Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0723829	09/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Michigan Institute Of Medicine, P C	38525 8 Mile Road, Livonia, 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
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the testing personnel, the laboratory failed to have the appropriate amount of reagents for routine chemistry and endocrinology testing for 3 (2/23/18 to 5/7/18) of 24 months reviewed. Findings include: 1. A review of patient charts revealed patient #1 had a specimen collected on 2/23/18 and orders for the following tests: a. Free Thyroxine (FT4) b. Triiodothyronine (T3) c. Thyroid Stimulating Hormone (TSH) d. Vitamin B12 e. Folate 2. A review of patient charts revealed the date of testing for the specimen collected on 2/23/18 was 5/7/18. 3. A review of the laboratory's established "Handling Procedure" revealed a section stating, "If testing is unable to be done because the machine is down or the tech is out of town, all patient samples will be sent to the reference lab for blood work." 4. An interview on 9/16/19 at 12:29 pm with the testing personnel revealed ample reagents were not available for patient testing between 2/13 /18 and 5/7/18. 5. A record review of "Communications, Complaints, Problems" biannual log from the period of 2/7/18 to 8/8/18 revealed no problems and/or complaints were reported and no corrective action was taken. 6. An interview on 9/16 /19 at 12:29 pm with the testing personnel confirmed the above findings. B. Based on observation, record review, and interview with the testing peronnel, the laboratory failed to have sufficient equipment for the testing it performs for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. An observation on 9/16/19 at 8:54 am by the surveyor revealed a Sterling Diagnostics IsoComp I without a roll of printer paper. 2. A review of the Sterling Diagnostics IsoComp I analyzer data revealed a lack of instrument printouts to verify transcribed data from September 2017 to September 2019 for the following processes: a. Background counts b. Quality control c.

	Calibrations d. Patient test results 3. An interview on 9/16/19 at 9:29 am with the testing personnel revealed the printer was broken. 4. An interview on 9/16/19 at 9:29 am with the testing personnel confirmed the above findings.
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 the testing personnel, the laboratory failed to retain analytic instrument printouts for quality control, patient tests, used in routine chemistry and endocrinology testing for 2 (September 2017 to September 2019) of 2 years. Findings include: 1. A review of the Sterling Diagnostics IsoComp I analyzer data revealed a lack of instrument printouts to verify transcribed data of the following processes: a. Background counts b. Quality control c. Calibrations d. Patient test results 2. An interview on 9/16/19 at 9:29 am with the testing personnel confirmed instrument printouts were not available for the Sterling Diagnostics IsoComp I analyzer.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on record review and interview with the testing personnel, the laboratory failed to ensure patient specimen integrity from the time of collection through the completion of testing for 1 (patient #1) of 10 patient charts reviewed. Findings include: 1. A review of patient charts revealed patient #1 had a specimen collected on 2/23/18 and orders for the following tests: a. Free Thyroxine (FT4) b. Triiodothyronine (T3) c. Thyroid Stimulating Hormone (TSH) d. Vitamin B12 e. Folate 2. A review of patient charts revealed the date of testing for the specimen collected on 2/23/18 was 5/7/18. 3. An interview on 9/16/19 at 12:29 pm with the testing personnel stated specimens are kept frozen until testing is performed. 3. A review of the Vitamin B12 and Folate reagent package insert revealed the section "Storage of Samples" stating, "Store samples before analysis at 2-8 degrees Celsius. If storage is expected to exceed 4 hours, the sample should be stored at -20 degrees Celsius or below. Samples are stable for 6-8 weeks at this temperature. 4. A record review of the laboratory established "Specimens" procedure states, "Unacceptable specimens must be redrawn for lab testing. Reasons for rejecting a specimen shall include: hemolysis, insufficient specimen, improper labeled specimen, wrong tube collection, improper storage." 5. A record review of "Communications, Complaints, Problems" biannual log from the period of 2/7/18 to 8/8/18, no problems and

	complaints were reported and no corrective action was taken. 6. An interview on 9/16 /19 at 12:29 pm with the testing personnel confirmed specimen storage exceeded the manufacturer-established storage time.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the testing personnel, the laboratory failed to meet the laboratory's and the manufacturer's criteria for acceptable Thyroid Stimulating Hormone (TSH) quality control for 36 patients receiving testing on 1/15 /18. Findings include: 1. A record review of the laboratory's established "Quality Control Criteria" revealed the section "Criteria for rejecting quality control run" stating "2 of 2 controls are outside 2 SD, 1 level of control outside 3 SD, the range (difference between two controls) within a run exceeds 4 SD." 2. A record review of the "Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2 and 3" revealed the level 1 control range was 0.340-0.520 with a mean of 0.430. 3. A review of the quality control results from 1/15/18 revealed the level 1 control had a value of 0.62, more than 3 standard deviations from the mean. 4. A review of the patient testing log from 1 /15/18 revealed 36 patients had been tested the day quality control was unacceptable. 5. A review of the "Maintenance, Calibration, and Quality Control- QA Tracking Sheet" from the evaluation period 12/3/18 to 8/30/19 revealed quality control was reviewed and no problems or corrective actions were documented. 6. An interview on 9/16/19 at 10:28 am with the testing personnel confirmed quality control for TSH was out of range on 1/15/18.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . The laboratory failed to meet applicable postanalytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to ensure test results are accurately sent to patients' charts. Refer to D5801. 2. The laboratory failed to make patient test report information maintained as part of patients' charts available to the surveyor upon request. Refer to D5803.
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 record review and interview with the testing personnel, the laboratory failed to ensure test results are accurately sent to the patient chart for 8 (patients #1, #2, #4, #5, #6, #7, #9, and #10) of 10 patient charts reviewed. Findings include: 1. On 9/16/19 at approximately 12:00 pm, the surveyor requested 10 test orders and report information maintained in patient charts. 2. A record review of patient charts revealed a lack of test orders and reports in patient charts for the following patients: a. Patient #1, tested on 9/27/17 b. Patient #2, tested on 11/2/17 c. Patient #4, tested on 4/18/18 d. Patient #5, tested on 7/16/18 e. Patient #6, tested on 9/20/18 f. Patient #7, tested on 12 /10/18 g. Patient #9, tested on 6/26/19 h. Patient #10, tested on 8/5/19 3. An interview on 9/16/19 at 1:14 pm with the testing personnel confirmed test results were not available for the patients listed above.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: . Based on record review and interview with the testing personnel, the laboratory failed to make patient test report information maintained as part of patients' charts available to the surveyor upon request for 5 (patients #2, #4, #5, #7, and #10) of 10 patient charts reviewed. Findings include: 1. On 9/16/19 at approximately 12:00 pm, the surveyor requested 10 test orders and report information maintained in patient charts. 2. A record review of patient testing logs revealed the following patients had testing performed by the laboratory: a. Patient #2 b. Patient #4 c. Patient #5 d. Patient #7 e. Patient #10 2. In an interview on 9/16/19 at 1:10 pm with the testing personnel revealed 5 patients charts were not available.