Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2149889	06/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Mid Michigan Pain Specialty, Pc	42500 Hayes Rd Suite 800, Clinton Township, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: . Based on procedure review, lack of documentation, and interview with Testing Personnel #1 (TP1), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified for the laboratory systems for 10 (August 2018 to June 2019) of 10 months reviewed. Findings include: 1. "Mid-Michigan Pain Specialty General Policies and Procedures" review revealed in section 3.2.2 Pre-Analytic Phase on page 17 stated: "five requisitions, chosen at random, are reviewed for name and address of person/facility ordering the tests, patient identification (first, last, and unique identifier), specimen source, date and time of collection, and tests ordered." 2. Quality assurance review revealed lack of documentation to show the test requisitions had been reviewed for 10 months. 3. During the interview on June 11, 2019 at approximately 12:00 pm, TP1 acknowledged chart review of patient test requisitions were not been performed and documented.
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 patient chart review, procedure review, and interview with Testing Personnel #1 (TP1), the laboratory failed to have a written request for patient testing from an authorized person for drug screen testing for 10 (patients #1-#10) of 10 patient charts reviewed. Findings include: 1. A patient chart review conducted on 10 (patients #1-#10) chosen patient charts revealed the laboratory did not have a written request or standing order for routine drug screen testing. 2. A review of the "Authorization for Ordering Tests" procedure revealed a section stating, "The laboratory will perform testing when receiving a written request from a licensed healthcare provider." 2. An interview on 6/11/19 at 11:29 am with TP1 confirmed no written request for patient testing from a authorized person had been documented in the patient charts.
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 patient chart audit and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure test results were sent to the patient chart in a timely manner for 1 (patient #9) of 10 patient charts audited. Findings include: 1. A patient chart audit revealed Patient #9, tested on 4/16/19, did not have final results in their chart. 2. An interview on 6/11/19 at 11:29 am with TP1 confirmed the patient did not have results in their chart from 4/16/19.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 with Testing Personnel #1 (TP1), the Laboratory Director failed to ensure all proficiency testing reports received were reviewed by the appropriate staff for 2 (third event of 2018 and the first event of 2019) of 2 proficiency testing events reviewed. Findings include: 1. A record review of proficiency testing data revealed a lack of signed review by the Laboratory Director and the appropriate testing personnel for the third event of 2018 and the first event of 2019. 2. An interview on 6/11/19 at 10:35 am with TP1 confirmed proficiency testing reports had not been reviewed by the Laboratory Director or appropriate staff for two proficiency testing events.

D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #1 (TP1), the Laboratory Director failed to follow an approved corrective action plan when any proficiency testing result is found to be unacceptable or unsatisfactory for 2 (third event of 2018 and the first event of 2019) of 2 proficiency testing events reviewed. Findings include: 1. A record review of proficiency testing documents revealed the following: a. The third event of 2018 did not have results or corrective action available. 1. No results were provided when requested by the surveyor on 6/11/19 at 10:35 am. 2. No corrective action was present for this event. b. The first event of 2019 1. The result of "No Data Received" was issued. 2. No corrective action or self grading was present for this event. 2. An interview on 6/11/19 at 10:35 am with TP1 confirmed corrective action or self grading was not available for the two proficiency testing events.