

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2115207	<b>(X3) Date Survey Completed</b> 01/30/2019
<b>Name of Provider or Supplier</b> Ael - Conway	<b>Street Address, City, State</b> 2425 Dave Ward Drive, Conway, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Through a review of the Laboratory ' s quality assessment plan, lack of documentation, as well as interview with staff, it was determined the laboratory failed to follow their own quality control assessment procedure to correct problems identified in the general laboratory system. As evidenced by: A. The American Esoteric Laboratory "Quality Control Assessment" policy states: "This laboratory has established the following goals for our Quality Assessment Program. The laboratory intends to: 1) evaluate the effectiveness of our written policies and procedures: 2) correctly perform and review all quality control and calibrations performed and document properly. Each of the following systems in our laboratory will be evaluated at least twice annually to be sure that it meets the quality goals set. " B. The following problems were not identified through the laboratory's quality assessment program: 1. Failure to ensure effective quality control system: refer to D5481 2. The laboratory failed to take corrective action when controls were unacceptable: refer to D5783 3. The Laboratory Director failed to identify errors in quality as they occurred: refer to D6021. 4. The laboratory director monthly review for August and December 2018 failed to identify errors in processing quality controls: refer to D6021.</p>
<b>D5481</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the</p>

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:

. Through a review of the laboratory policy and procedure manual, quality control (QC) records for six of twelve months of 2018, patient medical records, as well as interviews with staff, it was determined that patients were reported when results of QC material failed to meet the laboratory's criteria for acceptability. As evidenced by:

A. The laboratory utilizes the Medonics Hematology analyzer to perform Complete Blood Counts (CBC). A review of the laboratory policy and procedure manual revealed the QC protocol: "Three levels of QC will be ran each day of patient testing. If three controls levels are run (Hematology) at least 2 of the 3 levels must be within the established acceptable range before reporting patients. Patient results must not be reported for a test when controls are out of range." B. A review of Hematology quality control results for February, March, May, August, September and October of 2018 ( six of twelve months) revealed on 08/07/2018 Hematology Normal Control for Red Blood Cell Count (RBC) was reported as 1.27 ( with an acceptable range of 3.80 to 4.16). Hematology Low Control for Red Blood Cell Count was reported as 2.28 (with an acceptable range of 2.03 to 2.27). C. A review of Hematology quality control results for February, March, May, August, September and October of 2018 (six of twelve months) revealed on 10/1/2018 and 10/29/2018 Hematology Low Control for Hemoglobin was reported as 5.7 (with an acceptable range of 5.0 to 5.6) and Hematology High Control for Hemoglobin was reported as 15.8 (with an acceptable range of 14.7 to 15.7). The laboratory had one level of quality control in acceptable range for 10/1/2018 and 10/29/2018. D. A review of Hematology quality control results for February, March, May, August, September and October of 2018 (six of twelve months) revealed on 10/8/2018 Hematology Low Control for Hemoglobin was reported as 5.7 ( with an acceptable range of 5.0 to 5.6). Hematology Normal Control for Hemoglobin was reported as 12.0 (with an acceptable range of 11.0 to 11.8) and Hematology High Control for Hemoglobin was reported as 16.0 (with an acceptable range of 14.7 to 15.7). All three controls levels for Hemoglobin were outside acceptable criteria for patient testing. E. A review of patient medical records revealed on 08/07/2018 six patients had RBC counts reported with only one level of acceptable quality control results: patient # 51661502, patient #51661469, patient #51661497, patient #51661521, patient #51661576 and patient #51661578. F. A review of patient medical records revealed on 10/1/2018 eight patients had Hemoglobin results reported with only one level of acceptable quality control results: patient #51698625, patients #51698668, patient 351698547, patient #51698673, patient #51698565, patient #51698562, patient #5168575 and patient #51698573. G. A review of patient medical records revealed on 10/8/2018 ten patients had Complete Blood Counts reported with all three levels of controls out of range: patient #718145, patient #718143, patient #71841, patient #717903, patient #717890, patient #717895, patient #718133, patient #717909, patient #717880, patient #717888, patient #717883 and patient #717889. H. A review of patient medical records revealed on 10/29/2018 eight patients had Hemoglobin results reported with only one level of acceptable quality control results: patient #51719755, patient #51719758, patient #51719642, patient #51719737, patient #51719752, patient #51719671, patient #51719657 and patient #51719724. I. In an interview on 01/30/2019 at 10:00, laboratory personnel #2 (as listed on the form CMS-209) confirmed that patients were reported when the quality control results were outside of acceptable range.

