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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>39D1099562      | <b>(X3) Date Survey Completed</b><br>07/27/2021 |
| <b>Name of Provider or Supplier</b><br>Genesis Diagnostics   | <b>Street Address, City, State</b><br>900 Towne Center Drive, Langhorne, PA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5407</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation, record review, and interview, the laboratory failed to ensure that changes in procedure were approved, signed, and date by the laboratory director prior to use. Findings: 1. During a tour of the laboratory, around 9:30 AM the surveyor asked for the current standard operating procedure. TS#1 provided copy of: "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) on Bio-Rad CFX384 and said it was the current copy in use. 2. The document has no signature under "Annual Review by Medical Director." The document states it was revised 07 /23/2021. 3. During an interview with the laboratory director on 7/27/2021 around 4 PM, when asked how often he is on site, the laboratory director said: "I come in once a week" ... "I'm only getting paid for one day a week."</p> |
| <b>D5425</b>              | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br/>CFR(s): 493.1253(b)(3)</p> <p>The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review, interview, and lack of documentation, the laboratory failed to determine the test system's control procedures based upon established performance specifications. Findings: 1. The laboratory's previous SOP "Rapid Real-time PCR-</p>   |

based Screening for SARS-CoV-2 (COVID-19) in Bio-Rad CFX384" in use 4/15 /2021 contained a chart titled : "Plate Acceptability of Controls" and for Sample NEC1 the acceptable CQ value was less than 34.51. For Sample NEC2 the acceptable CQ value was less than 34.51. For For Sample NTC the acceptable CQ value was 38-N/A. The laboratory's current SOP in use 7/27/2021 has a chart titled: "Plate Acceptability of Controls" and for Sample NEC1 the acceptable CQ value was less than 40. For Sample NEC2 the acceptable CQ value was less than 40. For Sample NTC the acceptable CQ value was 1-3, and 38-N/A. 2. On 7/27/2021 around 3 PM, in an interview with the Quality Assurance manager, when asked about studies documenting that the changes in the control procedures did not affect the accuracy of the testing, she said she would have to ask the Laboratory Director and that she did not have documentation available. 3. On 7/27/2021 around 3:20 PM in an interview with the Laboratory Director, when asked about changes in control procedures he said: "They look at the graphs, results with 1-3 were little blips and the SOP changed because I didn't want people to waste time, they're getting these results intermittently but they are not positive because they stay low on the graph" and when asked if the laboratory had documentation he said: "I wish I held onto the records."

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on interview, the laboratory director has failed to provide management and direction to the laboratory. Findings: 1. During an interview with the laboratory director on 7/27/2021 around 3:30 PM, when asked how often he reviews QC, he said that was the supervisor's responsibility. He then said he leaves it up to the supervisor and if she has a problem she [TS#1] brings it to him. The laboratory director failed to review the out of range QC referenced in D5481. 2. During an interview with the laboratory director on 7/27/2021 around 3:45 PM, when asked how specimen identity and integrity is ensured in preanalytics he said: "I believe a certain number of reqs [requisitions] a day to be checked. [IT manager] would know about that and [Preanalytics lead]. It's not something in the lab, its in accessioning." When asked do you have any oversight, he said: "[IT manager] is responsible for that." 3. During an interview with the laboratory director on 7/27/2021 around 3:45 PM, when asked about temperature monitoring in the laboratory and how it has been monitored he said: "I personally no, but the supervisors should look at the charts daily. That was the disconnect before, I now have supervisors, they are responsible, I'm not responsible. Nonworking fridge or freezing, nobody has told me about that." 4. During an interview with the laboratory director on 7/27/2021 around 4:00 PM, when asked how he monitors expired reagents in the laboratory he said somehow when the (former supervisor) person left on the molecular side there seemed to be missing records, [TS#1] is now the person in charge, she has the book and she checks the lot number before use. 5. In an interview with the laboratory director on 7/27/2021 around 4:10 PM, when asked if he had investigated other patients that were released as negative instead on inconclusive, he said: "I admit, I looked those up." When asked: "Have you investigated any other patients?" He said: "I'm limited to the amount of time, its not my job, its actually my tech's job." 6. In an interview with the laboratory director on 7 /27/2021 around 4 PM when asked how often he is on site he said: "I come in once a

week, this is only recently when I got the staff, I'm only getting paid for one, I'm back to where I belong." 7. During an interview on 7/27/2021 around 4:00 PM when asked how he ensures that the techs are releasing results correctly the laboratory director said: "Again I go back to my supervisors." 7. Refer to D3000, D5200, D5300, D5400, D5800, D6079, D6108, D6168.