

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1083614	(X3) Date Survey Completed 03/22/2018
Name of Provider or Supplier Eoh Acquisition Group Llc	Street Address, City, State 300 Central Avenue, East Orange, NJ	
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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the General Supervisor and Regulatory Consultant, the Laboratory Director (LD) failed to provide overall management and direction to the laboratory. The findings include: 1. The LD failed to ensure that competency assessment was performed accurately. Cross refer to D 6004. 2. The LD failed to ensure that Quality Control programs were maintained. Cross refer to D 6020. 3. The LD failed to establish that Quality Assessment programs were established and maintained. Cross refer to D 6021. 4. The LD failed to ensure that prior to testing patients' samples all testing personnel had the appropriate education. Cross refer to D 6029.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p>

This STANDARD is not met as evidenced by:
 Based on surveyor review of the Personnel Records (PR) laboratory records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure the competency of Testing Personnel (TP) in the performance of Blood Gas analysis was performed and documented correctly at the time of survey. The findings include: 1. Review of PR indicated that the evaluation for competency assessment of seven (7) of seventeen (17) TP did not include all six criteria as stated at 493.1413 (b) (8) (i) (ii) (iii) (iv) (v) (vi). 2. There were no records of competency assessment of 17 TP prior to 2017. 3. The designated GS on CMS-209 confirmed the lack of all required criteria in evaluating the competency assessment of TP. 4. While the signed CMS-209 (dated 3/24/2018) and the unsigned CMS-209 at the time of survey, indicated the laboratory director as the technical consultant, records indicated that the evaluation of competency assessment was performed by the assigned GS who had an associate degree. 5. The GS competency was performed by the TP # 14 the senior tech who had an associated degree. 6. The GS confirmed on 3/22/18 at 11:30 am that LD did not ensure the competency was performed and documented accurately.

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:
 a) Based on surveyor review of the Quality Control records and interview with the Regulatory Consultant and General Supervisor (GS), the laboratory director failed to maintain a Quality Control Program that verified the Quality Control (QC) materials performance prior to initial use for the Blood Gas analysis in the Gem 4000 analyzer. The findings include: 1. Review of QC records failed to show that QC values of BioRad lot # 2280 currently used at the time of survey was verified prior to use. 2. The designated GS on CMS-209 stated she did not know when the current QC material was initially put into use. 3. The GS confirmed on 3/22/18 at 1:00 pm that the lab had not been verifying the QC values of QC materials for the two of two GEM 4000 analyzer instruments. b) Based on review of QC records, observation, and interview with the GS and Regulatory Consultant, the laboratory director failed to establish and maintain a QC Program that evaluated and documented actions taken when testing for the BioRad External Quality Controls in 2017. The findings include: 1. There was no documentation by the testing personnel of the start of use of Bio Rad QC control materials. 2. The Levey-Jennings QC charts did not have documentation of QC lot number by the testing personnel. 3. There were no documentation seen when the Quality Control values exhibited shifts, trends, and failures. 4. The GS confirmed on 3/22/18 at 1:00 pm that QC activities were not being evaluated and documented.

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 laboratory records, observation, and interview with the General Supervisor (GS) and Regulatory Consultant (RC) , the laboratory director failed to ensure that the establishment and maintenance of Quality Assessment programs(QAP) in all phases (pre-analytical, analytical, post-analytical) of Blood Gas testing in the Gem 4000 analyzers at the time of survey. The findings include: 1. Review of laboratory records revealed that the laboratory had no written Quality Assessment program. 2. Although the manufacturer's package instruction stated that specimens for blood gas analysis be performed within 30 minutes of collection, the laboratory failed to demonstrate that it was following the manufacturer's instruction by failing to monitor that the time of collection was being documented in a consistent manner. 3. There was no documentation that the laboratory had evaluated its failure to establish patient record system (an assession log) when performing testing in two of two Gem 4000 blood gas analyzers. 4. Although the laboratory's procedure manual for "Correlation Between Methodologies and Instruments," stated on its Section III, Step 2 that "Studies be done at least semi-annually," the laboratory failed to provide documentation of following this step for the two Gem 4000 analyzers. 5. The laboratory did not report Reference Ranges accurately for blood gases analysis in the patient's final test report per procedure. Review of final patient test report indicated the following reference ranges : Partial pressure of Carbon Dioxide (pCO₂) was 35.0; Partial pressure of Oxygen (pO₂) was 75.0; Bicarbonate (HCO₃) was 22.0; Base Excess (BE) was -2.0 ; Saturated O₂ was 94.0; Sodium (NA) was 135.0; Potassium (K) was 3.5; Chloride (CL) was 96.0; and Calcium (CA) was 1.1. 6. There was no established procedure to evaluate, periodically, the reliability and accuracy of electronic data transmission and calculated data from two of two Gem 4000 analyzers to the Laboratory Information Systems (LIS), Cerner. 7. The GS confirmed on 3/22 /18 at 2:15 pm that the QAP was not established and maintained.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

a) Based on review of personnel records, interview with the General Supervisor (GS) and Regulatory Consultant, the laboratory director failed to ensure that appropriate

educational requirements were acceptable for four (4) of seven (7) testing personnel records that were reviewed at the time of survey. The GS confirmed on 3/22/18 at 12:40 pm the lack of educational records for the 4 testing personnel. b) Based on review of personnel records and interview with the GS and Regulatory Consultant, the laboratory director failed to ensure that the laboratory personnel, designated as the GS on CMS-209, was qualified to perform the competency assessment of testing personnel. The finding includes: 1. Personnel records indicated the designated GS had an associate degree.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
Based on surveyor review of CMS form 209 and interview with the General Supervisor(GS), the Technical Consultant (TC) failed to provide oversight and fulfill the requirements listed with 493.1413. 1. The TC did not perform responsibilities. Cross refer to D 6046

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel records and CMS-209, and interview with the designated General Supervisor (GS) and Regulatory Consultant, the technical consultant/laboratory director, designated as such on CMS-209 that was submitted to the surveyor on 3/22/2018, failed to perform the competency assessment of testing personnel in the performance of Blood gas analysis in 2017 and seven (7) out of seventeen (17) testing personnel records that were reviewed. The findings include: 1. Personnel records showed that the designated GS, that did not have the appropriate educational credentials, conducted the competency assessment. 2. There was no documentation that the designated GS was evaluated by the laboratory director for acceptable educational qualification to conduct testing personnel competency assessment. 3. The GS confirmed on 3/22/18 at 12:40 pm that technical consultant did not perform competency assessment.