| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D1074678 | 03/16/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| North Florida Pain Center Pa | 5851 Timuquana Road Suite 401, Jacksonville, FL | |

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 |
|---|---|
| **D0000** | At the time of the announced, on-site recertification survey, North Florida Pain Center Pa was found to NOT be in compliance with the CLIA laboratory requirements of 42 CFR 493. . |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory personnel, the laboratory did not have documentation of signed attestations for two of two events reviewed in 2020. The findings include: Review of the American Proficiency Institute (API) proficiency records for 2020 showed the Laboratory Director or Designee had not signed the attestations for Chemistry Miscellaneous Event 1 and Event 2. During an interview with General Supervisor on 3/16/21 at 1:00 PM, it was confirmed the Laboratory Director had not signed the attestations for the two events. . |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to provide documentation to verify the accuracy of the two testing methods used for the drug |

| | |
|---|---|
| | Tapentadol tested in urine toxicology from 2019-2020; at least twice annually. The findings include: Review of the API proficiency testing (PT) records for 2019 and 2020 showed that the drug Tapentadol was not included in the list of API urine toxicology analytes tested for drug screening on the Indiko Plus instrument. Review of the College of American Pathologists (CAP) PT records for 2019-2020 showed the Urine Toxicology Challenges (UT-B, UT-C) for drug confirmation on the liquid chromatograph mass spectrometer (LCMS) did not include Tapentadol. The laboratory provided documentation of split-sample testing for Tapentadol dated 4/23 /19 using LCMS instrumentation. There was no documentation of split-sample testing of Tapentadol on the LCMS (drug confirmation testing) again in 2019 or in 2020. There was no documentation showing split-sample testing of Tapentadol using a drug screening instrument in 2019 or 2020. The interview with the General Supervisor on 3 /16/21 at 1:00 PM confirmed the twice annual verification of accuracy for the drug Tapentadol had not been completed for either test method. . |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>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 general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory's Quality Assessment (QA) program failed to identify the drug Tapentadol was not tested twice annually for accuracy for two of two years reviewed. The findings include: The review of the QA documentation for 2019 and 2020 did not indicate there was a concern with the lack of split sample testing to confirm the drug screening and drug confirmation of Tapentadol. The interview with the General Supervisor on 3/16/21 at 1:00 PM confirmed the QA program did not identify and correct the missing twice annual verification of accuracy. . |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory director failed to ensure that the laboratory's quality assessment (QA) program appropriately monitored the laboratory's processes. The findings include: The review of the QA program showed the Laboratory Director failed to ensure the laboratory verified the accuracy of patient specimens at least twice a year for the drug Tapentadol. During the survey, it was determined that the laboratory had not verified the accuracy of the drug screening method used to screen for Tapentadol. The verification should occur at least twice a year. In 2019, the laboratory only performed the verification of the accuracy of the |

| | |
|---|---|
| | drug confirmation of Tapentadol once. During the interview with the General Supervisor on 3/16/21 at 1:00 PM, it was acknowledged that the Laboratory Director's QA program failed to identify the problems with accuracy of testing verification. |