

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2131703	(X3) Date Survey Completed 01/14/2020
Name of Provider or Supplier Mid Michigan Pain Management	Street Address, City, State 1230 S Linden Road Suite 4, Flint, MI	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC), the laboratory failed to 1) maintain the original proficiency testing (PT) program report forms and the instrument printouts for 2 (2nd events for 2018 and 2019) of 2 events reviewed and 2) maintain the signed attestation statement sheet for 1 (2nd event 2018) of 2 events reviewed, and 3) maintain documentation of review of the final graded proficiency testing reports for 1 (2nd event 2018) of 2 events reviewed. Findings include: 1. Record review of the American Association of Bioanalysts (AAB) and the American Proficiency Institute (API) final PT documents revealed the laboratory did not maintain the original proficiency testing program report forms and the instrument printouts as follows: a. AAB - 2nd event 2018 original PT program report forms and the instrument printouts b. API - 2nd event 2019 original PT program report forms and the instrument printouts. 2. Record review of the AAB final PT documents revealed the laboratory did not maintain the signed attestation statement sheet for the 2nd event 2018. 3. Record review of the AAB final PT documents revealed the laboratory did maintain documentation of review of the final PT reports for the 2nd</p>

event of 2018. 4. During the interview on 1/14/2020 at 10:25 am, the TC confirmed the above findings were not maintained by the laboratory.

D2016

SUCCESSFUL PARTICIPATION

CFR(s): 493.803(a)(b)(c)

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:

. Based on record review of the CMS database, American Association of Bioanalysts (AAB), and the American Proficiency Institute (API), and interview with the Technical Consultant (TC), the laboratory failed to be enrolled in a toxicology proficiency testing (PT) program for 2 (1st event 2018 and 2019) of 4 events in 2 years. Findings include: 1. Record review of the CMS database, the AAB and API proficiency testing program final reports revealed the laboratory was not enrolled in a proficiency testing program for 2 (1st event 2018 and 2019) of 4 events. 2. When queried on 1/14/2020 at 10:25 am, Testing Personnel #1 (TP1) stated the order for the 2019 API program did not go through. 3. During the interview on 1/14/2020 at 10:25 am, TP1 and the TC confirmed the laboratory was not enrolled in a PT program for the 1st events of 2018 and 2019.

D3027

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(1)

Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

This STANDARD is not met as evidenced by:

. Based on patient chart review and interview with Testing Personnel #1 (TP1) and the Technical Consultant (TC), the laboratory failed to retain patient written requisitions and/or electronic orders for 7 (January to July 2018) of 7 months of patient testing. Findings include: 1. Patient chart review revealed for 7 (January to July 2018) of 7 months of testing a lack of documentation of the patient's test requisition. 2. When queried on 1/14/2020 at approximately 1:15 pm, TP1 and the TC were unable to locate test requisitions for patient testing for 7 of 7 months in 2018. 3. During the

interviews on 1/14/2020 at approximately 1:15 pm, TP1 and the TC confirmed there was not a method to track patient test requisitions and/or electronic orders.

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1) and the Technical Consultant (TC), the laboratory failed to retain the chemistry Synermed IR 500 patient test results for 7 (January to July 2018) of 7 months reviewed for 2 years. Findings include: 1. Record review of the Synermed IR 500 instrument documents showed the instrument was in use from January to July of 2018. 2. Record review of the Synermed IR 500 documents revealed a lack of documentation of patient final test results for 7 of 7 months reviewed in 2018. 3. During the interview on 1/14/2020 1:15 pm, TP1 and TC confirmed patient final test results were not available on the day of the survey and retained for 2 years.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to perform and document method validation for the Medica EasyRa chemistry instrument for 17 (September 2018 to January 2020) of 17 months of patient testing. Findings include: 1. Record review of the Medica EasyRa chemistry instrument revealed there was no documentation to show the new instrument installed in 9/2018 was validated for accuracy, precision, reportable range, and verification of the patient normal ranges for 17 months of operation. 2. When queried on 1/14/2020 at 12:30 pm, the TC stated they had been performed. No documentation was available to the surveyor to show the performance specifications had been performed and documented. 3. During the interview on 1/14/2020 at 12:30 pm, the TC confirmed the performance verification documentation was not available on the day of the survey.

D6063

LABORATORY TESTING PERSONNEL

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to provide the educational requirements for 1 (Testing Personnel #1) of 1 testing personnel performing moderately complex toxicology testing. Refer to D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to ensure all testing personnel met the educational requirements at 493.1423 for 1 (Testing Personnel #1) of 1 testing personnel. Findings include: 1. Record review of testing personnel credentials revealed a lack of documentation of the equivalency evaluation for a foreign academic credentials for Testing Personnel #1 performing moderately complex toxicology testing. 2. During the interview on 1/14 /2020 at 9:40 am, the TC confirmed the above findings. 3. The laboratory was given 7 additional days to supply the necessary educational documents. The documents were not received.