Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0689395	03/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Encompass Health Rehabilitation Hospital Of	1160 Vanvoorhis Road, Morgantown, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, and interview with Testing Personnel #1(TP1), the Laboratory Director (LD) and testing personnel failed to sign the vendor's proficiency testing attestation statement for 6 of 6 proficiency testing events participated in from 2016-2017. Record review was from 2016-2017. The findings include: 1. Review of the laboratory's proficiency testing records revealed the LD and Testing Personnel did not sign the vendor's proficiency attestation statement for 2016 Accutest BGAS Blood Gas/Electrolytes Cycle 1, 2 and 3. 2. Review of the laboratory's proficiency testing records revealed the LD and Testing Personnel did not sign the vendor's proficiency attestation statement for 2017 Accutest BGAS Blood Gas/Electrolytes Cycle 1, 2 and 3. 3. On 3/15/18 at approximately 10:45 AM, TP1 confirmed the findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two

	years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, and interview with Testing Personnel #1(TP1), the laboratory failed to retain the instrument printouts for 6 of 6 proficiency testing events participated in from 2016-2017. Record review was from 2016-2017. The findings include: 1. Review of the laboratory's proficiency testing records revealed the laboratory did not retain the instrument printouts for 2016 Accutest BGAS Blood Gas/Electrolytes Cycles 1, 2, and 3. 2. Review of the laboratory's proficiency testing records revealed the laboratory did not retain the instrument printouts for 2017 Accutest BGAS Blood Gas/Electrolytes Cycles 1, 2, and 3. 2. On 3/15/18 at approximately 10:45 AM, TP1 confirmed the findings.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's policy and procedure manual and interview with Testing Personnel #1 (TP1), the laboratory failed to document the date of initial use of 1 of 1 new instrument procedures (ABL 80 Flex). Record review was from 2016-2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a procedure, "ABL 80 Flex", with no date of initial use. 2. On 3/15 /18 at approximately 11:15 AM, TP1 confirmed the findings. B. Based on review of the laboratory's policy and procedure manual and interview with Testing Personnel #1 (TP1), the laboratory failed to document the date of discontinuance of 1 of 1 retired instrument procedures (ABL 5). Record review was from 2016-2017. The findings include: 1. Review of the laboratory's policy and procedure manual identified a procedure, "ABL 5", with no date of discontinuance. 2. On 3/15/18 at approximately 11:15 AM, TP1 confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's Accutest proficiency testing (PT) records and interview with Testing Personnel #1 (TP1), the laboratory failed to review and evaluate PT results for 6 of 6 PT events for 2016-2017. Record review was from 2016 to 2017. The findings include: 1. Review of the laboratory's Accutest PT records revealed the LD did not sign as reviewed the PT results for 2016 BGAS Cycle 1, 2

	and 3. 2. Review of the laboratory's Accutest PT records revealed the LD did not sign as reviewed the PT results for 2017 BGAS Cycle 1, 2 and 3. 3. On 3/15/18 at approximately 10:45 AM, TP1 confirmed the findings.
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 the laboratory's Accutest proficiency testing (PT) records and interview with Testing Personnel #1 (TP1), the laboratory failed to document the corrective action taken for 2 of 2 "unacceptable" PT events. Record review was from 2016-2017. The findings include: 1. Review of the laboratory's Accutest PT records identified "unacceptable" results for the 2016 BGAS Cycle 1 was 86% and 2016 BGAS Cycle 3 was 93%. 2. Review of the laboratory's PT records identified no documentation of the corrective action taken for the "unacceptable" 2016 BGAS Cycles 1 and 2. 3. On 3/15/18 at approximately 10:45 AM, TP1 confirmed the findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with Testing Personnel #1 (TP1), the laboratory failed to establish a policy for the quality assessment of the general laboratory system. The findings include: 1. Review of the laboratory's policy and procedure manual identified no policy for the quality assessment of the general laboratory system. 2. On 3/15/18 at approximately 12:00 PM, TP1 confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with Testing Personnel #1 (TP1), the laboratory did not have the ABL Flex 80 procedure approved, signed and dated as approved for use by the laboratory director (LD). The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "ABL 80 Flex", that was not approved, signed and dated by the LD. 2. On 3 /15/18 at approximately 11:15 AM, TP1 confirmed the findings.

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's ABL 80 Flex calibration verification records and interview with Testing Personnel #1 (TP1), the laboratory failed to perform and document calibration verification every 6 months for the ABL 80 Flex. Record review was from 2016 to 2017. The findings include:. 1. Review of the ABL 80 Flex calibration verification records for 2016 identified calibration verification was performed on April 24, 2016. 2. Review of the ABL 80 Flex calibration verification records for 2017 identified calibration verification was performed on August 16, 2017. 3. On 3/15/18 at approximately 11:00 AM, TP1 confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with Testing Personnel #1 (TP1), the laboratory failed to establish a quality control plan which defined the type, number and frequency of controls for the blood gas analytes

