Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0363982	03/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Anchor Bay Clinic Family Medical Center	32901 23 Mile Road Suite 100, Chesterfield, 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 with the Laboratory Director (LD), Testing Personnel (TP) #1, and TP5, the Laboratory Director (and/or designee) and TP failed to attest to the routine integration of the hematology College of American Pathologists (CAP) proficiency testing samples into the patient workload for 1 (FH2-A in 2022) of 10 events reviewed. Findings include: 1. A record review of the CAP proficiency testing documents revealed the LD and TP did not sign the attestation statement sheets for 1 (FH2-A in 2022) of 10 events reviewed. 2. An interview on 3/01/2023 at 2:30 pm, the LD, TP1, and TP5 confirmed event FH2-A in 2022 was not signed by the LD and the TP.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with the Laboratory Director (LD), Testing Personnel (TP) #1, and #5, the laboratory failed to review and evaluate the College of American Pathologists (CAP) proficiency testing final graded report for 1 (CM-A in 2021) of 10 events reviewed. Findings include: 1. A record review of the CAP

	proficiency testing reports on 3/01/2023 at 10:25 am, revealed there was no documentation to show the laboratory had performed any type of evaluation and/or review for the proficiency testing scores obtained for 1 (CM-A in 2021) of 10 testing events reviewed. 2. An interview on 3/01/2023 at 2:30 pm, the LD, TP1, and TP5 confirmed there was no documentation of review for event CM-A in 2021.
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: . Based on record review and interview with the Laboratory Director (LD), Testing Personnel (TP) #1, and TP5, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to ensure reagents used on the Horiba Medical ABS Micro 60 hematology instrument were not used beyond their expiration dates. Refer to D5417.
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: . Based on observation and interview with Testing Personnel (TP) #1 and TP5, the laboratory failed to ensure reagents used on the Horiba Medical ABS Micro 60 hematology instrument were not used beyond their expiration dates for 2 of 2 reagents observed on the instrument. Findings include: 1. The surveyor observed the following expired reagents on the Horiba Medical ABS Micro 60 hematology instrument during a tour of the laboratory on 3/01/2023 at 9:16 am: a. ABX Alphalyse, expired on 2/26 /2023. b. ABX Miniclean, expired on 1/12/2023. 2. When queried on 3/01/2023 at 9: 16 am, the testing personnel were unaware that the reagents had expired. 3. An interview on 3/01/2023 at 9:24 am, TP1 and TP5 confirmed the reagents listed above were expired and had been used beyond their expiration dates. A report was pulled to show that 492 patients had been run on the instrument with expired reagents.
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 observation, lack of documentation, and interview with the Laboratory Director (LD), Testing Personnel (TP) #1, and TP5, the laboratory failed to perform and document the thermometer calibration checks as required by the manufacturer before the expiration for 3 (Fisher brand thermometers) of 3 thermometers in use in the laboratory. Findings include: 1. During a tour of the laboratory on 3/01/2023 at 9: 16 am, the surveyor observed a thermometer by the microscope (S/N 122583190 expiration date of 10/15/2014), in the GE refrigerator (S/N 192126383 expiration date of 4/23/2021), and in the GE freezer (S/N 19274992 expiration date of 12/20/2021) in use past their expiration dates. 2. A record review of the procedure manual revealed no maintenance procedure for the frequency of thermometer calibrations and/or replacement prior to expiration dates noted on the thermometer. 3. A record reviewed revealed a lack of documentation for the calibration of the 3 thermometers and/or replacement by the expiration dates noted on the serial tags. 4. A interview on 3/01 /2023 at 9:20 am, the LD, TP1, and TP5 confirmed the 3 thermometers were not calibrated and/or replaced before their expiration.
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 with the Laboratory Director (LD), Testing Personnel (TP) #1, and TP5, the LD and/or TP failed to ensure final proficiency testing reports were reviewed for 6 (CM-B in 2021, FH2 A-C and CM-A & B in 2022) of 10 testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists (CAP) final proficiency testing records revealed a lack of review by the LD and/or TP as follows: a. 2021 CM-B, no review by the testing personnel. b. 2022 FH2 A-C, no review by the Laboratory Director and the testing personnel. c. 2022 CMA & B, no review by the Laboratory Director and the testing personnel. 2. An interview on 3/01/3023 at 2:30 pm, the LD, TP1, and TP5 confirmed there was no documentation of the Laboratory Director and/or testing personnel reviewing the final proficiency testing event performances.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #1, and TP5, the Technical Consultant failed to evaluate the performance at least semiannually in the

	first year of employment for 1 (TP3) of 5 testing personnel recorded on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel records revealed TP3 initial competency was completed on 3/28/2022. 2. When queried on 3/01/2023 at 10:00 am, TP1 and TP5 were unable to provide the surveyor the competency assessment documentation requested for TP3. 3. An interview on 3/01/2023 at 10:07 am, TP1 and TP5 confirmed the Technical Consultant did not assess the competency of TP3 at least semiannually during the first year of patient specimen testing.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the Technical Consultant (TC), Testing Personnel (TP) #1, and TP5, the Technical Consultant failed to evaluate the annual competency for 3 (TP1, TP2, and TP5) of 5 TP performing the moderately complex testing in 2021. Findings include: 1. A record review of the competency evaluations revealed lack of documentation for the annual competency for 3 (TP1, TP2, and TP5) of 5 TP performing the moderately complex chemistry urine sediment and hematology testing. 2. When queried on 3/01/2023 at 9:56 am, TP1 and TP5 were not able to provide the surveyor the documentation requested. 3. A interview on 3/01 /2023 at 2:30 pm, the TC, TP1, and TP5 confirmed the annual competency assessments had not been performed and documented for 2021.