Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0723829	04/21/2023
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
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, 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 observations, review of records, and interviews, the laboratory failed to have a request for patient testing from an authorized person (Refer to D5301), failed to indicate the expiration dates of control materials used in endocrinology testing (Refer to D5415), failed to ensure control materials used in endocrinology testing had not exceeded their expiration date (Refer to D5417 A), failed to ensure supplies used in specimen collection had not exceeded their expiration dates (Refer to D5417 B), failed to establish the criteria for acceptability of control materials used in endocrinology testing (Refer to D5469), failed to perform corrective action when its Thyroid Stimulating Hormone (TSH) control testing had failed to meet the laboratory's acceptability criteria (Refer to D5783), and failed to ensure test reports were reliably sent to the final report destination (Refer to D5801).
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 with Collection Personnel, the laboratory failed to have a request for patient testing from an authorized person for 3 (Patients

	27, 3, and 25) of 7 patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed the following patients had thyroid testing performed: a. Patient #27 had Triiodothyronine (T3), Free Thyroxine (T4), and Thyroid Stimulating Hormone (TSH) testing performed on 12/16/21. b. Patient #3 had T3, Free T4, and TSH testing performed on 4/20/22. c. Patient #25 had T3, Free T4, and TSH testing performed on 6/24/22. 2. The surveyor requested the test requests for the patients listed above on 4/20/23 at 4:50 pm and the documentation was not made available. 3. An interview on 4/20/23 at 4:58 pm with Collection Personnel revealed the laboratory did not have documentation of the test requests for the patients listed above.
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 record review and interview with the Testing Personnel, the laboratory failed to have the name of the authorized person requesting testing on test requests for patient testing for 4 (Patients 7, 10, 28, and 13) of 7 patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed the following patients had thyroid testing performed did not indicate the name of the authorized person requesting testing: a. Patient #7 had Triiodothyronine (T3), Free Thyroxine (T4), and Thyroid Stimulating Hormone (TSH) testing performed on 3/5/22. c. Patient #10 had T3, Free T4, and TSH testing performed on 4/30/22. b. Patient #28 had T3, Free T4, and TSH testing performed on 8/24/22. d. Patient #13 had T3, Free T4, and TSH testing performed on 3/27/23. 3. An interview on 4/20/23 at 5:20 pm with the Testing Personnel confirmed the laboratory did not have the name of the authorized person requesting testing on test requests for the patients listed above.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: . Based on observation and interview with the Testing Personnel, the laboratory failed to label control materials with the expiration dates used in endocrinology testing for 2 (May 2021 to May 2023) of 2 years. Findings include: 1. The surveyor observed the laboratory's frozen Bio-Rad Lyphochek Immunoassay Plus control materials in the freezer during a tour on 4/20/23 at 1:02 pm indicating the reconstitution date as 4/17 /23. 2. A review of the laboratory's "Bio-Rad Lyphochek Immunoassay Plus Control" manufacturer's instructions for control materials revealed a section titled "Reconstituted and Frozen" stating, " When reconstituted and stored tightly capped at -20 to -70 degrees Celsius, this product will be stable as follows: a. All analytes: 20 days b. Except: ACTH, Aldosterone, Calcitonin and C-Peptide: No frozen stability provided." 3. An interview on 4/20/23 at 2:05 pm with the Testing Personnel confirmed the laboratory had not included the new expiration date on the reconstituted control materials.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . A. Based on observation and interview with the Testing Personnel, the laboratory failed to ensure control materials used in endocrinology testing had not exceeded their expiration date for 2 (May 2021 to May 2023) of 2 years. Findings include: 1. The surveyor observed the laboratory's frozen Bio-Rad Lyphochek Immunoassay Plus control materials in their original containers in the freezer during a tour on 4/20/23 at 1:02 pm indicating the reconstitution date as 4/17/23. 2. A review of the laboratory's "Bio-Rad Lyphochek Immunoassay Plus Control" manufacturer's instructions for control materials revealed a section titled "Reconstituted and Frozen" stating, " When reconstituted and stored tightly capped at -20 to -70 degrees Celsius, this product will be stable as follows: a. All analytes: 20 days b. Except: ACTH, Aldosterone, Calcitonin and C-Peptide: No frozen stability provided. Once thawed, do not refreeze this product. Discard the remaining material." 3. An interview on 4/20/23 at 2:05 pm with the Testing Personnel confirmed the laboratory had been using control materials beyond the 20-day stability as well as using the controls after several freeze and thaw cycles, against manufacturer guidance. B. Based on observation and interview with the Testing Personnel, the laboratory failed to ensure supplies used in specimen collection had not exceeded their expiration dates for 840 expired specimen collection supplies observed. Findings include: 1. The surveyor observed the laboratory's specimen collection supplies during a tour on 4/20/23 at 1:02 pm. Below were supplies beyond their expiration dates: a. Red top glass vacutainer tubes, 77 total, expired 7/31/21. b. BD vacutainer urinalysis preservative tubes, 95 tubes, expired 2/28 /23. c. Box of urine culture collection devices and tubes, 21 total, expired 11/2019. d. Box of swabs, 22 total, expired 7/2021. e. Oral collection device, expired 7/2021. f. One box of blood collection needles, 100 count, expired 3/2019. g. Two Intercept Oral Fluid Collection kits expired 4/2021 and 7/2021. h. One box of BD vacutainer eclipse blood collection needles with pre-attached holders, 67 total collection devices in box, expired 1/31/23. i. MedSchenker smart transport medium, 42 total, Expired 2/22/22. j. BD E swabs, 9 total, expired 9/30/21. k. Blue top sodium citrate blood collection tubes, 71 total in package, expired 12/31/2022. l. BD vacutainer eclipse blood

