

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0955789	<b>(X3) Date Survey Completed</b>  05/30/2019
<b>Name of Provider or Supplier</b>  Lister Labs, Llc	<b>Street Address, City, State</b>  2805 D West Mall Drive, Florence, AL	
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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the procedure manuals for two new analyzers and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to document his review and approval (as indicated by his signature and date) of new procedure manuals in use by the testing personnel for testing of Hematology and Chemistry / Endocrinology specimens. The findings include: 1. During the entrance tour of the laboratory on 5/30/2019 at approximately 11:00 AM, the Technical Consultant stated two analyzers were new since the previous survey; she listed the Horiba ABx Pentra XL-80 Hematology analyzer and the Beckman Coulter UniCel DxI used for Special Chemistry and Endocrinology testing. 2. A review of the installation and validation records revealed the UniCel DxI was installed and in use for patient testing since April 2017; patient CBC (Complete Blood Count) testing on the Pentra XL-80 began on 3/15/2018. 3. A review of the Users Procedure Manuals for both instrument revealed no Laboratory Director's signature and date. There was no evidence the procedures had been reviewed, and approved by the Laboratory Director in use for patient testing since installation. 4. During a review of the manuals with the Technical Consultant on 5/30/2019 at 2:50 PM, this observation was confirmed. .</p>
<b>D6013</b>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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</p>

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 reviews of the installation and validation records for the the Horiba ABx Pentra XL-80 Hematology analyzer and the Beckman Coulter UniCel DxI (used for Special Chemistry and Endocrinology testing), and an interview with the Technical Consultant, the surveyor determined the Laboratory Director failed to document his review and approval of the initial validation procedures for both instruments as verifying the manufacturer's performance specifications, before patient testing began. The findings include: 1. A review of the Horiba ABx Pentra XL-80 Hematology analyzer records revealed the instrument was installed and validation testing was performed on 3/14/2018. Patient testing began the following day on 3/15/2018, however the Laboratory Director did not approve the validation procedures as verifying the manufacturer's performance specifications until 3/19/2018 (Accuracy /Reportable Range studies) and 3/26/2019 (Accuracy/Correlation studies). 2. A review of the installation and validation procedures for the Beckman Coulter UniCel DxI analyzer revealed no documentation of review and approval by the Laboratory Director (as indicated by a signature and date) on the initial verification procedures performed in March/April 2017. Only the Technical Consultant signed the validation on 4/6/2017. 3. During an interview and review of these records on 5/30/2019 at 2:50 PM, the Technical Consultant confirmed the above noted findings. SURVEYOR ID# 32258 Licensure and Certification Surveyor