Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0708436	(X3) Date Survey Completed 04/24/2018
Name of Provider or Supplier Southgate Medical Clinic	**Street Address, City, State** 13819 Trenton Rd, Southgate, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to enroll in a proficiency testing program for one (1st event in 2018) of five events reviewed for Rheumatoid factor (RA/RF) in the subspecialty general immunology. Findings include: 1. On April 24, 2018 11:37 AM, record review of the CMS database and Medical Laboratory Evaluation (MLE) proficiency testing documents revealed there was no documentation of proficiency testing for 1st event 2018 for Rheumatoid factor (RA /RF). 2. During the interview on April 24, 2018 at 11:45 AM, testing personnel #3 confirmed the laboratory was not enrolled in a proficiency testing program for 1st event in 2018 for RA/RF. 3. During a phone interview on May 2, 2018 at 3:02 PM, the MLE PT provider confirmed the laboratory was not enrolled in proficiency testing for RA/RF.
D2004	ENROLLMENT CFR(s): 493.801(a)(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different

	program and must notify CMS before any change in designation; This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to participate with the same proficiency provider for one year for one (3rd event in 2017) of three routine chemistry and endocrinology events in 2017 . Findings include: 1. On April 24, 2018 at 11:47 AM, record review of the CMS database, Medical Laboratory Evaluation, and American Academy Family Physicians (AAFP) proficiency testing results revealed a change in provider during the calendar year as follows: a. Medical Laboratory Evaluation - 1st event 2017 b. American Academy of Family Physicians - 3rd event of 2017 2. On April 24, 2018 at approximately 12:00 PM, the office manager confirmed the proficiency testing provider was switched during a calendar year. 3. During a phone interview on May 2, 2018 at 3:02 PM, the MLE PT provider confirmed the laboratory did not participate in event #2 and #3 during 2017 due to nonpayment.
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, the laboratory failed to successfully participate in a CMS approved proficiency testing program for general immunology, endocrinology, and routine chemistry for the following analytes: 1) general immunology rheumatoid assay/rheumatoid factor (RA/RF); 2) routine chemistry - cholesterol-total, cholesterol-high density lipoprotein (HDL), triglycerides (trig) and 3) endocrinology - cortisol, free thyroxine (FT4), triiodothyronine (T3), and thyroid stimulating hormone (TSH). Findings include: 1. The laboratory failed to return the general immunology, chemistry, and endocrinology proficiency testing (PT) results by the due date for one (3rd event of 2016) of six events reviewed. See D2081, D2093, and D2104. 2. The laboratory failed to achieve satisfactory performance for four of five consecutive PT events for the subspecialty general immunology and analyte Rheumatoid factor. See D2084 and D2085. 3. The laboratory failed to achieve satisfactory performance for three out of four consecutive PT events for the subspecialty routine chemistry and the analytes cholesterol-total and triglycerides and

	two out of three consecutive proficiency testing events for the analyte cholesterol-HDL. See D2096 and D2097. 4. The laboratory failed to achieve satisfactory performance in two out of three consecutive PT events for the analyte triiodothyronine (T3) and three out of five consecutive proficiency testing events for the subspecialty endocrinology and analytes cortisol, thyroid stimulating hormone (TSH), and free thyroxine (FT4). See D2107 and D2108.
D2081	GENERAL IMMUNOLOGY CFR(s): 493.837(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to return the general immunology proficiency testing results for one (3rd event of 2016) of six events reviewed. 1. On April 24, 2018 at 11:30 AM, record review of the CMS database and the Medical Laboratory Evaluation (MLE) final graded proficiency testing report revealed the laboratory received a score of 0% "failure to participate". 2. During the interview on April 24, 2018 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the proficiency testing results within the allotted time frame.
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(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 in four out of five consecutive proficiency testing events constituting subsequent unsuccessful performance for subspecialty general immunology analyte Rheumatoid factor (RA/RF). Findings include: 1. Record review of the CMS database, Medical Laboratory Evaluation (MLE) and the American Academy of Family Physician (AAFP) proficiency testing (PT) reports revealed the following: RA /RF PT Event Score 3rd event 2016 0% 2nd event 2017 failed to participate 3rd event 2017 failed to participate 1st event 2018 not enrolled 2. During the interview on April 24, 2017 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the 3rd event 2016 proficiency testing results within the allotted time frame. 3. During the phone interview on May 2, 2018 at 3:02 PM, the MLE PT provider confirmed the laboratory did not participate in event 2 and 3 during 2017 due to nonpayment and was not enrolled for 2018.
D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(g) Failure to achieve an overall testing event score of satisfactory performance for 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 four of five consecutive proficiency testing (PT) events constituting subsequent unsuccessful performance for general immunology. Findings include: 1. Record review of the CMS database, Medical Laboratory Evaluation (MLE), and the American Academy of Family Physician (AAFP) proficiency testing (PT) reports revealed the following: general immunology PT Event Score 3rd event 2016 0% 2nd event 2017 failed to participate 3rd event 2017 failed to participate 1st event 2018 not enrolled 2. During the interview on April 24, 2017 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the 3rd event 2016 proficiency testing results within the allotted time frame. 3. During the phone interview on May 2, 2018 at 3:02 PM, MLE PT Provider confirmed the laboratory did not participate in event 2 and 3 during 2017 due to nonpayment and was not enrolled for 2018.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to return the general chemistry proficiency testing results for one (3rd event of 2016) of six events reviewed. 1. On April 24, 2018 at 11:30 AM, record review of the CMS database and the Medical Laboratory Evaluation (MLE) final graded proficiency testing report revealed the laboratory received a score of 0% "failure to participate". 2. During the interview on April 24, 2018 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the proficiency testing results within the allotted time frame.
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 in two out of three consecutive proficiency testing events for cholesterol-HDL constituting initial unsuccessful performance and three out of four consecutive proficiency testing events constituting subsequent unsuccessful performance for cholesterol-total and triglycerides. Findings include: 1. Record review of the CMS database, Medical Laboratory Evaluation (MLE) and the American Academy of Family Physician (AAFP) proficiency testing (PT) reports revealed the following: cholesterol-HDL PT event Score 3rd event 2016 0% 2nd event 2017 failure to

