

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2071787	(X3) Date Survey Completed 10/15/2018
Name of Provider or Supplier Michigan Advanced Pain And Spine	Street Address, City, State 27101 Schoenherr Road Suite 200, Warren, 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
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 record review and interview, the laboratory director and the testing personnel failed to attest to the integration of the routine chemistry and toxicology proficiency testing samples into the patient workload for four (3rd event 2016, 1st and 2nd events 2017, and 1st event 2018) of four events reviewed. Findings include: 1. On October 15, 2018 at 10:00 AM, record review of the American Proficiency Institute (API) routine chemistry and toxicology proficiency testing documents revealed the laboratory director and the testing personnel did not sign the attestation statement sheets for the following events: a. 3rd event in 2016 b. 1st and 2nd events in 2017 c. 1st event in 2018 2. During the interview on October 15, 2018 at 10:00 AM, the office liaison confirmed the attestation statement sheets were not signed.</p>
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</p>

system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to retain the original American Proficiency Institute (API) proficiency testing program report forms and the Thermo Scientific Indiko Plus instrument printouts for four (3rd event 2016, 1st and 2nd events 2017, and 1st event 2018) of four testing events reviewed. Findings include: 1. On October 15, 2018 at 10:00 AM, record review of the final API proficiency testing reports revealed the laboratory failed to retain the original proficiency testing program report forms and the chemistry instrument printouts as follows: a. 3rd event 2016 b. 1st and 2nd events 2017 c. 1st event 2018 2. During the interview on October 15, 2018 at 10:00 AM, the office liaison confirmed the laboratory did not retain all the documentation for the proficiency testing events. .

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, the laboratory failed to retain 1) the temperature logs for two (December 2016 and April 2018) of 24 months and 2) the monthly quality assessment checklists for two (November 2016 and April 2018) of 24 months reviewed for two years. Findings include: 1. On October 15, 2018 at 12:40 PM, record review of the monthly temperature logs and the quality assessment checklists revealed the laboratory did not retain the documentation for two years as follows: a. temperature logs - no documentation for December 2016 and April 2018 b. quality assessment checklists - no documentation for November 2016 and April 2018 2. During the interview on October 15, 2018 at approximately 3:15 PM, the office manager, liaison, and testing personnel #2 as listed on the CMS-209 confirmed the temperature logs and the quality assessment checklists were not retained for two years.

D5022

TOXICOLOGY

CFR(s): 493.1213

If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

. Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Toxicology as specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to implement competency assessments. Refer to D5209. 2. The laboratory failed to verify the accuracy of the urine toxicology specific gravity, pH, and creatinine testing. Refer to D5217. 3. The laboratory failed to have an electronic request for patient testing. Refer

to D5301. 4. The laboratory failed to monitor and document temperatures. Refer to D5413. 5. The laboratory failed to perform and document refrigerator, room temperature/humidity thermometer validations. Refer to D5429. 6. The laboratory failed to perform the daily quality control for the routine chemistry and toxicology testing. Refer to D5445. 7. The laboratory failed to document corrective action for humidity readings outside stated ranges. Refer to D5785. 8. The laboratory failed to provide a record system that included the identify of the testing personnel performing the routine chemistry and toxicology testing. Refer to D5787.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to ensure written competency policies were implemented for two (#1 and #2) of two testing personnel performing the routine chemistry and toxicology testing. Findings include: 1. On October 15, 2018 at 9:45 AM, record review for the competency assessments revealed there was no documentation to show that testing personnel #1 and #2 had been evaluated initially during the training period per the "Performance/Competency Testing" procedure approved by the Laboratory Director on June 30, 2014. 2. On October 15, 2018 at approximately 9:45 AM when requested, the office manager was not able to provide the surveyor with the initial competency assessments. 3. During the interview on October 15, 2018 at approximately 9:45 AM, the office manager confirmed the testing personnel did not have initial competency assessments.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
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 procedure review, record review, and interview, the laboratory failed to verify the accuracy for the urine toxicology validation testing for two (2017 and 2018) of two years as least twice annually. Findings include: 1. On October 15, 2018 at approximately 11:00 AM, review of the "Policies and Procedure" manual section "6.0 Quality Control", procedure review "Periodic Calibration, Calibration Verifications (AMR) and Assay Correlations" revealed "the laboratory must revalidate at least every six months", if a low, midpoint, and high value calibrators are not used. 2. On October 15, 2018 at approximately 12:00 PM, record review of the "Laboratory Records 2017" manual revealed there was no documentation to show the twice a year validation for accuracy was being performed for the Dri pH-Detect Assay, Dri Gravity-Detect Assay, and the Dri Creatinine-Detect Assay in 2017 and 2018. 3. During the interview on October 15, 2018 at approximately 12:00 PM testing personnel #2 as listed on the CMS-209 confirmed the twice a year verification of accuracy was not performed and documented. ***Repeat Deficiency from October 18, 2016 survey***

