Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0365862	10/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Aggarwal And Assoc, Mds, Pc	29610 Ryan, Warren, 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 observation, record review, and interview with the Technical Supervisor (TS), the laboratory failed to retain analytic system records used in routine chemistry and endocrinology testing for 2 (October 2017 to October 2019) of 2 years. Findings include: 1. An observation made by the surveyor on 10/16/19 at 9:24 am revealed the following instruments were used in laboratory testing: a. Diazyme SMART performing homocysteine, cystatin C, and high-sensitivity C-reactive protein (hsCRP) testing b. Frend performing Prostate Specific Antigen (PSA) testing 2. A review of the Diazyme SMART and Frend analyzer data revealed a lack of instrument printouts or electronic data to verify the manually transcribed data of the following processes: a. Quality control b. Calibrations c. Patient test results 3. On 10/16/19 at 9:47 am, the surveyor requested analytic system records for the assays listed above. 4. An interview on 10/16/19 at 9:47 am with the TS confirmed analytic system records from the instruments listed above were not available.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the

	original report, as well as the corrected report. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to maintain the original test report for 1 (patient #2) of 11 patient charts audited. Findings include: 1. A record review of patient charts revealed patient #2 had a specimen drawn on 8/1/19. The test report had whiteout used on the name portion concealing the original entry. 2. An interview on 10/16/19 at 10:41 am with the TS confirmed the use of whiteout on the patient report to cover the original entry.