	participate cholesterol-total PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate 3rd event 2017 0% triglycerides PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate 3rd event 2017 40% 2. During the interview on April 24, 2017 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the 3rd event 2016 proficiency testing results within the allotted time frame. 3. On April 24, 2018 at approximately 12:00 PM, the office manager confirmed the proficiency testing provider was switched from MLE to AAFP during calendar year 2017 for the third event. 4. During the phone interview on May 2, 2018 at 3:02 PM, the MLE PT provider confirmed the laboratory did not participate in event 2 2017 due to nonpayment.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) Failure to achieve an overall testing event score of satisfactory performance for 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 routine chemistry for three of four consecutive PT events constituting subsequent unsuccessful performance. Findings include: 1. Record review of the CMS database, Medical Laboratory Evaluation (MLE), and the American Academy of Family Physicians (AAFP) proficiency testing (PT) report revealed the following: routine chemistry PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate 3rd event 2017 46% 2. During the interview on April 24, 2018 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the 3rd event 2016 proficiency testing results within the allotted time frame. 3. On April 24, 2018 at approximately 12:00 PM, the office manager confirmed the proficiency testing provider was switched from MLE to AAFP during calendar year 2017 for the third event. 4. During the phone interview on May 2, 2018 at 3:02 PM, the MLE PT provider confirmed the laboratory did not participate in the 2nd event of 2017 due to nonpayment.
D2104	ENDOCRINOLOGY CFR(s): 493.843(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to return the endocrinology proficiency testing results for one (3rd event of 2016) of six events reviewed. 1. On April 24, 2018 at 11:30 AM, record review of the CMS database and the Medical Laboratory Evaluation (MLE) final graded proficiency testing report revealed the laboratory received a score of 0% "failure to participate". 2. During the interview on April 24, 2018 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the proficiency testing results within the allotted time frame.

D2107	ENDOCRINOLOGY CFR(s): 493.843(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 in two out of three consecutive proficiency testing events for triiodothyronine (T3) constituting initial unsuccessful performance and three out of five consecutive proficiency testing events for cortisol, thyroid stimulating hormone (TSH), and free thyroxine (FT4) constituting subsequent unsuccessful performance. Findings include: 1. Record review of the CMS database, Medical Laboratory Evaluation (MLE), and the American Academy of Family Physician (AAFP) proficiency testing (PT) reports revealed the following: T3 PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate cortisol PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate 1st event 2018 20% TSH PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate 1st event 2018 60% FT4 PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate 3rd event 2017 60% 2. During the interview on April 24, 2018 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the 3rd event 2016 proficiency testing results within the allotted time frame. 3. On April 24, 2018 at approximately 12:00 PM, the office manager confirmed the proficiency testing provider was switched from MLE to AAFP during calendar year 2017 for the third event. 4. During the phone interview on May 2, 2018 at 3:02 PM, the MLE PT provider confirmed the laboratory did not participate in event 2 2017 due to nonpayment.
D2108	ENDOCRINOLOGY CFR(s): 493.843(g) Failure to achieve an overall testing event score of satisfactory performance for 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 endocrinology in three out of five consecutive proficiency testing events constituting subsequent unsuccessful performance. Findings include: 1. Record review of the CMS database, Medical Laboratory Evaluation (MLE), and the American Academy of Family Physicians (AAFP) proficiency testing (PT) reports revealed the following: endocrinology PT event Score 3rd event 2016 0% 2nd event 2017 failure to participate 1st event 2018 65% 2. During the interview on April 24, 2018 at approximately 12:00 PM, the office manager confirmed the laboratory failed to return the 3rd event 2016 proficiency testing results within the allotted time frame. 3. On April 24, 2018 at approximately 12:00 PM, the office manager confirmed the proficiency testing provider was switched from MLE to AAFP during calendar year 2017 for the third event. 4. During the phone interview on May 2, 2018 at 3:02 PM, the MLE PT provider confirmed the laboratory did not participate in event 2 2017 due to nonpayment.

