

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2175510	(X3) Date Survey Completed 07/07/2021
Name of Provider or Supplier Right Way Laboratory	Street Address, City, State 750 Hamburg Tpke, Pompton Lakes, NJ	
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
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the area where Molecular amplification procedures were performed and interview with the General Supervisor (GS), the laboratory failed to have a unidirectional workflow for specimen preparation, reagent preparation, product detection and amplification from November 2020 to the date of the survey. The GS confirmed on 7/7/21 at 2:00 pm the laboratory did not have a unidirectional work flow.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to follow the PM for COVID-19 tests performed on the QuantStudio 5 from March 2021 to the date of the survey. The findings include: 1. The PM stated under Quality Control "A no template (negative) (NTC) is included in each run" 2. A review of the data revealed the laboratory did not</p>

run a NTC. 3. The GS confirmed 7/7/21 at 2:10 pm that the laboratory did not follow the PM.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Molecular COVID-19 on the DiaSorinx Liaison MDX (MDX) and QuantStudio 5 (QS5) analyzer from November 2020 to the date of survey. The findings include: 1. Raw data to confirm Method Comparison results was not found for the MDX. 2. Raw data was not found for the QS5 analyzer to confirm Accuracy results. 3. There was no documented evidence that validation was performed for: a. Sample stability b. Accuracy of extraction phase c. The transmission of patient results through the portal. 4. The GS confirmed on 7/7/21 at 11:00 am that PS were not adequate.