Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2131703	04/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mid Michigan Pain Management	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
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 procedure manual review and interview, the laboratory failed to ensure written competency policies were established that contained the requirements from subpart M for the testing personnel performing the highly complex chemistry and toxicology testing. Findings include: 1. On April 23, 2018 at approximately 9:30 AM, review of the testing personnel files in the "Mid Michigan Pain Management Personal Files" notebook revealed testing personnel #1 as listed on the CMS-209 was evaluated initially by a checklist. 2. On April 23, 2018 at 11:50 AM, procedure manual review revealed the laboratory did not establish a written competency policy that included the six requirements from subpart M for the high complex chemistry and toxicology testing that included the following: a. Direct observations of routine patient test performance, patient preparation, specimen handling, processing, and testing. b. Monitoring the recording and reporting of patient test results. c. Review of test results, worksheets, quality control records, proficiency testing results, and preventive maintenance. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed samples. f. Assessment of problem solving skills. 3. During the interview on April 23, 2018 at 11:50 AM, testing personnel #1 confirmed the laboratory did not establish a competency policy that contained the requirements from Subpart M.
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 written request or standing order for patient testing from an authorized person for the routine chemistry and toxicology testing for nine (#1 - #9) of nine patient charts audited. Findings include: 1. On April 23 2018 at 12:15 PM, record review revealed for nine (#1-#9) of nine patient charts audited the laboratory did not have a written request or standing order for the routine chemistry and toxicology testing by an authorized person. 2. During the interview on April 23, 2018 at 12:15 PM, testing personnel #1 as listed on the CMS-209 confirmed a written request or standing order by an authorized person was not available on the day of the survey.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: . Based on test requisition review and interview, the laboratory failed to provide the name and address of the testing facility for nine (#1-#9) of nine patient charts audited. Findings include: 1. On April 23, 2018 at 12:15 PM, test requisition review revealed the name and address of the testing facility was not included on the requisition for nine (#1-#9) of nine patient charts audited. 2. During the interview on April 23 2018 at 12:15 PM, testing personnel #1 as listed on the CMS-209 confirmed the test requisition did not contain all the laboratory specific information.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date five of five Enzyme Immunoassay and one of one validity policies and procedures before they were put into use. Findings include: 1. On April

	23, 2018 at 11:47 AM, procedure manual review revealed there was no documentation to show for five of five Enzyme Immunoassay and one of one validity testing policies and procedures had been approved, signed, and dated before they were put into use as follows: a. Enzyme Immunoassay 1. IR 500 Benzodiazepine Enzyme Immunoassay 2. IR 500 Cocaine Metabolite Enzyme Immunoassay 3. IR 500 Opiate Enzyme Immunoassay 4. IR 500 Oxycodone Enzyme Immunoassay 5. IR 500 Cannabinoids (cTHC) 50 Enzyme Immunoassay b. Validity testing 1. IR 500 Urine Creatinine Validity Test 2. During the interview on April 23, 2018 at 11:47 AM, testing personnel #1 as listed on the CMS-209 confirmed the policies and procedures were not signed before being put into use.