Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0366080	03/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mhp Dba South Macomb Internists	11885 E 12 Mile Road #100b, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: . Based on record review and interview, the testing personnel and the laboratory director failed to attest to the routine integration of the American Association of Bioanalysts (AAB) proficiency testing samples into the patient workload for two (1 and 2 for 2017) of five testing events reviewed. Findings include: 1. On March 12, 2018 at 10:34 and 11:00 a.m., record review of the final electronically generated "AAB Proficiency Testing Services" report revealed the testing personnel and the laboratory director did not manually sign the electronically submitted attestation sheets as follows: a. 1st event 2017 - testing personnel and the laboratory director did not sign "Hematology, Cell ID, Coagulation, RF, Basic Chem, Comp Chem, Special Chem, TIBC-UIBC, Lipids and Urinalysis" attestation sheets b. 2nd event 2017 - no director signature on "Basic Chem, Comp Chem, TIBC-UIBC, Lipids, and Special Chem attestation sheets c. 2nd event 2017 - no testing personnel and laboratory director signature - "Urinalysis" attestation sheet 2. During the interview on March 12, 2018 at 10:34 and 11:00 a.m., the laboratory liaison confirmed the electronically submitted attestation sheets did not contain a manual signature.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, 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 Chemistry as specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to follow procedures for an ongoing mechanism to monitor, assess, and correct problems as specified for the laboratory systems. Refer to D5291. 2. The laboratory failed to review, evaluate, and approve the verification data for the chemistry endocrinology FREND instrument prior to patient testing. Refer to D5421. 3. The laboratory failed to perform and document maintenance function checks for the timers, thermometers, and the chemistry Nanotech Frend instrument. Refer to D5429. 4. The laboratory failed to perform and evaluate the chemistry endocrinology Nanotech FREND calibration verifications at least once every six months. Refer to D5439. 5. The laboratory failed to perform quality control as required for the endocrinology testing. Refer to D5445.
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 record review and interview, the laboratory failed to follow procedures for an ongoing mechanism to monitor, assess, and correct problems as specified for the laboratory systems for two of eight sections reviewed in 2016 to 2018. Findings include: 1. On March 12, 2018 at 2:29 p.m., record review of the "Quality Assurance Lab Personnel" manual revealed for two (specimen handling, collection and storage and test tracking) of eight sections to be reviewed the laboratory did not have any documentation to show the quarterly review was completed as follows: a. specimen handling, collection, and storage - no documentation for July 2017 and January 2018 b. test tracking - no documentation for January 2018 2. During the interview on March 12, 2018 at 2:29 p.m., the laboratory liaison confirmed the quarterly reviews were not completed and documented.
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, the laboratory failed to identify the contents, the preparation date, and expiration date on the staining reservoir for the manual hematology complete blood cell count (CBC) differential testing . Findings include: 1. On March 12, 2018 at 9:47 a.m. during a tour of the laboratory the surveyor observed

	an unlabeled staining reservoir filled with reagents. 2. On March 12, 2018 at 9:47 a.m. when queried, testing personnel #2 as listed on the CMS-209 identified the contents of the reservoir as the differential stain for the manual CBC differential count. 3. During the interview on March 12, 2018 at 9:47 a.m., testing personnel #2 confirmed the reagent reservoir was not labeled with the contents, preparation date, and expiration date.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to review, evaluate, and approve the verification data for the chemistry endocrinology Nanotech Frend instrument for 13 of 13 months of operation prior to testing patient samples. Findings include: 1. On March 12, 2018 at 1:40 p.m., record review of the performance verification for the Nanotech Frend instrument revealed for 13 (February 1, 2017 to March 12, 2018) of 13 months of operation the instrument verification studies were not reviewed, evaluated, and approved by the laboratory director for the thyroid stimulating hormone and free thyroxine testing. 2. During the interview on March 12, 2018 at 1:40 p.m., the office liaison confirmed the director did not review, evaluate, and approve the verification process prior to testing patient samples.
