Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0720914	12/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Birmingham Royal Oak Medical Group	5130 Coolidge Hwy, Royal Oak, 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 (2018) of two years reviewed in the speciality of hematology for the analytes: white blood cell differential, red blood cell count, hematocrit, hemoglobin, white blood cell count, and platelets. Findings include: 1. On December 5, 2018 at 10:37 AM, record review of the CMS database and the American Proficiency Institute (API) proficiency testing documents revealed there was no documentation to show the laboratory was enrolled in a proficiency testing program in 2018. 2. During the interview on December 5, 2018 at 10:37 AM, testing personnel #1 as listed on the CMS-209 confirmed the laboratory was not enrolled in a proficiency testing program for the speciality of hematology in 2018.
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 establish and follow written procedures for the hematology testing. Findings include: 1. On December 5, 2018 at 9:20 AM, review of the "Procedure Manual " revealed the laboratory did not have procedures for the following: a. Operating, maintenance, normal ranges, panic value, instrument generated flag procedures for the Sysmex XP-300 hematology analyzer b. Quality Control, new lot assessment, troubleshooting, and end of lot procedures for the Sysmex XP-300 hematology analyzer. c. Competency procedures d. Proficiency Testing procedures e. Temperature - room, refrigerator, humidity monitoring, and corrective action for out of range readings f. Reagent open expiration date, storage, and use g. Quality Assurance procedure that monitors the general, pre-analytic, analytic, and postanalytic test systems h. Retention of medical records, patient records, and laboratory testing i. Calibration policy and procedures 2. During the interview on December 5, 2018 at 10:55 AM, testing personnel #1 as listed on the CMS-209 confirmed the above policy and procedures were not accessible on the day of the survey.
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 label the hematology quality control material (low, normal, and high levels) with the open and open expiration date for the current bottles in use. Findings include: 1. On December 5, 2018 at 9:15 AM during a tour of the laboratory, the surveyor observed the Sysmex Eightcheck -3WP X-tra quality control material Lot # 83100 with no open and open expiration dates recorded on the bottles in use. 2. During the interview on December 5, 2018 at 9:15 AM, testing personnel #1 as listed on the CMS-209 confirmed the open and open expiration dates were not recorded on the control material or a log.
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 weekly and monthly maintenance for the hematology Sysmex XP-300 instrument for two (December 2016 to December 2018) of two years reviewed. Findings include: 1. On December 5, 2018 at 9:17 AM, record review of the "Weekly

	Bleach Log" revealed the laboratory did not perform the function weekly as follows: a. no documentation for March -December 2017 b. function not performed weekly in April - July and September - November of 2018 as follows: 1. April - two of four weeks missing 2. May - three of four weeks missing 3. June - one of four weeks missing 4. July - one of four weeks missing 5. September - three of four weeks missing 6. October - two of four weeks missing 7. November - two of four weeks missing 2. On December 5, 2018 at 10:25 AM, record review of the "Sysmex XP-300 Maintenance Log" revealed for the weekly tasks 1) "Clean SRV Tray" and for the monthly tasks 1) "Clean RBC and WBC Transducer" and 2) "Clean Waste Chamber". There was no documentation to show the weekly and monthly maintenance tasks had been performed and documented for two of two years as follows: a. weekly - no documentation of completion for every week in the following months 1. February - December 2017 2. January to May, July to September, and November 2018 b. monthly - no documentation for June and November 2017 3. During the interview on December 5, 2018 at 10:25 AM, testing personnel #1 as listed on the CMS-209 confirmed the weekly and monthly maintenance had not been performed and documented. ***Repeat Deficiency from April 21, 2011 survey***
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory director failed to ensure the final graded American Proficiency Institute (API) hematology proficiency testing reports were reviewed by the appropriate staff for three (1st - 3rd events in 2017) of four events reviewed. Findings include: 1. On December 5, 2018 at 10:37 AM, record review of the API proficiency testing reports revealed there was no documentation to show the laboratory director and testing personnel reviewed the final graded proficiency testing reports in 2017. 2. During the interview on December 5, 2018 at 10:37 AM, testing personnel #1 as listed on the CMS-209 confirmed the laboratory director and the appropriate staff did not review the final graded proficiency testing events.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Based on record review and interview, the technical consultant (TC) failed to ensure 1) that competency was assessed for three (#1 - #3) of five testing personnel

	performing moderately complex hematology testing in 2017 and 2) that training was assessed by a qualified TC for four (#2 - #5) of five testing personnel in 2018. Findings include: 1. On December 5, 2018 at 10:05 AM, record review of the CMS-209 form signed by the laboratory director on December 5, 2018 listed one technical consultant certified to evaluate testing personnel competency. 2. On December 5, 2018 at 10:05 AM when requested, the laboratory was unable to provide the surveyor the documentation to show annual competency was assessed and that the assessor was qualified to perform the competencies as follows: a. annual competency not documented - testing personnel #1 - #3 in 2017 b. competency assessor not qualified in 2018 - testing personnel #2 - #5 3. During the interview on December 5, 2018 at 10: 05 AM, testing personnel #1 as listed on the CMS-209 confirmed the annual competencies were not accessible and that the assessor was not qualified.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to provide the educational requirements for two (#4 and #5) of five testing personnel who perform moderately complex hematology testing. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to ensure that all testing personnel met the educational requirements at 493.1423 for two (#4 and #5) of five testing personnel as listed on the CMS-209 performing moderately complex hematology testing. Findings include: 1. On December 5, 2018 at 10:05 AM, testing personnel credential record review revealed the educational requirements for performing moderately complex hematology testing was not met. 2. During the interview on December 5, 2018 at 10:05 AM, testing personnel #1 as listed on the CMS-209 confirmed the educational requirements were not met. 3. On December 5, 2018 at 10:05 AM, the laboratory was given five additional days to supply the necessary educational documents. The documents were not received.