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:

. Through a review of laboratory quality control policy, quality control records for six of twelve months, lack of documentation as well as interview with staff, it was determined the laboratory failed to document all corrective actions when quality control results failed to meet the laboratory's established criteria for acceptability. As evidenced by: A. A review of laboratory policy and procedure manual revealed the policy for corrective actions regarding failed quality controls: "The following steps should be followed when a control performance is unacceptable. 1) Do not report patient results; 2) Review the procedure for any identifiable errors; 3) Repeat the control. If the repeated result is still outside of the expected range, documented corrective action should be initiated." B. A review of quality control records for six of twelve months in 2018 (February, March, May, August, September and December) revealed on 8/7/2018, 10/1/2018, 10/8/2018 and 10/29/2018 the laboratory failed to follow their corrective action policy when quality control results were outside the laboratory's established criteria for acceptability. The laboratory failed to document correction actions taken for the days QC was outside of acceptable limits. C. In an interview at 10:00 on 1/30/2019, laboratory personnel #2 (as listed on the form CMS-209) confirmed that no corrective actions were documented for quality control failures on 8/7/2018, 10/1/201/, 10/8/2018 and 10/29/2018.

**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:

. 1. Through a review of quality assessment policy, quality control (QC) records for February, March, May, August, September and October of 2018, lack of documentation, as well as interviews with staff, it was determined the Laboratory Director failed to ensure that the quality control and quality assessment programs identified failures in quality as they occurred. As evidenced by: A. The Laboratory Director failed to establish a QC program to monitor the accuracy and precision of the Hematology test system as cited at D5481. The Laboratory Director failed to ensure the quality assessment programs failed to identify errors in quality as they occurred as cited at D5291. 2. Through a review of the QC records for August and October 2018 (two of two months), laboratory's monthly quality assurance records, lack of

documentation as well as interviews with staff it was determined, the laboratory director failed to identify errors in quality assessment. As evidenced by: A. A review of Hematology QC results for August revealed on 8/7/2018 the laboratory reported six patients with only one level (Hematology High Control) of quality control results within the acceptable range. B. A review of the laboratory's monthly quality assurance record for August 2018 ( signed by laboratory director on 9/14/18) revealed the patient test management quality assessment review: which states " no patient test results were reported this month without acceptable control performance." C. A review of Hematology QC results for October revealed on 10/1/2018 the laboratory reported eight patients with only one level of acceptable QC in range: on 10/8/2018 the laboratory reported ten patients with all three levels of Hematology QC outside of acceptable limits and on 10/29/2018 the laboratory reported eight patients with only one level of acceptable QC in range. D. A review of the laboratory's monthly quality assurance record for October 2018 (signed by the laboratory director 12/5/2018) revealed the patient test management quality assessment review which states "no patient test results were reported this month without acceptable control performance."

**D6030**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:  
. Through a review of laboratory monthly quality assessment checklist, lack of documentation as well as interviews, it was determined the laboratory director failed to ensure remedial training of one of three testing personnel for continuing education to improve laboratory skills as evidenced by: A. A review of the monthly quality assessment checklist (signed by laboratory director 12/5/18) revealed the following comment stated by laboratory director: " On 10/8/18 all three Hematology controls were out of range, investigation of patients and retraining of testing personnel #3 (as listed on form CMS 209) will need to occur. B. Upon request, the laboratory could not produce documentation of patient remediation for 10/8/18 or remedial training records for testing personnel #3.