D5301

TEST REQUEST
CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to have a electronic request for patient testing from an authorized person for the routine chemistry and toxicology testing for two (#4 and #5) of 11 patient charts audited. Findings include:
1. On October 15, 2018 at 1:40 PM, record review of patient charts revealed the laboratory did not have an electronic request for the laboratory testing performed on patient # 4 and #5 for the routine chemistry and toxicology testing. 2. On October 15, 2018 at 1:40 PM when queried, testing personnel #2 as listed on the CMS-209 was unable to locate the electronic order in the patient's electronic medical records (EMR). 3. During the interview on October 15, 2018 at 1:40 PM, testing personnel #2 confirmed no electronic request was available for the testing performed.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to monitor and document the refrigerator temperatures for two (September and October 2018) of 24 months reviewed to ensure reliable chemistry instrument operation. Findings include: 1. On October 15, 2018 at approximately 12:25 PM, record review of the "Michigan Advanced Pain and Spine" monthly temperature logs revealed the laboratory did not record and document temperatures every day of operation as follows: a. September 2018 - 24, and 26-27 b. October 2018 - 1-5, 8-11, and 15 2. On October 15, 2018 at approximately 12:25 PM when queried, testing personnel # 2 as listed on the CMS-209 stated "the thermometers were inoperable". 3. During the interview on October 15, 2018 at approximately 12:25 PM, testing personnel #2 confirmed the thermometers were inoperable and temperatures were not monitored and recorded.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. Based on observation, procedure review, and interview, the laboratory failed to perform and document thermometer calibrations for three (Fisher Scientific Traceable) of three thermometers in use. Findings include: 1. During a tour of the laboratory on October 15, 2018 at 9:12 AM, the surveyor observed a Fisher Scientific Traceable thermometer in both (#1 and #2) Igloo refrigerators and a Fisher Scientific Traceable thermometer used in the laboratory to monitor the room temperature/humidity. Refrigerator #1 there was no calibration date noted on the thermometer, refrigerator #2 the calibration due date was May 18, 2018, and the room temperature /humidity thermometer the calibration due date was May 12, 2018. 2. On October 15, 2018 at 12:25 PM, procedure review "Policies and Procedure" manual "Section 4.0 Equipment" revealed the thermometer/hygrometer are to be "validated annually". There was no documentation to show the validation of the traceable thermometers had been performed and documented in 2016 to 2018. 3. On October 15, 2018 at 12:25 PM, testing personnel #2 as listed on the CMS-209 confirmed the thermometers were not validated annually.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to perform the routine chemistry and toxicology quality control as required prior to reporting out patient testing for two (#2 and #4) of 11 patient charts audited. Findings include: 1. On October 15, 2018 at 13:40 PM, record review of patient charts audited revealed for two patients the daily quality control was not performed and documented using at least two levels of control for the urine drug screen panel that includes a urine validation and the drug screen testing. 2. During the interview on October 15, 2018 at 13:40 PM, testing personnel #2 as listed on the CMS-209 confirmed the quality control documentation was not available on the day of the survey.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:
. Based on document review and interview, the laboratory failed to document corrective action for the humidity readings below the stated range of "40-80%" for the proper operation of the chemistry/toxicology Thermo Scientific Indiko Plus instrument for 13 (December 2016, February - June 2017, October - December 2017,