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, the laboratory failed to retain 1) the routine chemistry and endocrinology temperature logsheets for 12 of 24 months reviewed and 2) the manufacturer's product instruction sheets for 24 of 24 months reviewed for the Pointe Scientific chemistry controls for two years. Findings include: 1. On April 24, 2018 at 12:50 PM, record review of the temperature logsheets (waterbath, refrigerator, freezer, room temperature and the humidity) revealed the laboratory did not retain the logsheets for April-December 2016 and January-April 2018 for two years reviewed. 2. On April 24, 2018 at approximately 3:00 PM, record review of the quality control Levy-Jennings charts revealed the laboratory did not retain the manufacturer's product instructions sheet for 24 (April 2016 to April 2018) of 24 months reviewed. 3. During the interview on April 24, 2018 at approximately 12:50 PM and 3:15 PM, the office staff and the laboratory director as listed on the CMS-209 confirmed the above findings were not retained for two years.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to follow the manufacturer's package instructions to monitor and record for 62 (October to December) days of operation in 2017 the temperatures for the basement refrigerator, freezer, room temperature, and the humidity readings before patient testing. Findings include: 1. On April 24, 2018 at 2:15 PM, record review of the temperature logsheets to monitor the equipment revealed the laboratory did not take temperatures for 62 days of operation in 2017 as follows: a. refrigerator - 61 (October, November, and December) days of operation b. freezer - 44 (October 25 to December) days of operation c. room temperature - 62 (October to December) days of operation d. humidity - 62 (October, November, and December) days of operation 2. During the interview on April 24, 2018 at 2:15 PM, the office manager confirmed the temperatures were not monitored and recorded.
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 quality control as required for the routine chemistry and endocrinology testing for one (#9) of nine patient charts audited. Findings include: 1. On April 24, 2018 at 3:00 PM, review of quality control records for routine chemistry analytes cholesterol, triglycerides, cholesterol-high density lipoprotein, and low density lipoprotein and the endocrinology analytes triiodothyronine, free thyroxine, thyroid stimulating hormone, and vitamin D revealed for one (#9) of nine patient charts reviewed the laboratory did not run at least two levels of acceptable control material. 2. During the interview on April 24, 2018 at 3:00 PM, the office manager and laboratory director confirmed two different levels of acceptable controls had not been performed before testing patient samples.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to document the corrective action taken for the out of range temperatures for 1) "basement refrigerator" for 22 days (January 1-2, 20-23 and February 2-6, 12-13, 16-18, 20, 23-27) and for 2) "basement freezer" for 11 days (April 27-31 and May 1, 4-8) and for 3) "basement humidity" for 17 days (February 25-27, March 12-13, 23-25, and April 1-3, 6-9, and 16-17) of operation in 2017 to ensure reliable routine chemistry and endocrinology instrument operation, specimen, and reagent storage. 1. On April 24, 2018 at 12:50 PM, record review of the "Basement Refrigerator", "Basement Freezer", and "Basement Humidity" logsheets revealed there was no documentation to show corrective action was taken for the temperatures and/or humidity readings out of the stated ranges on the logsheets as follows: a. "basement refrigerator" (35-46 degree F) - January 1-2, 20-23, and February 2-6, 12-13, 16-18, 20, 23-27) temperatures were below the stated range b. "basement freezer" (-5 to -15 degree C) - April 27-31 and May 1, 4-8 temperatures were below the stated range c. "basement humidity" (35-46 degree F) 1. February 25-27, March 12-13, 23-25 and April 16-17 temperatures were above the stated range 2. April 1-3 and 6-9 temperatures were below the stated range 2. On April 24, 2018 at 12:50 PM, the office manager confirmed no corrective action was taken for the temperatures readings outside of the stated ranges of operation.
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, the laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's paper medical chart for three (#1, #2, and #9) of 9 patient charts audited. Findings include: 1. On April 24, 2018 at 3:00 p.m., record review for three of 9 patient charts audited revealed the final patient test result was not included in the patient's medical chart as follows: a. chart #1 - no testosterone result b. chart #2 - no folate result c. chart #9 - no cholesterol, triglycerides, cholesterol-high density lipoprotein, low density lipoprotein, triiodothyronine, free thyroxine, thyroid stimulating hormone, and vitamin D. 2. During the interview on April 24, 2018 at 3:00 p.m., the office manager and the laboratory director confirmed the final patient testing results were not in the medical chart.