

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2160761	(X3) Date Survey Completed 01/16/2025
Name of Provider or Supplier Laboratory For Dna-Guided Medicine	Street Address, City, State 10 Jefferson St, Unit C3, Hartford, CT	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities for the general supervisor (GS) and the technical supervisor (TS) in the specialties of chemistry and hematology. Findings include: 1. Record review on 01/16/2025 of the staff 'training and competency files' revealed lack of competency assessment documentation for the regulatory positions of GS and TS. 2. Record review on 01/16/2025 of the laboratory's standard operating procedures revealed lack of established competency assessment policy and procedures to assess competency for the regulatory positions and defining frequency of assessment. 3. Staff interview on 01/16/2025 at 10:00 AM with the laboratory's technical supervisor (TS) confirmed the above finding. The TS further commented that he/she was unaware of this requirement. 4. The laboratory performs 130 tests annually in the specialties of chemistry and hematology.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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)</p>

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 surveyor observation, record review and staff interview, the laboratory failed to define and provide evidence of monitoring and documenting humidity requirements in the specialties of chemistry and hematology. Findings include: 1. Surveyor observation on 01/16/2025 at 9:45 AM of the laboratory work bench area revealed the following instruments in use: a. QuantStudio 7 Pro Real-Time PCR System b. NanoDrop One, Micro-UV/Vis Spectrophotometer 2. Record review on 01/16/2025 of the laboratory's maintenance records for 2023 and 2024 revealed lack of documentation of humidity levels for all laboratory areas. 3. Record review on 01/16/2025 of the 'QuantStudio 6 Pro Real-Time PCR System and QuantStudio 7 Pro Real-Time PCR System User Guide' revealed an acceptable relative humidity requirement of 15% - 80% (non-condensing) while operational. 4. Record review on 01/16/2025 of the 'NanoDrop Micro-UV/Vis Spectrophotometer, NanoDrop One User Guide' revealed an acceptable relative humidity requirement of 20% - 80% (non-condensing) while operational. 5. Staff interview on 01/16/2025 at 10:00 AM with the laboratory's technical supervisor (TS) confirmed the above findings. The TS further commented that he/she was unaware of this requirement. 6. The laboratory performs 130 tests annually in the specialties of chemistry and hematology.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to perform the manufacturer required maintenance and function checks to ensure accurate and reliable test results are obtained prior to patient testing in the specialties of chemistry and hematology. Findings include: 1. Surveyor observation on 01/16/2025 at 9:45 AM of the laboratory work bench area revealed a 'NanoDrop One, Micro-UV/Vis Spectrophotometer' in use. 2. Record review on 01/16/2025 of the laboratory's 'NanoDrop One, Micro-UV/Vis Spectrophotometer' maintenance records for 2023 and 2024 revealed lack of documentation of performance verification every 6 months for the 'NanoDrop One, Micro-UV/Vis Spectrophotometer'. 3. Record review on 01/16/2025 of the 'NanoDrop Micro-UV/Vis Spectrophotometer, NanoDrop One User Guide' revealed 'run performance verification every 6 months to confirm pathlength accuracy is within specifications'. 4. Staff interview on 01/16/2025 at 10:20 AM with the laboratory's technical supervisor (TS) confirmed the above findings. The TS further commented that he/she was unaware of this requirement. 5. The laboratory performs 130 tests annually in the specialties of chemistry and hematology.