	performed on the ABL 80 Flex. The findings include: 1. Review of the laboratory's procedure manual identified no policy which defined the type, number and frequency of controls for the ABL 80 Flex. 2. On 3/15/18 at approximately 11:15 AM, TP1 confirmed the findings.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's ABL 80 Flex quality control records, patient testing records and interview with Testing Personnel #1 (TP1), the laboratory failed to perform and document one quality control each 8 hours of patient testing for 4 of 4 days reviewed. Record review was from 2/2017 to 5/2017. The findings include: 1. Review of the laboratory's quality control records for the ABL 80 Flex identified documentation of the Qualichek 4+ levels 1, 2, and 3 for 2/11/17, 3/31/17, 4/12/17 and 5/4/17. 2. Review of the laboratory's patient testing records identified patient testing was performed on the following days: 2/15/17, 3/24/17, 4/11/17, and 5/2/17. 3. On 3/15/18 at approximately 12:00 PM, TP1 stated that they run the 3 levels Qualichek 4+ once per month or when they change reagent cassettes.
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 policy and procedure manual and interview with Testing Personnel #1 (TP1), the laboratory failed to establish a policy for the assessment of the analytic system. The findings include: 1. Review of the laboratory's policy and procedure manual identified no policy for the assessment of the analytic system. 2. On 3/15/18 at approximately 12:00 PM, TP1 confirmed the findings.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with Testing Personnel #1 (TP1), the laboratory failed to establish a policy for the

	assessment of the post-analytic system. The findings include: 1. Review of the laboratory's policy and procedure manual identified no policy for the assessment of the post-analytic system. 2. On 3/15/18 at approximately 12:00 PM, TP1 confirmed the findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, quality control records, proficiency testing records, instrument verification records and interview with Testing Personnel #1 (TP1), the laboratory director (LD) failed to provide overall management and direction of the laboratory by not: ensuring the verification of the ABL 80 Flex (see D6013); ensuring PT records are retained (see D6016); reviewing and evaluating PT results (see D6018); ensuring corrective action was followed for unacceptable PT events (see D6019); establishing and maintaining a quality control program (D6020); establishing a quality assessment program (D6021); having an approved procedure manual available (D6031).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of laboratory verification/validation records and interview with Testing Personnel #1 (TP1), the laboratory director failed to ensure the verification of the performance specifications of the ABL 80 Flex serial number 313125 installed in April 2016. The laboratory began patient testing 5/2016. Record review was from 2016-2017. The findings include: 1. Review of the laboratory's verification/validation records identified the laboratory performed verification of the performance specifications for the ABL 80 Flex in April 2016. 2. Review of the verification records identified the LD did not sign as approved the verification report for the ABL Flex 80 prior to patient testing. 3. On 3/15/18 at approximately 11:15 AM, TP1 confirmed the findings.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with Testing Personnel #1 (TP1), the laboratory director failed to ensure that the proficiency testing records were retained (See D2015).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's Accutest proficiency testing (PT) records and interview with Testing Personnel #1 (TP1), the laboratory director failed to review and evaluate PT results for 6 of 6 PT events for 2016-2017 (see D5221) .
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with Testing Personnel #1 (TP1), the laboratory director failed to ensure that a corrective action plan was followed when proficiency testing results were unacceptable (See D5221).
D6020	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 program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, ABL 80 Flex quality control records and interview with Testing Personnel #1 (TP1), the laboratory director failed to ensure that the quality control program was established (see D5441) and maintained (see D5537).
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 review of the laboratory's policy and procedure manual, and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure that the quality assessment program was established (see D5291, D5791, and D5891).
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with Testing Personnel #1 (TP1), the Laboratory Director failed to ensure that an approved procedure manual was available to testing personnel (see D5407).
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with testing personnel #1 (TP1), the technical consultant failed to directly observe routine test performance on the ABL 80 Flex for 2017 for 14 of 14 testing personnel. Record

	review was from 2016-2017. The findings include: 1. Review of the laboratory's personnel competency records identified a lack of direct observation of test performance on the ABL 80 Flex for 14 of 14 testing personnel for 2017. 2. On 3/15 /18 at approximately 10:15 AM, TP1 confirmed the findings.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with testing personnel #1 (TP1), the technical consultant failed to monitor the recording and reporting of patient test results for 14 of 14 TP for 2017. Record review was from 2016-2017. The findings include: 1. Review of the laboratory's personnel competency records identified a lack of monitoring of the recording and reporting of patient test results for 14 of 14 TP for 2017. 2. On 3/15/18 at approximately 10:15 AM, TP1 confirmed the findings.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with testing personnel #1 (TP1), the technical consultant failed to review quality control records, proficiency testing results, and preventive maintenance records for 14 of 14 TP for 2017. Record review was from 2016-2017. The findings include: 1. Review of the laboratory's personnel competency records identified a lack of review of quality control records, proficiency testing results, and preventive maintenance records for 14 of 14 TP for 2017. 2. On 3/15/18 at approximately 10:15 AM, TP1 confirmed the findings.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with testing personnel #1 (TP1), the technical consultant failed to observe the performance of instrument maintenance on the ABL 80 Flex for 2017 for 14 of 14 testing personnel. Record review was from 2016-2017. The findings include: 1. Review of the laboratory's personnel competency records identified a lack of observation of the

	performance of maintenance on the ABL 80 Flex for 14 of 14 testing personnel for 2017. 2. On 3/15/18 at approximately 10:15 AM, TP1 confirmed the findings.