

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2116298	(X3) Date Survey Completed 08/11/2022
Name of Provider or Supplier Etowah Pain Associates	Street Address, City, State 3015 Steele Station Road, Rainbow City, AL	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and an interview with the current Laboratory Director, the previous Laboratory Director failed to sign the attestation statements for four of seven survey events reviewed from 2019 to 2022. The findings include: 1. A review of the API records revealed the previous Laboratory Director failed to sign the attestation statements for the following surveys: a. 2019 Miscellaneous Chemistry Event #1. b. 2019 Miscellaneous Chemistry Event #2. c. 2020 Miscellaneous Chemistry Event #2. d. 2021 Miscellaneous Chemistry Event #1. 2. A review of the API Attestation Statement page revealed the following instructions: "SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results. ...". The surveyor noted the words "physically sign" were underlined. 3. During the exit interview on August 11, 2022, at 2:50 PM, the Laboratory Director confirmed the above findings. .</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the American Proficiency Institute (API) proficiency testing records and an interview with the current Laboratory Director, the previous Laboratory Director failed to document review of results for four of seven 2019 - 2022 survey events. The findings include: 1. A review of the API records revealed the previous Laboratory Director failed to document review of the results (scores) for the following surveys: a. 2019 Miscellaneous Chemistry Event #1. b. 2019 Miscellaneous Chemistry Event #2. c. 2020 Miscellaneous Chemistry Event #2. d. 2021 Miscellaneous Chemistry Event #1. 2. During the exit interview on August 11, 2022, at 2:50 PM, the Laboratory Director confirmed the above findings. .

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 a review of the American Proficiency Institute (API) proficiency testing records and an interview with the current Laboratory Director, the Laboratory failed to verify the accuracy of an analyte not graded by API. This was noted for Buprenorphine (BUP), not graded on three of seven 2019 to 2022 survey events. The findings include: 1. A review of the API records revealed BUP was not graded due to less than ten participants. Surveyor noted no evidence the laboratory reviewed the participant summary, and performed an internal evaluation of their results for the following survey events: a. 2019 Miscellaneous Chemistry Event #2 b. 2020 Miscellaneous Chemistry Event #2 c. 2021 Miscellaneous Chemistry Event #1 2. During the exit interview on August 11, 2022, at 2:50 PM, the current Laboratory Director confirmed the above findings. .

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and an interview with the current Laboratory Director, the Laboratory failed to submit results by the cutoff dates established by the PT provider. The laboratory scored zero percent due to failure to participate on two of four 2020 - 2021 survey events. The laboratory further failed to perform an internal evaluation to verify the accuracy of their results on one of four 2020 - 2021 survey events. The findings include: 1. A review of the API records revealed the laboratory scored zero percent due to failure to participate on the following PT surveys: a. 2020 Miscellaneous Chemistry Event #1. b. 2021 Miscellaneous Chemistry Event #2. 2. A further review of 2020 Miscellaneous Chemistry Event #1 records revealed the results were due on May 13, 2020, and the laboratory performed the testing on December 9, 2020. A

review of the corrective action revealed, "Do self evaluation after results are posted", however the surveyor noted no documentation of a self evaluation to verify the accuracy of the laboratory's results. 3. During the exit interview on August 11, 2022, at 2:50 PM, the current Laboratory Director reviewed and confirmed the above findings. In addition the Director explained the laboratory was not performing patient testing (September 2021 through February 7, 2022) when the 2021 Miscellaneous Chemistry Event #2 was received. However the laboratory failed to notify API. .

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) proficiency testing (PT) records and an interview with the current Laboratory Director, the laboratory failed to perform and document corrective action for an analyte with a score of zero percent. This was noted for pH on one of two 2021 survey events. The findings include: 1. A review of the API records revealed pH received a score of zero percent in 2021 Miscellaneous Chemistry Event #1 with no documentation of an investigation or the corrective actions taken. 2. During an exit interview on August 11, 2022, at 2:50 PM, the Laboratory Director confirmed the above findings. SURVEYOR ID's #46291 and #32558 Licensure and Certification Surveyors