

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2264589	(X3) Date Survey Completed 02/28/2023
Name of Provider or Supplier Quantgene Inc	Street Address, City, State 228 Shady Ave, Pittsburgh, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the general supervisor (GS), the laboratory failed to establish a competency assessment procedure to assess the competency of 1 of 1 GS for their supervisory responsibilities from 08/16/2022 to the date of the survey. Findings include: 1. On the day of survey, 02/28/2023 at 01:15 pm, the GS could not provide a competency assessment policy to assess the competency of 1 of 1 GS (CMS 209 personnel #1) for their supervisory responsibilities from 08/16/2022 to 02/28/2023. 2. The GS confirmed the finding above on 02/28/2023 around 03:00 pm.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the Quidel Lyra Direct analyzer validation records and interview with the general supervisor (GS), the laboratory failed to establish criteria for acceptable performance specifications for 1 of 1 virology analytes performed on the Quidel Lyra Direct analyzer from 08/29/2022 to 02/28/2023. Findings Include: 1. On the day of survey, 02/28/2022 at 02:20 pm, review of the Quidel Lyra Direct analyzer validation records revealed the validation performed on 08/29/2022 for SARS-CoV 2 testing did not include the laboratory's acceptable performance criteria for precision, accuracy, and reportable ranges from 08/29/2022 to 02/28/2023. 2. The GS confirmed the findings above on 02/28/2023 around 03:00 pm.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on lack of quality assurance (QA) documentation and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure a QA program was established and maintained to ensure the quality of services provided by the laboratory from 08/16/2022 to the date of the survey. Findings include: 1. On the date of the survey, 02/28/2023 at 02:16 pm, the laboratory could not provide a complete procedure or documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes from 08/16/2022 to 02/28/2023. 2. The GS confirmed the finding above on 02/28/2023 around 03:00 pm.