Voa Park Dr Ste D, West Chester, OH	
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>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the Office Manager (OM), the laboratory failed to report SARS-CoV-2 data to the appropriate state or local public health department as required for all 516 patients tested between 07/16/2020 and the date of this inspection, 11/04/2020, Findings Include: 1. Review of the laboratory's Form CMS-116, approved and signed by the Laboratory Director on 10/30/2020, revealed SARS-CoV-2 rapid antigen testing listed under section VI of waived testing. 2. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of the inspection found no instructions for the reporting of SARS-CoV-2 results. 3. The inspector requested the laboratory's SARS-CoV-2 reporting records from 07/16/2020 to 11/04/2020 from the OM. The OM stated the laboratory had tested 516 patients but did not report SARS-CoV-2 test results and was unable to provide the requested documentation on the date of inspection. The interview occurred on 11/04/2020 at 1:30 PM.</p>
<b>D5217</b>	<b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b>

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 an interview with the Office Manager (OM), the laboratory failed to perform test accuracy verification (TAV) for unregulated analytes at least twice annually. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice.

Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of inspection found no instructions for TAV of unregulated analytes. 2. The inspector requested the TAV records for all unregulated analytes tested under the subspecialty of toxicology. 3. The OM confirmed no TAV of unregulated analytes had been performed and was unable to provide the requested documentation. The interview occurred on 11/04/2020 at 2:15 PM.

**D5407**

**PROCEDURE MANUAL**

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office manager (OM), the Laboratory Director (LD) failed to ensure policies and procedures were approved, signed and dated before use. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual", provided on the date of the inspection revealed an approval signature and date by the LD on 05/2020. 2. Further review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" revealed the following statement: "Laboratory Director Responsibilities General Responsibilities...Ensure that an approved procedure manual is available to all laboratory personnel" 3. The OM confirmed the LD approved and signed the "Policy and Procedure Manual" after the start of toxicology testing 03/26/2020. The interview occurred on 11/04/2020 at 3:25 PM.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with Testing Personnel (TP) #1, the laboratory failed to include on the final test report the specimen source for patient results. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of three out of three of the laboratory's final patient toxicology test reports did not find any specimen source listed. 2. TP#1 confirmed no specimen source was indicated on patient toxicology test reports. The interview occurred on 11/04/2020 at 2:30 PM.

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure policies and procedures were established for monitoring individuals who conducted preanalytical, analytical, and post analytical phases of testing. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209 signed and dated by the LD on 10/30/2020 revealed two staff listed as testing personnel (TP). 2. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of the inspection found no instructions for competency assessments of TP. 3. The inspector requested the laboratory's policy and procedure for assessing the competency of TP from the OM. The OM provided a "Competency Questionnaire" problem solving quiz for TP#1 and TP#2 dated 11/03/2020. The OM was unable to provide a competency assessing policy and procedure. The interview occurred 11/04/2020 at 1:15 PM.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Office Manager (OM), the

Technical Consultant (TC) failed to include direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing in the evaluation of the competency of Testing Personnel (TP) #1 and TP#2. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 10/30/2020, revealed two individuals indicated as TP. 3. The inspector requested the laboratory's 2020 competency assessment records for TP#1 and TP#2 that included direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing from the OM. The OM provided a "Competency Questionnaire" problem solving quiz for TP #1 and TP#2 dated 11/03/2020. The OM was unable to provide the requested documentation on the date of inspection. The interview occurred on 11/04/2020 at 1:30 PM.

**D6048**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Office Manager (OM), the Technical Consultant (TC) failed to include monitoring of the recording and reporting of test results in the evaluation of the competency of Testing Personnel (TP) #1 and TP#2. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 10/30/2020, revealed two individuals indicated as TP. 3. The surveyor requested the laboratory's 2020 competency assessment records for TP#1 and TP#2 that included monitoring of the recording and reporting of test results from the OM. The OM provided a "Competency Questionnaire" problem solving quiz for TP#1 and TP#2 dated 11/03/2020. The OM was unable to provide the requested documentation on the date of inspection. The interview occurred on 11/04/2020 at 1:30 PM.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Office Manager (OM), the Technical Consultant (TC) failed to include the review of intermediate test results or

worksheets, quality control (QC) records and preventive maintenance records in the evaluation of the competency of Testing Personnel (TP) #1 and TP#2. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS-209, signed by the Laboratory Director on 10/30/2020, revealed two individuals indicated as TP. 3. The surveyor requested the laboratory's 2020 competency assessment records for TP#1 and TP#2 that included the review of intermediate test results or worksheets, QC records and preventive maintenance records from the OM. The OM provided a "Competency Questionnaire" problem solving quiz for TP#1 and TP#2 dated 11/03/2020. The OM was unable to provide the requested documentation on the date of inspection. The interview occurred on 11/04/2020 at 1:30 PM.

**D6050**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Office Manager (OM), the Technical Consultant (TC) failed to include direct observation of performance of instrument maintenance and function checks in the evaluation of the competency of Testing Personnel (TP) #1 and TP#2. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 10/30/2020, revealed two individuals indicated as TP. 3. The surveyor requested the laboratory's 2020 competency assessment records for TP#1 and TP#2 that included direct observation of performance of instrument maintenance and function checks from the OM. The OM provided a "Competency Questionnaire" problem solving quiz for TP#1 and TP#2 dated 11/03/2020. The OM was unable to provide the requested documentation on the date of inspection. The interview occurred on 11/04/2020 at 1:30 PM.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:  
Based on record review and an interview with the Office Manager (OM), the Technical Consultant (TC) failed to include assessment of test performance through

testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of Testing Personnel (TP) #1 and TP#2. All patients tested under the subspecialty of toxicology from 03/26/2020 to 11/04/2020 had the potential to be affected by this deficient practice.

Findings Include: 1. Review of the laboratory's policy and procedure manual titled "Policy and Procedure Manual" approved and signed by the Laboratory Director on 05/2020 and provided on the date of the inspection found no instructions for competency assessments of TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 10/30/2020, revealed two individuals indicated as TP. 3. The surveyor requested the laboratory's 2020 competency assessment records for TP#1 and TP#2 that included assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples from the OM. The OM provided a "Competency Questionnaire" problem solving quiz for TP#1 and TP#2 dated 11/03/2020. The OM was unable to provide the requested documentation on the date of inspection. The interview occurred on 11/04/2020 at 1:30 PM.