

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 99D2280565	(X3) Date Survey Completed 04/23/2023
Name of Provider or Supplier Jilab Inc	Street Address, City, State 6 Biokatu, Not Available, FN	
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
D0000	Remote Survey April 19-20, 2023 The laboratory had standard level deficiencies cited:
D3009	Based on interview with the General Supervisor, review of the laboratory testing records, and lack of documentation, the laboratory failed to hold a New York state license when testing patients, 5 of 110 were patients reviewed from November 1, 2022 to the date of the survey were from New York state as evidenced by: 1. The laboratory could not provide evidence of licensure from New York. 2. Review of the laboratory testing records from November 1, 2022 to the date of the survey revealed the following patients from New York state were tested by the laboratory: a. 0135-004 b. 0126-001 c. 0135-007 d. 0135-008 e. 0135-010 3 In interview with the General Supervisor at 0200 on April 19, 2023, he stated that they did not have a New York license.
D5209	Based on review of laboratory procedures, personnel records, and interview with the Laboratory Director, the laboratory failed to establish written procedures and have competency assessment for 1 of 1 General supervisor as evidenced by: 1. Review of laboratory's procedures, the laboratory did not provide a procedure for General supervisor's competency assessment. 2. Review of the General Supervisor's personnel records revealed the laboratory failed to have documentation of competency assessment for the GS based on the responsibilities. 3. In interview on April 19, 2023 at 0115 the laboratory director stated that he didn't have competency assessment for the general supervisor.
D5313	Based on review of patient test reports and interview with the General Supervisor, the laboratory failed to have a system in place for documenting time it receives specimens for 20 of 20 specimens received from November 1, 2022 to the date of the survey as evidenced by: In review of random 20 patient testing reports, the following patients did not have the time received in the laboratory: a. 0101-006 b. 0109-011 c. 0131-004 d. 0111-053 e. 0109-012 f. 0121-024 g. 0135-004 h. 0111-054 i. 0104-011 j. 0118-001 k. 0126-001 l. 0105-020 m. 0111-038 n. 0111-055 o. 0107-009 p. 0127-030 q. 0132-

005 r. 0134-010 s. 0127-033 t. 0111-056 In interview with the General Supervisor on April 19,2023 at 0223, he stated that they do not document the time specimens were received in the laboratory.

D6121

Based on review of the laboratory's policy, CMS-209 form, and interview with the Laboratory Director, the technical supervisor failed to establish and include a procedure for all components of competency assessment for 2 of 2 testing personnel in 2022 as evidenced by: In review of laboratory's procedures, the laboratory did not provide a procedure for testing persons competency assessment. The laboratory failed to provide documentation of 2022 competency assessment for Testing Person-1 and Testing Person-2 that included the following: 1. Direct observations of routine patient test performance, including patient preparation, 2. Monitoring the recording and reporting of test results 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records 4. Direct observation of performance of instrument maintenance 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and 6. Assessment of problem solving skills In interview on April 19, 2023 at 0115 am the laboratory director stated that he didn't have competency assessment for the testing personnel.