

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2103500	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Phoenix Neurological Institute	Street Address, City, State 2000 E Southern Ave Ste 106, Tempe, AZ	
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	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of QC records i-Stat testing performed in 2020 and interview with the testing personnel, the laboratory failed to retain the i-Stat instrument printouts for the PT/INR quality control (QC) results for the testing performed on 04/23/2020. Findings include: 1. No QC records that includes instrument printouts of two levels of liquid controls and a simulator electronic control pass/fail were presented for review for the testing date 04/23/2020. 2. Patient test reports reviewed included patient ID #1553 who was tested for PT/INR on 04/23/2020. 3. The testing personnel acknowledged that the printouts indicated above were missing.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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. (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.</p>

This STANDARD is not met as evidenced by:

Based on review of patient test reports (ID #1491 03/12/2020 and ID #1552 04/23 /2020) as indicated on the i-Stat instrument printouts and interview with the laboratory personnel, the testing personnel as indicated by the testing personnel's initials on the printouts for ACT testing did not have any documentation of initial training for ACT testing and had not been listed on the CMS-209 (Personnel Report) submitted by the laboratory during the survey. Findings include: 1. The two instrument printouts indicated above had the initials J.D. on them. There was no other evidence of the specific testing personnel that performed the test. The Operator ID as indicated on each printout was identical (#84014) on each printout regardless of whose initials were indicated on the printouts. 2. The initial training documents and competency assessment documents did not include any individuals with the initials J.D. 3. The laboratory personnel indicated that they were unaware that J.D. initialed the printouts.