

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2033974	(X3) Date Survey Completed 08/02/2022
Name of Provider or Supplier Greentree Medical Center	Street Address, City, State 995 Greentree Rd, 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
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: Based on review of the QIAstat-DX Respiratory SARS-CoV 2 Panel (Quiagen) analyzer validation records and interview with Testing Personnel # 2 (TP), the laboratory failed to establish criteria for acceptable performance specifications for the 17 of 17 virology and 3 of 3 bacteriology analytes performed on the QIAstat-DX Respiratory SARS-CoV 2 Panel (Quiagen) analyzer from 03/06/2021 to 08/02/2022. Findings Include: 1. On the day of survey, 08/02/2022 at 11:45 am, review of the QIAstat-DX Respiratory SARS-CoV 2 Panel (Quiagen) analyzer validation records revealed, the validation performed on 02/16/2021 did not include the acceptable criteria for performance specifications for precision and accuracy. 2. Review of the CMS116 form showed that the annual testing volume for bacteriology/virology was 12,390 in 2021. 3. TP# 2 confirmed the findings above on 08/02/2022 around 03:00 pm.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of quality control records and interview with Testing Personnel # 2 (TP), the laboratory failed to include a negative and positive control material, each day of patient testing for Respiratory SARS-CoV-2 Panels analyzed on the Quiagen QIASTAT-Dx Respiratory SARS-CoV-2 Panel Analyzer from 03/06/2021 to the date of survey. Findings include: 1. On the day of survey, 08/02/2022 at 11:45 am , review of Respiratory SARS-CoV-2 Panel quality control records revealed that the laboratory performed external quality controls on the Quiagen:QIASTAT-Dx Respiratory SARS-CoV-2 Panel analyzer only when new lots of reagent were put into use from 03/03/2021 to 08/02/2022. 2. In 2021, 12,390 bacteriology/virology testing was performed. 3. TP #2 confirmed the findings above on 08/03/2022 around 03:00 pm.