January - February 2018, and May- June 2018) of 24 months reviewed. Findings include: 1. On October 15, 2018 at approximately 12:25 PM, record review of the "Michigan Advance Pain and Spine" monthly temperature logs revealed the humidity readings were below the stated range of 40-80% (incorrect range of 30-80% from June 2017 to present) as follows: a. December 2016 - 2, 5-9, 13-16, 19, 21-23, 27, and 29-30 b. February 2017 - 1-3, 6-10, 12-17, 20-24, and 27-28 c. March 2017 - 1-3, 6-7, 9-10, 13-17, 21-24, 27, and 29-31 d. April 2017 - 3-7, 10, 12-14, 17-21, 24, and 28 e. May 2017 - 1-5, 8-12, 15-16, 19, and 24 f. June 2017 - 1-2 and 7-8 g. October 2017 - 6, 13, 19, 27, and 30-31 h. November 2017 - 6-10, 13-17, 20-21, and 27-30 i. December 2017 - 1, 4-8, 11-15, 18-22, and 26-29 j. January 2018 - 2-5, 8-12, 15-19, 22-26, and 29-31 k. February 2018 - 1-2, 5-9, 12-16, 19-23, and 26-28 l. May 2018 -1-5, 7-12, 15, 18, and 21-25 m. June 2018 - 1, 5, 11, and 13-14 2. During the interview on October 15, 2018 at approximately 3:15 PM, the office manager, liaison, and testing personnel #2 as listed on the CMS-209 confirmed no corrective action was taken for the humidity readings below the stated range.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to maintain a record system that included the identity of the testing personnel performing the routine chemistry and toxicology testing for 11 (#1 - #11) of 11 patient charts audited. Findings include: 1. On October 15, 2018 at 1:40 PM, record review of 11 patient charts audited revealed the identity of the testing personnel who performed and reported out the routine chemistry and toxicology testing was not recorded on the final report or logged on a worksheet. 2. During the interview on October 15, 2018 at 1:40 PM, testing personnel #2 as listed on the CMS-209 confirmed the laboratory did not have a tracking system in place to show who performed and reported out the laboratory testing.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to evaluate the

laboratory's chemistry and toxicology proficiency testing performance to ensure 1) for four (3rd event 2016, 1st and 2nd events 2017, and 1st event 2018) of four testing events the final reports were not reviewed and 2) for three (1st and 2nd events 2017 and 1st event 2018) of four testing events the final reported grade was less than 80% and 3) the performance grade for one (1st event 2018 "UDS Opiates" specimen "UDS-02") of three specimens received a "Not Graded 2" score. Findings include: 1. On October 15, 2018 at 10:00 AM, record review of the final proficiency testing events revealed the following: a. 3rd event 2016, 1st and 2nd events 2017 and 1st event 2018 the laboratory director and testing personnel failed to review the final proficiency testing events b. 1st and 2nd events 2017 and 1st event 2018 the laboratory failed to document corrective action for the final pH and creatinine scores less than 80% c. 1st event 2018 "UDS Opiates" specimen "UDS-02" received a "Not Graded 2" score and no corrective action or self grading was performed and documented. 2. On October 15, 2018 at 10:00 AM when queried, the office liaison was unable to provide the surveyor documentation to show the proficiency testing events had been reviewed by the laboratory director and the testing personnel and that corrective action was taken for the failed events. 3. During the interview on October 15, 2018 at 10:00 AM, the office liaison confirmed the laboratory did not review and evaluate the final proficiency testing events.