Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0674920	(X3) Date Survey Completed 10/22/2020
Name of Provider or Supplier Oak Grove Medical Clinic	**Street Address, City, State** 708 East Main Street, Oak Grove, LA	

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
D0000	A Certification Survey was performed on October 22, 2020 at Oak Grove Medical Clinic, CLIA ID # 19D0674920. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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, record review and interview with personnel, the laboratory failed to document weekly, bi-weekly, and monthly maintenance for the Horiba Medical ABX Micros 60 Hematology analyzer. Findings: 1. Observation by surveyor during the laboratory tour on October 22, 2020 at 11:30 am revealed the laboratory utilizes the Horiba Medical ABX Micros 60 Hematology analyzer for Complete Blood Count (CBC) testing. 2. Review of the laboratory's Micros 60 Maintenance Log revealed the laboratory performs the following maintenance: a) Daily: Check Reagents Start-up Passed Standby (end of day) b) Weekly: Backflush X3 Concentrated Clean c) Bi-Weekly: Change Controls d) Monthly: Change Reagents Print Graphs/Statistics 3. Review of the laboratory's maintenance logs for January 2019 through September 2020 revealed the laboratory did not perform the following maintenance: a) Weekly: February 3, 2019 through February 8, 2019 February 26, 2019 through February 28, 2019 March 4, 2019 through March 8, 2019 March 18, 2019 through March 22, 2019 April 1, 2019 through April 5, 2019 April 15, 2019 through April 18, 2019 August 5, 2019 through August 9, 2019 October 1, 2019 through October 4, 2019 October 14, 2019 through October 18, 2019 October 28, 2019 through October 31, 2019 February 24, 2020 through February 28, 2020 March

	9, 2020 through March 13, 2020 June 8, 2020 through June 12, 2020 September 21, 2020 through September 25, 2020 b) Bi-Weekly: January 2019 February 2019 March 2019 April 2019 June 2019 July 2019 August 2019 c) Montly: January 2019 February 2019 March 2019 June 2019 October 2019 November 2019 December 2019 February 2020 March 2020 April 2020 May 2020 June 2020 August 2020 4. In interview on October 22, 2020 at 11:05 am, Personnel 6 stated that the maintenance is being performed because the instrument requires it before continuing but the laboratory personnel is not documenting when completed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to follow their established procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory's policy and procedure manual under "Quality Assurance" revealed the following: a) Specific Objectives: * Monitor and evaluate the overall quality of the total testing process, which includes 3 phases: pre-analytic, analytic, and post-analytic * Evaluate the effectiveness of established policies and procedures * Provide guidelines for identifying and correcting problems, documentation of corrective actions, and implementation of updated testing methods * Assure the accuracy and timeliness of test results * Assess the competency of testing personnel b) Specific Monitors: * Patient Test Management * Quality Control * Personnel Assessment & Competency Evaluations * Proficiency Testing * Complaint Investigations 2. Futher review of the laboratory's policy under "Procedure" revealed " These specific objectives will be achieved by weekly monitoring and monthly reviews conducted by the technical consultant and medical director. A monthly summary will be written containing any issues found and corrective action taken, which will be given to the medical director for review". 3. Interview on October 22, 2020 at 11:34 am, Personnel 6 stated that there was no documentation available for Quality Assurance records since it was not being performed as needed by the technical consultants and medical director.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory

	Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5791.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance and calibration to ensure acceptable levels of analytical performance. Refer to D5429.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D5429.