Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0365545	11/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Practice Care Pllc	28351 Schoenherr Road, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on record review and interview, it was determined the laboratory failed to successfully participate in a CMS approved proficiency testing program for the chemistry analyte total bilirubin for two (2nd and 3rd) of two testing events in 2018. Findings include 1. On November 8, 2018 at approximately 10:00 AM, record review of the CMS database and the American Association of Bioanalysts (AAB) final proficiency testing reports revealed two consecutive unsatisfactory performances for the chemistry analyte total bilirubin for the 2nd and 3rd events in 2018. 2. On November 8, 2018 at approximately 10:00 AM, technical consultant #2 as listed on the CMS-209 confirmed the unsuccessful performance for the total bilirubin.

D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to achieve satisfactory performance for the chemistry analyte total bilirubin for two (2nd and 3rd) of two consecutive testing events in 2018. Findings include: 1. On November 8, 2018 at approximately 10:00 AM, record review of the CMS database and the American Association of Bioanalysts (AAB) final proficiency testing reports revealed for two of two consecutive testing events the chemistry total bilirubin had unsuccessful performance in 2018 as follows: total bilirubin a. 2nd event - 0% b. 3rd event - 40% 2. On November 8, 2018 at approximately 10:00 AM, technical consultant #2 as listed on the CMS-209 confirmed the unsuccessful performance for the total bilirubin.
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 for patient testing from an authorized person for the chemistry and endocrinology testing for two (#2 and #7) of ten patient charts audited. Findings include: 1. On November 8, 2018 at 1:45 PM, record review revealed for two of ten patient charts audited, the laboratory did not have a written request for the testing performed as follows: a. patient #2 - folate and hemoglobin A1C b. patient #7 - triiodothyronine (T3) 2. During the interview on December 12, 2017 at 4:39 p.m., the technical consultant #2 as listed on the CMS-209 confirmed there were no written orders for the patient testing. ***Repeat Deficiency from 12/12/2017 complaint survey investigation***
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to follow written procedures to "perform an document calculation checks every six months" for the

	chemistry testing. Refer to D5401. 2. The laboratory director failed to approve, sign, and date policy and procedure manuals prior to testing patient samples. Refer to D5407. 3. The laboratory failed to perform and document every day of testing the background count. Refer to D5431. 4. The laboratory failed to perform and document the quality control as required for the hematology complete blood cell testing each day of patient testing. Refer to D5445. The cumulative effect of the failure of the laboratory to meet the requirements of 493.1251 through 493.1289 constitutes condition-level noncompliance. ***Repeat Deficiencies from December 12, 2017 and July 11, 2018 complaint survey investigations***
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: . Based on procedure review and interview, the laboratory failed to follow written procedure to "perform an document calculation checks every six months" on the Mindray BS-200 analyzer chemistry test values reported using an instrument generated calculation for one (2nd six month period) of one six month periods in 2018. Findings include: 1. On November 8, 2018 at 11:08 AM, "Patient Test Management (test tracking) System" procedure review stated "calculation checks were to be performed and documented every six months on five patient specimens". 2. On November 8, 2018 at 11:08 AM when queried, technical consultant #2 as listed on the CMS-209 was not able to provide the surveyor the 2nd six months of 2018 calculations for the following testing: a. very low density lipoprotein (VLDL) b. urea nitrogen (BUN)/creatinine ratio c. % saturation for the total iron binding count 3. During the interview on November 8, 2018 at 11:08 AM, technical consultant #2 confirmed the procedure for calculation checks was not performed and documented.
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 three ("Quality Assurance Manual", "Procedure Manual", and the "MedTest") of three procedure manuals before they were put into use. Findings include: 1. On November 8, 2018 at 11:40 AM, procedure manual review revealed the laboratory director did not sign, approve, and date three procedure manuals before they were put into use as follows: a. "Quality Assurance Manual" b. Beckman Access II "Procedure Manual" c. Mindray BS-200 "MedTest" manual 2. During the interview on November 8, 2018 at 11:40 AM, technical consultant #2 as listed on the CMS-209 confirmed the procedure manuals were not approved, signed, and dated by the laboratory director prior to testing patient samples.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to document for one (#7) of ten patient charts audited the daily background count for the Beckman Coulter AcT diff 2 hematology instrument as defined by the manufacturer. Findings include: 1. On November 8, 2018 at 2:27 PM, record review for patient #7 chart audit revealed there was no documentation of the instrument background count for the day of testing. 2. On November 8, 2018 at 2:27 PM when queried, technical consultant #2 as listed on the CMS-209 was unable to provide the surveyor the documentation requested. 3. During the interview on November 8, 2018 at 2:27 PM, technical consultant #2 confirmed an acceptable background count was not documented before patient testing.
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 record review and interview, the laboratory failed to perform the hematology complete blood cell count (CBC) quality control each day of patient testing for one (#7) of ten patient charts audited. Findings include: 1. On November 8, 2018 at 2:27 PM, record review of the daily CBC quality control records revealed the laboratory did not run at least two different levels of controls on the day of patient testing. 2. During the interview on November 8, 2018 at 2:27 PM, technical consultant #2 as listed on the CMS-209 confirmed as least two different levels of controls had not been performed and documented on the day of testing for patient #7. ***Repeat Deficiency from the December 12, 2017 and July 11, 2018 complaint survey investigations***
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 document review and interview, the laboratory failed to have the final chemistry testing maintained as part of the patient's chart or medical record for one (#2) of ten patient charts audited. Findings include: 1. On November 8, 2018 at 1:45 PM, document review for patient #2 chart audit revealed the final report did not contain a magnesium that was ordered on the manual requisition. 2. On November 8, 2018 at 1:45 PM when queried, technical consultant #2 as listed on the CMS-209 was not able to provide documentation to show the magnesium testing was performed. 3. During the interview on November 8, 2018 at 1:45 PM, technical consultant #2 confirmed the final report did not contain the testing requested from the manual requisition.
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, the laboratory failed to include the patient's scanned final report in the electronic medical records (EMR) for one (#6) of ten patient charts audited. Findings include: 1. On November 8, 2018 at 2:15 PM, record review for one of ten patient charts audited revealed the final complete blood cell count (CBC) was not scanned into the patients EMR file. 2. On November 8, 2018 at 2:15 PM when queried, technical consultant #2 as listed on the CMS-209 was not able to provide the surveyor the final report in the EMR file. 3. On November 8, 2018 at 2: 15 PM, technical consultant #2 confirmed the final CBC report was not scanned into the EMR file. ***Repeat Deficiency from the July 11, 2018 complaint survey investigation***