Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0371252	05/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Donald M Birch, Md, Pc	330 W Tienken Suite C, Rochester Hills, 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
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 the 1) Beckman Coulter AcT diff 2 maintenance, temperature, and humidity reading logs and 2) Beckman Coulter AcT diff 2 background counts and quality control data for two years. Findings include: 1. On May 24, 2018 at 10:45 AM, record review of the Beckman Coulter AcT diff 2 maintenance, temperature, and humidity reading logs revealed for six (June to December 2016) of 24 months reviewed the laboratory did not retain the documentation for two years. 2. On May 24, 2018 at 11:45 AM, record review of the Beckman Coulter AcT diff 2 records revealed for six (#1 - #5, and #7) of nine patient charts audited the laboratory did not retain the background counts and the daily quality control data for two years as follows: a. six (#1-#5 and #7) of nine patient charts audited - no background counts b. three (#1-#3) of nine patient charts audited - no quality control data 3. During the interview on May 24, 2018 at 10:45 and 11:45 AM, technical consultant #2 as listed on the CMS-209 confirmed the records were not retained for two years. .
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 scanned patient final test results were entered into the patient's electronic medical record (EMR) file for one (#8) of nine patient charts audited. Findings include: 1. On May 24, 2018 at 11:45 AM, record review for one (#8) of nine patient charts audited revealed the final patient test result for the hematology complete blood cell count was not scanned into the patient's EMR file. 2. On May 24, 2018 at 11:45 AM when queried, testing personnel #1 as listed on the CMS-209 was unable to provide the surveyor the final scanned patient test result in the patient's EMR file. 3. During the interview on May 24, 2018 at 11:45 AM, technical consultant #2 as listed on the CMS-209 confirmed the final hematology testing results were not scanned into the patient's EMR file.