

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2094053	(X3) Date Survey Completed 08/02/2024
Name of Provider or Supplier Chinatown True Care Medical Group Pllc	Street Address, City, State 2619 Francis Lewis Blvd, Basement, Flushing, NY	
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
D3041	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: Based on review of patients Y.C. Req# 10934528, M.L. Req# 10934447, and S.J. Req# 10937660 Rendr Laboratory test results, Interface Result Printouts, standard operating procedures (SOPs) as well as interview with the Laboratory Director (LD), the laboratory failed to retain copies of original patient test result reports for at least two years after the date of reporting. FINDINGS: 1. There was no documentation of original Rendr Laboratory patient test reports including initial HbA1C results for patients Y.C. Req# 10934528, M.L. Req# 10934447, and S.J. Req# 10937660. It was noted that Interface Result Printouts did include the respective initial HbA1C results. 2. The current, approved Post-Examination Procedures: Reporting SOP did not include instructions for retaining original Rendr Laboratory patient test result reports for at least two years after the date of reporting. 3. The LD confirmed the findings on August 2, 2024, at approximately 11:30 A.M.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:

Based on review of patients Y.C. Req# 10934528, M.L. Req# 10934447, and S.J. Req# 10937660 Rendr Laboratory results as well as interview with the LD, the laboratory failed to comply with instructions indicated in the current, approved Post-Examination Procedures: Reporting SOP. FINDINGS: 1. The laboratory failed to document "HbA1C result was repeated and amended. Please use this result", on the amended Rendr Laboratory for patient Y.C. Req# 10934528. 2. The laboratory failed to document original report date of HbA1C results on the amended Laboratory Report Rendr Laboratory for patients Y.C. Req# 10934528, M.L. Req# 10934447, and S.J. Req# 10937660. 3. These were contrary to instructions indicated in Post-Examination Procedures: Reporting SOP. 4. The LD confirmed the findings on August 2, 2024, at approximately 12:00 P.M.