	collection needles, 11 total, expired 1/31/22. m. Vanishpoint syringe, 1 total, expired 2 /28/22. n. BD PrecisionGlide Needle Sterile 21 gauge, 22 total, expired 8/31/22. o. BD PrecisionGlice 22 G needles, 15 total, expired 2/28/21. p. Loose needles (not in packaging): i. 2 with the expiration date of 11/2013. ii. 12 total with the expiration date of 9/2014. iii. 1 with the expiration date of 4/2015. iv. 4 with the expiration date of 6/2017. v. 9 with the expiration date of 3/2019. q. Loose Green top lithium heparin blood collection tubes not in packaging: i. 1 expired 3/31/20. ii. 1 expired 1/31/22. iii. 32 total expired 4/30/22. iv. 4 expired 5/31/22. v. 7 expired 7/31/22. r. Loose blue top sodium citrate blood collection tubes not in packaging: i. 2 expired 7/31/19. ii. 2 expired 4/30/20. iii. 8 expired 8/31/20. iv. 10 expired 9/30/20. v. 14 expired 8/31/21. s. Loose purple top EDTA blood collection tubes not in packaging: i. 1 expired 1/31 /22. ii. 3 expired 3/31/22. iv. 3 expired 6/30/22. t. Loose gold top serum separator blood collection tubes not in packaging: i. 1 expired 12/31/20. ii. 1 expired 1/31/22. iii. 1 expired 9/30/22. iv. 1 expired 11/30/22. v. 1 expired 12/31/22. vi. 1 expired 2/28 /23. u. Loose navy top K2EDTA Trace Element blood collection tubes not in packaging: i. 4 expired 4/30/20. ii. 3 expired 5/30/20. iii. 4 expired 8/31/20. iv. 5 expired 11/30/20. v. 1 expired 12/31/20. vi. 25 expired 1/31/21. vii. 1 expired 4/30/21. viii. 1 expired 10/31/21. ix. 8 expired 1/31/22. x. 1 expired 2/28/22. v. Loose grey top sodium fluoride blood collection tubes not in packaging: i. 1 expired 12/2016. ii. 2 expired 7/2017. iii. 16 expired 5/31/20. iv. 1 expired 1/31/22 w. Loose tiger top red serum separator blood collection tubes not in packaging: i. 1 expired 12/31/19. ii. 1 expired 8/31/21. iii. 3 expired 9/30/21. x. White top no additive tubes specimen tubes: i. 10 expired 7/15/21. ii. 6 expired 8/12/21. iii. 4 expired 3/24/22. iv 3 expired 3/31/22. y. Flocked swabs, 20 total, Expired 7/2022. z. Loose plastic red top serum blood collection tubes not in packaging: i. 1 expired 12/31/20. ii. 1 expired 7/31/21. iii. 34 expired 5/31/22. aa. Loose Puritain UniTrans-RT Transport System viral transport media collection tubes not in packaging: i. 2 expired 3/28/22. bb. Loose grey top urine culture preservative collection tubes not in packaging: i. 2 expired 11/2021. ii. 1 expired 4/30/2022. 2. An interview on 4/20/23 at 5:20 pm with the Testing Personnel confirmed the specimen collection supplies listed above had been expired.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 establish the criteria for acceptability of control materials used in endocrinology testing for 1 (Bio-Rad Lyphocheck Immunoassay Plus Control Lot 40380 used between April 2021 and August 2022) of 2 lots reviewed. Findings