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 record review and interview, the laboratory failed to perform and document the 1) timer calibrations for 24 of 24 months; 2) the thermometer calibrations for refrigerator #1 for 56 of 56 days; 3) thermometer calibrations for refrigerator #2 for 49 of 49 days and 4) failed to perform and document the weekly maintenance on the Nonotech Frend for three of 13 months reviewed. Findings include: 1. On March 12, 2018 at 9:40 and 9:47 a.m., record review of the gray binder labeled "Temperature Log" revealed no documentation for the timers for 24 (March 2016 to March 2018) of 24 months, thermometer calibrations for refrigerator #1 for 56 (January 15 to March 12, 2018) of 56 days, thermometer calibrations for refrigerator #2 for 49 (January 22 to March 12, 2018) of 49 days and the Nanotech Frend weekly maintenance for three (July-September 2017) of 13 months reviewed in 2017 and 2018 as follows: a. timers - 1. Fisher Scientific calibration "due 09/03" 2. CE 99105629 and 99105127 calibration "due 02/22/01" 3. Control Company timer

	101418089 - calibration "due 01/16/12" 4. Control Company timer 72385187 - calibration "due 7/19/09" b. refrigerator #1 thermometer - calibration "due 01/15 /2018" c. refrigerator #2 thermometer - calibration "due 01/22/2018" d. Nonotech Frend weekly maintenance 1. July 2017 - no documentation for the month 2. August - September 2017 - no documentation for two of four weekly maintenance 2. During the interview on March 12, 2018 at 9:40 and 9:47 a.m., the laboratory liaison confirmed the calibrations were not performed and documented. ***Repeat Deficiency from the January 30, 2012 survey***
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to perform and evaluate one of two chemistry endocrinology Nanotech Frend calibration verifications at least once every six months as required. Findings include: 1. When requested on March 12, 2018 at 3:06 p.m., the laboratory liaison was not able to provide documentation showing the calibration verification was complete for one (second calibration in 2017) of two every six months calibrations in 2017 as follows: a. second calibration in 2017 - thyroid stimulating hormone and free thyroxine b. second calibration in 2017 - vitamin D 2. During the interview on March 12, 2018 at 3:06 p.m., the laboratory liaison confirmed the calibration verification was not completed at least every six months in 2017.
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 operator's manual, interlaboratory memo, record review, and interview, the laboratory failed to perform quality control as required for the endocrinology testing for 13 (February 2017 to March 2018) of 13 months reviewed. Findings include: 1. On March 12, 2018 at 1:40 p.m., operator's manual review revealed the Nanotech Frend Instrument does not meet the minimum requirement of at least two levels of controls each day of patient testing or perform an individualized quality assurance plan (IQCP). 2. On March 12, 2018 at 1:40 p.m., interlaboratory memo dated "February 2017" states: "It is the policy of the laboratory of SMI to run controls on the Nanotech Frend Instrument on each new lot and/or once monthly". 2. On March 12, 2018 at 1:40 p.m., record review revealed for 13 (February 2017 to March 2018) of 13 months the laboratory did not perform two levels of controls each day of patient testing and a IQCP was not established. 3. During the interview on March 12, 2018 at 1:40 p.m., the laboratory liaison confirmed two levels of controls were had not been performed each day of testing and that an IQCP had not been implemented to decrease the number or frequency of running external controls.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to detect an incorrect result reported out for one of 15 randomly chosen patient charts audited on the day of the survey. Findings include: 1. On March 12, 2018 at 1:30 p.m., record review for one (#14) of 15 randomly chosen patient charts audited revealed the final test report in the patient's electronic medical record (EMR) did not contain the correct result for the International Normalized Ratio (INR) that was recorded on the daily worksheet. 2. During the interview on March 12, 2018 at 1:30 p.m., testing personnel #2 as listed on the CMS-209 confirmed the final report in the patient's EMR did not match the result reported on the daily worksheet. ***Repeat Deficiency from the August 11, 2015 survey***