

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2169186	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Unity Holding Groups Llc	Street Address, City, State 1 Alberigi Drive, Suite 109, Jessup, PA	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality management and assessment plan and interview with the general supervisor (GS), the laboratory failed to follow written policies to assess ongoing mechanisms to monitor the general laboratory systems for December of 2019. Findings Include: 1. The quality management and assessment plan, analytical systems assessment plan, point 11 states, "Monthly audit of the records to ensure accuracy and reliability of information. The audit will consist of retroactive review of 10 randomly selected patient records to check for the following: does the name on the record match the name of the test request, are all the tests requested displayed on the test report, does the test report match the raw data generated by the instrument, and has the test report been saved." 2. On the day of survey, 01/22/2020, the laboratory did not follow their policy, and could not provide the monthly audit assessed for December of 2019. 3. In December of 2019, 8 patient specimens were performed on the Biofire Filmarray Torch Analyzer for respiratory panels. 4. The GS confirmed the findings above on 01/22/2020 around 11:00 am.</p>