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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 32D2182725 | (X3) Date Survey Completed 04/07/2021 |
| Name of Provider or Supplier Vanguard Genetics Llc | Street Address, City, State 3655 Research Drive, Las Cruces, NM | |
| 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 |
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| D0000 | During a complaint survey completed on 04/07/2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR Part 493.1403 Laboratory Director 42 CFR Part 493.1415 Clinical Consultant Complaint Intake NM00048723 was substantiated. |
| D3000 | <p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on the review of the patient test records for Healgen COVID-19 Rapid serological assay (antibody test for COVID19), Quality Assurance Manual, and interview with the Laboratory Director, the laboratory failed to have a reporting policy /procedure for COVID-19. The laboratory also failed to report and track results for both positive and negative to the local/state Department of Health (NMDOH) from January 12, 2021 through Feb 05, 2021 for 9 of 9 tests performed. Findings are: A. Review of the SARS-CoV-2 Patient test records from January 8, 2021 through February 05, 2021 the following was revealed: 1. For the month of January a total of 9 tests were performed. a. Of the total 9 tests performed, 5 were positive, and 4 were negative. 2. Patient test results for the months of February and March 2021 were requested during the on-site survey and via email on March 8, 2021 at 3:04 pm but not</p> |

provided by April 12, 2021. B. Review of the Quality Assurance Manual revealed there was not a policy or procedure for COVID-19 test reporting to the NMDOH. 1. Facility had been running COVID-19 testing since May 19, 2020. The Quality Assurance Manual revealed competencies acknowledgement forms completed and filled out by Laboratory Director, General Supervisor, and one Laboratory Technician for "qualitative serological assays (measure antibodies against the S protein) - lateral flow-immunoassays (diagnostic device used to check presence of target antibodies against COVID 19) -Moderate complexity, waived, and LDTs (laboratory developed test)." This was the documentation of training of the testing personnel for the COVID-19 antibody testing. C. During interview on April 7, 2021 at 9:52 am, the Laboratory Director stated that he did not know if the corporate office/IT (Information Technology) was reporting to NMDOH. He stated that he had contacted New Mexico Department of Health (NMDOH) via email and that NMDOH did not respond to his email. The surveyor requested a list of all patients tested (date tested, date resulted, and date reported) from Jan 8th to March 7th. The surveyor also asked for all emails from the facility to the NMDOH. No further documentation was received as of April 12, 2021 confirming that the facility attempted to report. D. Review of an email to the Laboratory Director from the surveyor on May 18, 2020 at 1:28 pm confirmed the Laboratory Director was given the the reporting requirements and where to send the information to the New Mexico Department of Health.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on the review of the patient test records, email, Quality Assurance Manual and interview with the Laboratory Director, the laboratory failed to have a written polity for reporting COVID19 test results to the New Mexico Department of Health. 9 Patients were tested 01/08/2021 - 02/05/2021. Findings are: A. Review of the SARS-CoV-2 Patient test records from January 8, 2021 through February 05, 2021 revealed: 1. For the month of January a total of 9 tests were performed. a. Of the total 9 tests performed, 5 were positive, and 4 were negative. 2. Patient test results for the months of February and March 2021 were requested during the on-site survey and via email on March 8, 2021 at 3:04 pm but not provided by April 12, 2021. B. Review of the Quality Assurance Manual dated 09/01/2020 had no policy for reporting COVID19 test results to the New Mexico Department of Health. C. During interview on 04/07 /2021 at 9:52 am, the Laboratory Director stated that he had attempted to contact the New Mexico Department of Health regarding the reporting of test results per the guidance of one of the surveyors. He also stated that no one from the department contacted him. D. Review of an email to the Laboratory Director from the surveyor on 05/18/2020 at 1:28 pm confirmed the Laboratory Director was given the the reporting information to the New Mexico Department of Health.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to

ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of email, patient test records and interview with the Laboratory Director, the laboratory failed to ensure SARS-CoV-2 (COVID19) results were submitted to the New Mexico Department of Health. Findings are: A. Review of the SARS-CoV-2 Patient test records from January 8, 2021 through February 05, 2021 revealed: 1. For the month of January a total of 9 tests were performed. a. Of the total 9 tests performed, 5 were positive, and 4 were negative. 2. Patient test results for the months of February and March 2021 were requested during the on-site survey and via email on March 8, 2021 at 3:04 pm but not provided by April 12, 2021. B. During interview on 04/07/2021 at 9:52 am., the Laboratory Director stated that he had attempted to contact the New Mexico Department of Health regarding the reporting of test results per the guidance of one of the surveyors. He also stated that no one from the department contacted him. C. Review of an email to the Laboratory Director from the surveyor on 05/18/2020 at 1:28 pm confirmed the Laboratory Director was given the the reporting requirements and where to send the information to the New Mexico Department of Health.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on the review of laboratory procedures, patient reports/handouts, Association of State Medical Boards website, New Mexico Medical Board website, CMS (Centers for Medicare and Medicaid Services) Personnel Report Form 209, and interview with the Laboratory Director, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: The Laboratory Director failed to ensure the Clinical Consultant met the licensure requirements. See D6004

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapporitions performance of his or her responsibilities, he or

she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the review of laboratory procedures, patient reports/handouts, Association of State Medical Boards website, New Mexico Medical Board website, CMS (Centers for Medicare and Medicaid Services) Personnel Report Form 209, and interview with the Laboratory Director, the Laboratory Director failed to ensure the Clinical Consultant met the licensure requirements. Findings are: A. Review of the CMS 209 sent by the Laboratory Director via email on 03/19/2021 indicated that the Clinical Consultant was a Medical Doctor (MD). B. During interview on 04/07/2021 at 10:35 am, the Laboratory Director stated he "thinks" the Clinical Consultant has a New Mexico Medical license to practice medicine but did not have a copy of his New Mexico Medical license. He also stated that the Clinical Consultant was based in Vancouver and was currently in Spain. C. During interview on 04/06/2021 at 10:46 am, the Laboratory Director stated that he provided a COVID19 treatment protocol (published on the Internet) recommended by the Clinical Consultant via email on 11/24/2020 to patients if requested, a duty that would fall under the duties of a Clinical Consultant. D. Review of the laboratory's Quality Assurance Manual indicated on page 7, Organization Chart, that the designated Clinical Consultant was an MD. E. Searches conducted at the websites for Association of State Medical Boards, New Mexico Medical Board, New Mexico Boards and Commissions (which licenses Doctors of Osteopathy[bone] and Podiatry[feet]), and the American Board of Medical Specialties revealed no one under the name of the Clinical Consultant as having a license to practice medicine in the United States.

D6056

CLINICAL CONSULTANT
CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:

Based on the review of laboratory procedures, patient reports/handouts, Association of State Medical Boards website, New Mexico Medical Board website, CMS (Centers for Medicare and Medicaid Services) Personnel Report Form 209, and interview with the Laboratory Director, the laboratory failed to have a qualified Clinical Consultant. Findings are: The Clinical Consultant did not have a New Mexico license for Medical Doctor, Doctor of Osteopathy or Doctor of Podiatric Medicine. See D6057

D6057

CLINICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on the review of laboratory procedures, patient reports/handouts, Association of State Medical Boards website, New Mexico Medical Board website, CMS (Centers for Medicare and Medicaid Services) Personnel Report Form 209, and interview with the Laboratory Director, the Clinical Consultant did not have a New Mexico license for Medical Doctor, Doctor of Osteopathy or Doctor of Podiatric Medicine, and did not qualify as a Clinical Consultant. Findings are: A. Review of the CMS 209 sent by the Laboratory Director via email on 03/19/2021 indicated that the Clinical Consultant was a Medical Doctor (MD). B. During interview on 04/07/2021 at 10:35 am, the Laboratory Director stated he "thinks" the Clinical Consultant has a New Mexico Medical license to practice medicine but did not have a copy of his New Mexico Medical license. He also stated that the Clinical Consultant was based in Vancouver and was currently in Spain. C. During interview on 04/06/2021 at 10:46 am, the Laboratory Director stated that he provided a COVID19 treatment protocol (published on the Internet) recommended by the Clinical Consultant via email on 11/24/2020 to patients if requested. D. Review of the laboratory's Quality Assurance Manual indicated on page 7, Organization Chart, that the designated Clinical Consultant was an MD. E. Searches conducted at the websites for Association of State Medical Boards, New Mexico Medical Board, New Mexico Boards and Commissions (which licenses Doctors of Osteopathy and Podiatry), and the American Board of Medical Specialties revealed no one under the name of the Clinical Consultant as having a license to practice medicine in the United States.