Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0975396	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr John Howard Jr Md Psc	2200 E Parrish Ave Suite 202b, Owensboro, KY	

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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview on 10/24/2018, the laboratory failed to ensure the results of control materials were within acceptable ranges prior to reporting patient results for three of fifteen (15) days for Vitamin B12 testing reviewed in October, 2017. The laboratory reported a total of thirteen (13) patient Vitamin B12 results on 10/17/2017, 10/19/2017, and 10/23/2017 when controls were out of the acceptable range. Findings include: Three patient Vitamin B12 results were reported 10/17/2017. Level 1 and Level 3 fell outside the laboratory's acceptable limits. Three patient Vitamin B12 results were reported 10/19/2017. Level 1 and Level 3 fell outside the laboratory's acceptable limits. Seven patient Vitamin B12 results were reported 10/23/2017. Level 1 and Level 3 fell outside the laboratory's acceptable limits. Interview with the Technical Consultant at 11:55 AM 10/24/2018, revealed the laboratory failed to have a system in place to ensure quality control results were within the laboratory's acceptable limits prior to reporting patient results.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The

	laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on record review and staff interview on 10/24/2018, the laboratory failed to perform and document corrective action when control results for the chemistry analyte Vitamin B12 failed to meet the laboratory's acceptable criteria three consecutive days of testing (10/17/2017, 10/19/2017, and 10/23/2017). Findings include: The results for Biorad Level 1 read 205 pg/ml on 10/17/2017, 254 pg/ml on 10/19/2017, and 259 pg /ml on 10/23/2017. The laboratory's acceptable range was 269 - 397 pg/ml. The results for Biorad Level 3 read 499 pg/ml on 10/17/2017, 546 pg/ml on 10/19/2017, and 559 pg/ml on 10/23/2017. The laboratory's acceptable range was 568 - 1014 pg /ml. Record review failed to provide performance and documentation of corrective action. Interview with the Technical Consultant at 11:55 AM on 10/24/2018, revealed the laboratory failed to have a system in place to ensure quality control results were reviewed and corrective action performed and documented when results fell outside the laboratory's acceptable criteria.