	include: 1. A review of the laboratory's "Quality Control Material New Lot Verification Policy" revealed a section stating, "Upon receipt of QC material, compare lot number with current QC in use. If lot number is different, proceed with parallel study to allow enough time for a minimum of test dates and data assessments. Established control lot is run in conjunction with new lot number controls. When the parallel run is completed, review the results. All old lot control values should be within established range for the new control lot values to be considered valid for assessment. If assayed controls are used, all new lot values should be within assayed ranges and the means and standard deviations should be close to what are indicated on the QC package insert. All controls must be within +/- 2SDs of the established mean. Document if the new lot range is acceptable when compared to expected values. If the new lot number is acceptable, proceed with testing using said lot." 2. A review of the laboratory's control results revealed the laboratory had been using the ranges provided by the manufacturer with the controls and had not established their acceptability criteria or statistical parameters for the Bio-Rad Lyphochek Immunoassay Plus Controls Lot 40380 used between April 2021 and August 2022. The acceptability criteria the laboratory was using for its Level 3 Thyroid Stimulating Hormone (TSH) was greater than 22.4. No range had been established. 3. An interview on 4/20/23 at 4: 00 pm with the Testing Personnel revealed the laboratory had not established acceptability criteria for its TSH Level 3 control for lot 40380.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to perform corrective action when its Thyroid Stimulating Hormone (TSH) control testing had failed to meet the laboratory's acceptability criteria for 1 (4/20/22) of 7 patient testing dates reviewed. Findings include: 1. A review of the laboratory's control testing records revealed the following control testing results obtained on 4/20 /23 that had failed: a. Bio-Rad Lyphocheck Immunology Control Lot 40381 had a range of 0.32 to 0.63 IU/mL with a result of 0.93 IU/mL. b. Bio-Rad Lyphocheck Immunology Control Lot 40382 had a range of 3.92 to 7.79 IU/mL with a result of 7.9 IU/mL. 2. A review of the laboratory's "Quality Control Criteria" policy revealed a section stating, "Criteria for rejecting quality control run: 2 of 2 controls are outside 2 SD 1 level of control is outside 3 SD The range (difference) between two controls within a run exceeds 4 SD" and a section titled "Corrective Action for Out of Control Results" stating, "When a control result exceeds the limits, the appropriate action is as follows: 1. Reanalyze the same control (not patient samples) immediately, but do not report patient results. 2. Record both control values if the reanalyzed control now fans within acceptable limits. The patient samples may now be run and reported." 3. A review of the laboratory's patient testing log revealed a total of 48 patients received

	TSH testing on 4/20/22 when controls were out of range. 4. An interview on 4/20/23 at 5:20 pm with the Testing Personnel confirmed the laboratory had not performed corrective action for the failed controls on 4/20/22 and had reported patient results.
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 Collection Personnel, the laboratory failed to ensure test reports were reliably sent to the final report destination for 3 (Patients 27, 3, and 25) of 7 patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed the following patients had thyroid testing performed: a. Patient #27 had Triiodothyronine (T3), Free Thyroxine (T4), and Thyroid Stimulating Hormone (TSH) testing performed on 12/16/21. b. Patient #3 had T3, Free T4, and TSH testing performed on 4/20/22. c. Patient #25 had T3, Free T4, and TSH testing performed on 6/24/22. 2. The surveyor requested the test reports for the patients listed above on 4/20/23 at 4:50 pm and the documentation was not made available. 3. An interview on 4/20/23 at 4:58 pm with Collection Personnel revealed the laboratory did not have documentation of the test reports for the patients listed above. ***This is a repeated deficiency from the 9/16/19 recertification survey***
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the laboratory failed to have test reports of patient testing that included the name of the laboratory location that performed testing for 4 (Patients 7, 10, 28, and 13) of 7 patient test records reviewed. Findings include: 1. A review of the laboratory's testing logs revealed the following patients had thyroid testing performed and indicated the laboratory location that performed testing as "Keith J. Pierce, MD" instead of "Michigan Inst of Medicine": a. Patient #7 had Triiodothyronine (T3), Free Thyroxine (T4), and Thyroid Stimulating Hormone (TSH) testing performed on 3/5/22. c. Patient

	#10 had T3, Free T4, and TSH testing performed on 4/30/22. b. Patient #28 had T3, Free T4, and TSH testing performed on 8/24/22. d. Patient #13 had T3, Free T4, and TSH testing performed on 3/27/23. 3. An interview on 4/20/23 at 5:20 pm with the Testing Personnel confirmed the laboratory did not have the name of the laboratory location that performed testing on the test reports for the patients listed above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on review of records and interviews, the Laboratory Director failed to ensure the laboratory's quality control program was maintained (Refer to D6093) and patient test results were reported only when the test system is functioning properly (Refer to D6097).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure the laboratory's quality control program was maintained. Refer to D5417 and D5469.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: . Based on record review and interview with the Testing Personnel, the Laboratory Director failed to ensure patient test results were reported only when the test system is functioning properly. Refer to D5783.