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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>03D2180037             | <b>(X3) Date Survey Completed</b><br><br>07/14/2022 |
| <b>Name of Provider or Supplier</b><br><br>Tgen North, Clinical Laboratory   | <b>Street Address, City, State</b><br><br>3051 W Shamrell Blvd, Ste 106, Flagstaff, AZ |   |
| 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>D6127</b>              | <p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b><br/>CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on lack of documentation of a semi-annual competency evaluation for one testing personnel and interview with the facility personnel, the technical supervisor failed to evaluate and document the performance of an individual responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens. Findings include: 1. No semi-annual competency evaluation documentation was presented for review for one testing personnel who was initially trained in September 2020. 2. During the survey conducted on July 14, 2022 at approximately 1:30pm, the facility personnel confirmed that the laboratory failed to have documentation of a semi-annual competency evaluation for the testing personnel indicated above. 3. The laboratory began patient testing on March 16, 2020 in the sub-specialty of Virology, with an approximate annual test volume of 18,182.</p> |