

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1037004	(X3) Date Survey Completed 04/06/2021
Name of Provider or Supplier Pain Management Institute	Street Address, City, State 10181 Lincoln Hwy, Frankfort, IL	
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
D3000	<p>FACILITY ADMINISTRATION 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 review of the laboratory's application for CLIA Certification (CMS 116); COVID test results; COVID reporting; and interview with personnel from the doctor's office and the technical consultant, the laboratory failed to report its waived rapid COVID-19 Antigen testing to the Illinois Department of Public Health (IDPH). Findings: 1. On April 6, 2021 at 2:00 PM, surveyor review of the laboratory's (CMS 116) revealed that the laboratory performs the following tests: a. Toxicology - Moderate Complexity Testing using the Medica Easy RA analyzer b. Rapid HCG - Waived Test using McKesson Consult Rapid Cassette c. Rapid COVID-19 Antigen using Care Start Rapid Cassette 2. On April 6, 2021 at 4:30 PM, the surveyor requested testing logs for COVID-19 Antigen Tests. The technical consultant told the surveyor that her laboratory was not the personnel performing any of the waived testing. Doctors on the floor above the laboratory performed waived testing under the labs CLIA Certificate. 3. On April 6, 2021 at 5:00 PM, at the request of the surveyor, personnel from the doctor's office made copies of the COVID-19 Antigen testing logs and patients' test reports for the surveyor. The surveyor received the following documentation: a. COVID-19 Antigen testing logs with 61 patients' names from 01/13</p>

/21 to 03/24/21 where 1 of 61 patients' test results was documented in the log as "POS". b. 7 patients' test reports from 03/24/2021- all reported as 'NEGATIVE'; no Reference Range is documented on the report. c. 21 patients' test reports from 03/31/2021 - all reported as 'NEGATIVE'; no Reference Range is documented on the report. 4. On April 2021 at 5:00 PM, in an interview with office staff it was revealed that the laboratory reported only positive COVID- 19 test results to IDPH, telling the surveyor that they only had one positive COVID-19 patient test thus far. There were no negative test results reported to IDPH for 7 of 7 patients tested on 03/24/2021 and 21 of 21 patients tested on 03/31/2021. 5. On April 2021 at 5:30 PM, the surveyor asked the technical consultant if she was aware that both positive and negative COVID-19 tests should be reported to IDPH. The technical consultant said she is aware of the requirements for reporting all COVID results to IDPH but did not ensure the doctor's office knows the requirement for reporting all COVID-19 test results to IDPH.

D5789

TEST RECORDS
CFR(s): 493.1283(b)

Records of patient testing including, if applicable, instrument printouts, must be retained.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedures manual; patients' testing logs; patient's test reports; and interview with the technical consultant, the laboratory failed to retain patients' toxicology test records for at least 2 years. Findings: 1. The laboratory's procedures manual contained a page which lists retention requirements of at least 2 years for the following information: a. Requisitions b. Test Records c. Test Reports d. Quality Control Records e. Calibration Records f. Maintenance Records g. Proficiency Test Records 2. On April 6, 2021 at 4:00 PM, the surveyor reviewed the patients' test logs. 3. The surveyor selected a total of 5 patients names from the patients' testing logs and requested the following documents for each patient: a. the patients' test reports b. corresponding Quality Control records for patients' test reports selected. 4. On April 6, 2021 at 4:00 PM, surveyor review of patient's test records revealed, there was no test report for 1 of 5 patients test records selected for review. 6. On April 6, 2021 at 4:30 PM, the technical consultant confirmed the surveyor's findings.

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 observations; review of the laboratory's procedures manual; patients' testing

logs; patient's test reports; and interview with the technical consultant, the laboratory failed to ensure test results and patient specific data are accurately and reliably sent from the point of data entry to final report destination in a timely manner. Findings: 1. On April 6, 2021 at 4:00 PM, the surveyor observed that the laboratory performs toxicology testing where a physical result is printed and manually entered into patients' Electronic Medical Record (EMR) that is shared with the lab's reference laboratory. 2. There were no written procedures that describes the laboratory's process for how it ensures all patients test result get entered in the EMR. 3. On April 6, 2021 at 4:00PM the surveyor selected a total of 5 patients names from the patients' testing logs. The surveyor requested the patients' test reports and corresponding Quality Control records for each patient selected. The EMR shows the results of toxicology test results performed by a reference laboratory on July 23, 2019 for 1 of 4 patients reports selected for review. However, there was no record of the toxicology screening test reports entered in the EMR for 1 of 5 patients test records selected for review. 5. Review of the testing logs shows that the patients' specimen for the missing toxicology report was collected on July 16, 2019. 6. On April 6, 2021 at 4:30 PM, the technical consultant confirmed the surveyor's findings.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's procedures manual; patients test records; and interview with the technical consultant, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the post analytic systems specified in 493.1291. Findings: 1. There were no procedures that described how the laboratory ensures its toxicology screening results are entered in patient's Electronic Medical Records (EMR). 2. On April 6, 2021 at 4:00 PM, review of patient's tests reports revealed that there was no record of test performance for 1 of 5 patients' test results reviewed. See tag D5789 3. On April 6, 2021 at 4:00 PM, review of patient's tests reports revealed that there was no record of test results in the Electronic Medical Record for 1 of 5 patients' test results reviewed. See tag D5801 4. On April 6, 2021 at 4:30 PM, the technical consultant confirmed the surveyor's findings.