Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0895261	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Charles E Porterfield Do	3771 Robert C Byrd Drive, Beckley, WV	

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 review of quality control records and interview with Testing Personnel #1 (TP1), the laboratory failed to retain all blood gas instrument printouts of quality control testing. Findings include: 1. Comparison of the daily quality control (QC) logs against the blood gas instrument QC printouts from January 1, 2017 to December 30, 2017 demonstrate that the all QC printouts were not retained. 2. The only printouts found from 1/1/17 - 12/31/17 include: 3/5, 3/7, 27, 4/ 5, 4/19, 4/25, 5/2, 5/9, 5/11, 6/6 and 12/23, all others 2017 QC printouts were missing. The QC logs and patient testing frequency demonstrated patient testing being conducted at a more frequent basis. 3. On 8/28/2018 at approximately 12:30PM, the TP stated that she did not know where the other printouts were located.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of blood gas proficiency testing (PT) records and interview with testing personnel #1 (TP1), the laboratory failed to document corrective action taken on all unsatisfactory and missed PT challenges. Findings include: 1. The 1st College of American Pathologists (CAP) Proficiency testing event of 2017 for Critical Care

	Aqueous Blood Gas (AQ-A) received a 40% unsatisfactory score for PC02. The laboratory did not document corrective action taken to determine the cause of the failure. 2. The 3rd CAP Proficiency testing event of 2017 for Blood Oximetry received an 80% score for PO2. The laboratory did not document corrective action taken. 3. The laboratory's Proficiency Testing Procedure step #10 stated "If unsatisfactory results are found, complete a plan of correction (etc. Education and training). There was no documentation to support the policy was followed. 4. The proficiency testing assessment were performed 3 times per year documented all 100% scores. However, none of the PT assessment documented corrective action for the 1st event 2017 40% CO2 score or the 3rd event 2017 Blood Oximetry 80% PO2 scores. Each score report was signed by the director and TP1 but there was no documentation of any troubleshooting scores less than 100% 5. On 8/28/2018 at approximately 11: 00PM, the TP1 stated that she did not know the corrective action needed documented for any scores less than 100% for all six (6) proficiency testing events for which they were participating.
D6022	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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of Quality Assessment and Proficiency testing records for blood gas testing and interview with testing personnel #1 (TP1), the laboratory director did not have an effective system to identify failures in quality as they occurred. Findings include: 1. The Quality Assurance Review Report checklist was documented three (3) times per year with Yes and No responses. All reports provided a "yes" response for PT results 80% or greater even though the 1st PT event had a 40% score. 2. The Quality Assurance Review Reports documented preparation by TP1 but were not signed by the laboratory director for review. 3. The Quality Assurance Review Reports do not contain supporting documentation. 4. The Quality Control Log for the Rapid Point 405 Blood Gas Analyzer was used as a substitute for the discontinued Bayer QC Assessment Program. They were not signed as reviewed the Laboratory Director. There was no evidence the QC logs were monitored for shift or trends over time.