

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2147003	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Molecular Diagnostics Laboratory	Street Address, City, State 140 Oxmoore Blvd Suite 140, Birmingham, AL	
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
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on a review on the laboratory's policy and procedure manual, a review of temperature/humidity and maintenance records, a review of the laboratory's hours of operation, indicated on the CMS form #116, and an interview with the owner of the laboratory and the Technical Supervisor (also noted as the General Supervisor), the surveyor determined the Laboratory Director failed to ensure records/systems for this laboratory were maintained separately from another laboratory at the same location, housed in the same suite. The findings include: 1. During the initial tour of the laboratory on 9/05/18 at 10:00 AM, the surveyor discussed with the owner the shared space of two laboratories in the same suite. The surveyor stated to the owner the requirement to maintain separate systems, equipment/reagents (storage spaces), records, hours of operation, etc. These same requirements had been discussed with the owner in June of 2018, when CLIA attempted to schedule an initial survey and was informed the original building/space for the laboratory was no longer available. 2. A review of the policy and procedure manual indicated procedures not performed by this laboratory (CLIA identification #01D2147003). The manual included quality control procedures for Hematology (not performed at this laboratory), but by the laboratory, also occupying space in the suite. At 10:57 AM on 9/05/18, the owner of the laboratory stated the unnecessary procedures needed to be removed from the manual. 3. Further review of the temperature/humidity logs and maintenance records revealed maintenance documentation for Hematology, including microscope maintenance, a specialty not performed by 01D2147003. The temperature/humidity records failed to indicate the area of the laboratory, assigned the above mentioned CLIA identification</p>

number or the ranges specific to the systems and equipment operated by this laboratory (as identified in the policy and procedure manual). a) Magpix and Aries (Luminex) Room Temperature should be maintained at 15-35 degrees Celcius. Humidity should be 20 - 80 % (percent). The ranges indicated on these logs were as follows: humidity, 28-85% and room temperature, 18- 27 degrees Celcius. 4. These instruments (Magpix and Aries) are housed within two separate areas of the laboratory, as observed during initial tour of the laboratory. 5. On 9/18/18, further review of the CMS form #116 for both laboratories revealed the same operating hours for Monday through Friday from 8:00 AM - 5:00 PM. The hours indicated for laboratory #01D2147003 included "on call to adjust hours of operation seasonally."

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on a review of the policy and procedure manual, a review of personnel training records, a review of CAP (College of American Pathology) proficiency testing records, a review of the CMS form #209 (Personnel List), and an interview with the Technical Supervisor (TS), also identified as the General Supervisor (GS), and the owner of the laboratory, the surveyor determined the Laboratory Director (LD) failed to implement a letter of delegation to assign specific responsibilities and technical oversight of the laboratory to qualified technical supervisors and consultants. The findings include: 1. The policy and procedure manual was reviewed on 9/05/18 at 10:50 AM. The manual failed to include a letter of delegation by the Laboratory Director to assign specific responsibilities and technical oversight of the laboratory to qualified technical supervisors and consultants (two identified on the CMS form #209, list of personnel). 2. A review of the CAP proficiency testing records for Event IDR B 2018 (Infectious Diseases - Respiratory) revealed the LD had not reviewed and signed the results. One of the technical supervisors had signed the results of the proficiency testing; however, there was no letter of delegation authorizing this review and signature. 3. A review of the personnel training records (check-lists) revealed records for testing personnel, including the technical supervisors and consultants had been signed by a manufacturer representative or other staff excluding the LD. 4. At 12:00 PM on 9/05/18, the surveyor discussed the letter of delegation with the Technical Supervisor (also noted as the General Supervisor) and the owner of the laboratory. The laboratory staff and owner confirmed there was no letter of delegation by the LD, authorizing qualified staff to provide specific technical oversight of laboratory systems. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor