

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2064071	(X3) Date Survey Completed 01/21/2020
Name of Provider or Supplier M I Lab	Street Address, City, State 246 E Janata Blvd, Ste 260, Lombard, IL	
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
D3001	<p>FACILITIES CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review, and interview; the laboratory failed to be maintained to ensure the ventilation necessary for conducting all phases of the testing process. Findings: 1. On January 21, 2020 at 2:30 PM, the surveyor observed that a pipetting station was set up under fume hood in the laboratory. 2. Review of maintenance records revealed that there were no records that show that the lab's fume hood was maintained for all of 2018 and all of 2019. 3. Testing personnel told the surveyor that he used the fume hood while pipetting specimens. 4. On January 21, 2020 at 3:00 PM, testing personnel confirmed the surveyor's findings.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and proficiency testing (PT) records and interview with testing personnel; the laboratory failed to verify the accuracy of its Natural Killer Cell Activation Assay at least twice annually. Findings: 1. On January 21, 2020 at 2:00 PM, the surveyor reviewed the laboratory's PT policy. 2. A section in the procedures manual titled, "Semi-Annual", it says, "Proficiency Testing: Proficiency Testing is done at least twice annually. Split-samples are run</p>

simultaneously at MI lab and FC Lab. These samples are run identically and independently. The results are correlated and documented and stored in the Proficiency Testing binder. 3. Specimen collection procedures instruct testing personnel to ship or store the specimen up to 24 hours at room temperature. The procedure also says that age and temperature of the specimen will affect the results. 4. Review of PT records revealed that split samples were not performed simultaneously as instructed for the following: a. PT # 1 was reported by MI lab on 05/09/2018; FC reported PT # 1 on 03/04/2019. b. PT # 2 was reported by MI lab on 05/16/2018; FC reported PT # 2 on 03/04/2019. c. PT # 3 was reported by MI lab on 11/23/2018; FC reported PT # 3 on 04/09/2019 d. PT # 4 was reported by MI lab on 11/23/2018; FC lab reported PT # 4 on 04/09/2019 5. On January 21, 2020 at 3:30 PM, testing personnel confirmed the surveyor's findings.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of test reports and laboratory records and interview with testing personnel; the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, correct problems identified in the post analytic systems as specified. Findings: 1. On January 21, 2020 at 2:00 PM, the surveyor reviewed 5 test reports. 2. Review of laboratory records revealed that 1 of 5 patients' tests was performed by a reference laboratory. 3. Test reports from the reference laboratory dated 01/11/2018 were manually entered and a report was generated. 4. Review of the test report from the reference laboratory shows that the entire report was unreadable. The entire report was completely smudged with black ink. 5. There was no documentation to show that a request for refaxing the reference lab's test report was made. 6. There was no documentation to show post analytic assessments were performed in 2018 and 2019. 7. On January 21, 2020 at 3:30 PM, testing personnel confirmed the surveyor's findings.