

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2151444	(X3) Date Survey Completed 08/06/2019
Name of Provider or Supplier Cnd Life Sciences, Inc	Street Address, City, State 9165 E Del Camino Dr Ste 101, Scottsdale, 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
D5407	<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 review of the laboratory's policy and procedure manual presented for review during the survey and interview with the facility personnel, the laboratory failed to have a procedure manual that was approved, signed, and dated by the current laboratory director. Findings include: 1. The laboratory's procedure manual presented for review during the survey conducted on August 6, 2019 failed to include the approval, signature and date of the laboratory director. 2. The facility personnel acknowledged that the procedure manual was not signed and dated by the laboratory director at the time of the survey. 3. The laboratory began patient testing in the sub-specialty of Histopathology in March 2019, with an approximate annual test volume of 1,000.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility</p>

personnel, the laboratory failed to document the acceptability of staining materials used for testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory began patient testing in March 2019, with an approximate annual test volume is 1,000. 2. No documentation of the H & E stain and Congo Red stain acceptability was presented for review for testing that occurred on 07/23/19 for case ID# 00001021. 3. The facility personnel confirmed that the laboratory failed to document the stain acceptability for the two stains performed on the specimen indicated above.