

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2329165	(X3) Date Survey Completed 01/21/2026
Name of Provider or Supplier Cnd Life Sciences	Street Address, City, State 261 Dickinson Dr, Reading, PA	
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus BX53F2 microscope used to perform histopathology microscopic slide examinations from 08/26/2025 to 01/21/2026. Findings include: 1. The manufacturers operating environment specifications stated, " Olympus BX53F2 microscope: 5-40 degrees Celsius (ambient temperature); maximum 80 % relative humidity." 2. On the day of the survey, 01/21/2026 at 9:30 am, the laboratory failed to provide documentation for the monitoring of room temperature and humidity to ensure operating conditions were met for the following instruments used to perform histopathology microscopic examinations from 08/26/25 to 01/21/2026: - 1 of 1 Olympus BX53F2 microscope 3. The laboratory performed 6,000 histopathology slide examinations in 2025 (CMS 116, estimated annual volume, dated 12/19/2025). 4. The LD confirmed the findings above on 1/22/2026 at 9:30 am.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the Laboratory Director (LD), the LD failed to ensure positive and negative staining reactivity was checked and documented each time of use of 2 of 2 immunohistochemistry (IHC) stains for microscopic histopathology immunofluorescent examinations were performed from 08/26/2025 to 01/21/2026. Findings include: 1. On the day of the survey, 01/22/2026 at 09:45 am, the laboratory failed to provide documentation of positive and negative staining reactivity checked each time of use when the following 2 of 2 IHC used for microscopic histopathology immunofluorescent examinations: - Phosphorylated alpha-synuclein (pS129) - P-glycoprotein (P-gp/ABCB1) 2. The laboratory performed 6,000 histopathology immunofluorescent examinations in 2025 (CMS 116, estimated annual volume, dated 12/19/2025). 3. The LD confirmed the findings above on 01/22/2026 at 10:00 am.