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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D1099562 | (X3) Date Survey Completed 04/15/2021 |
| Name of Provider or Supplier Genesis Diagnostics | Street Address, City, State 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. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D3009 | <p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on interview and record review the laboratory failed to ensure that the State of Pennsylvania regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests are being performed. Findings: 1. The laboratory's CMS 209 lists two general supervisors. One general supervisor has been delegated for all areas of testing. The other general supervisor has been delegated for Chem, Immuno, Endo, Allergy and Tox. 2. During an interview on 4/15/2021 at around 3:20 pm when asked how are supervisors available to staff when not on site the laboratory director said: "The supervisors are not at the site but they are available. Technical employees can call me anytime." When asked how the laboratory ensures that a supervisor is available to laboratory personnel when the director is unavailable, he answered: "There are other people there." The surveyor asked, "have those people been delegated?" The laboratory director said: "No. Only the 2 supervisors and the QA manager (have been delegated)."</p> |
| D5423 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as</p> |

applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory director, the laboratory failed to establish performance specifications before reporting patient test results for 19 thermocyclers for COVID-19 testing. Findings: 1. The laboratory has 19 thermocyclers for COVID-19 testing with the following serial numbers in use during the survey on 4/14/2021: a. 786BR06155 b. 786BR04978 c. 786BR05033 d. 786BR05026 e. 786BR05032 f. 786BR05288 g. 786BR05736 h. 786BR05730 i. 786BR05788 j. 786BR05781 k. 786BR06142 l. 786BR02042 m. 786BR02037 n. 786BR02040 o. 786BR06547 p. 786BR06392 q. 786BR06393 r. 786BR02063 s. 786BR02043 2. The laboratory provided a document titled "Validation of Rt-PCR for SARS-CoV-2 method using CDC Method Kit - Validation Method Plan." The document was signed by the laboratory director on 10/14/2020. The document stated instructions for the following studies: a. Limit of detection b. Precision/Accuracy c. Specificity d. Specimen stability e. Carryover f. Patient Comparison by COVID Method 3. The laboratory provided a document titled "Performance Characteristics." The document stated contained paragraphs titled: Limit of Detection (LoD), Precision /Accuracy, Specificity/Exclusivity Testing, Specimen Stability, Carryover (signed by laboratory director 7/8/2020), Method Comparison (signed by laboratory director 10 /14/2020), Comparison of Master Mix brands (signed by laboratory director 12/1 /2020). The document states: Original validation missing. Reconstructed from available date. It provides data from a thermocyclers with a serial number 786BR04953. 4. The laboratory provided a document titled "Comparison Verification of Performance All Bio-Rad CFX384 used for detection of SARS-CoV-2" which was signed by the laboratory director on 3/8/2021. The document did not follow the laboratory's document "Validation of Rt-PCR for SARS-CoV-2 method using CDC Method Kit - Validation Method Plan." 5. In an interview with the laboratory director on 4/15/2021 around 4 PM when asked if the laboratory had documentation of the establishment of performance specifications for all 19 thermocyclers the laboratory director said, "it's not a method, it's a machine" and also said that the laboratory did a comparison of all thermocyclers every 6 months. 6. Another document provided by the laboratory that was signed by the laboratory director on 12/1/2020 stated: "Comparison Study of Master Mix Brands: Supplies of the Master Mix are sometimes delayed in shipping or are in short supply. This can affect the testing process by stopping the ability to test or stop the testing process at a stage require deep freezing of the plate until the Master Mix is delivered. It was necessary to find alternate vendors of Master Mix that can be used interchangeably and have the same response to the Master mix currently in use. This study will be performed on several available Master Mix brands that could be used whenever there is a delay or a short supply of a brand we are currently using." 7. The Emergency Use Authorization titled "CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel - Instructions for Use" listed the following options for rRT-PCR Enzyme Mastermix Options: a. Quantabio qScript XLT One-Step RT-qPCR ToughMix (catalog numbers: 95132-100, 95132-02K, 95132-500) b. Quantabio UltraPlex 1-Step ToughMix (4X) (catalog numbers: 95166-100, 95166-500, 95166-01K) c. Promega GoTaq Probe 1- Step RT-qPCR System (catalog numbers: A6120, A6121) d. Thermofisher TaqPath (Trademark) 1-Step RT-qPCR Master Mix, CG (catalog numbers: A15299, A15300) 8. The laboratory's SOP "Rapid Real-time PCR based Screening for SARS-CoV-2 (COVID-19) on Bio-Rad

CFX384" listed the following options for Master Mix: a. Quantabio: Cat# 95112 b. Takara: Cat# RR60HW c. Promega Cat# M7133 d. LGC: Cat# ERT12925K + Cat# 30050-1 9. The laboratory provided a document titled "COVID-19 Detection in Nasopharyngeal Swabs" signed by the laboratory director on 4/17/2020. The document states: "Conclusions: Naso and oropharyngeal sample collections sites and medium of collection (PBS and VTM) do not influence the overall amplifications and COVID-19 result interpretations per se. Terminal amplifications can influence the false positives and false negatives rates. Hence, a visual inspection with RFU is taken as a base to interpret and distinguish from [sic] positive cases from false positives." 10. The laboratory's SOP "Rapid Real-time PCR based Screening for SARS-CoV-2 (COVID-19) on Bio-Rad CFX384" does not define a process for a visual inspection with RFU to distinguish positive cases from false positives.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of documentation, interview, and record review, the laboratory failed to ensure that the results of control materials met the laboratory's criteria for acceptability before reporting patient test results for 76 of 189 quality control records reviewed. Findings: 1. In a sampling of a review of quality control records, 76 of 189 contained control results out of range of the laboratory's control limits and no corrective action: 1. 11/2/2020 7:13 AM POS CONTROL 2. 11/2/2020 7:56 AM POS CONTROL 3. 11/2/2020 8:25 AM NEC2 POS CONTROLS 4. 11/3/2020 5:00 AM NTC CONTROL 5. 11/3/2020 6:58 AM NTC CONTROL 6. 11/3/2020 7:37 AM NEC2 POS CONTROLS 7. 11/3/2020 8:07 AM POS CONTROL 8. 11/3/2020 10:26 AM NTC CONTROL 9. 11/3/2020 6:57 PM POS NTC CONTROLS 10. 11/3/2020 9:09 PM NTC CONTROL 11. 11/4/2020 5:03 AM NTC CONTROL 12. 11/4/2020 5:53 AM NEC1 CONTROL 13. 11/4/2020 7:41 AM NTC CONTROL 14. 11/4/2020 9:04 AM POS CONTROL 15. 11/4/2020 11:33 AM NEC1 CONTROL 16. 11/4/2020 1:51 PM POS NTC CONTROLS 17. 11/4/2020 2:35 PM NEC1 CONTROL 18. 11/4/2020 10:00 PM NEC2 CONTROL 19. 11/4/2020 10:07 PM NEC1 CONTROL 20. 11/4/2020 3:53 AM NEC2 CONTROL 21. 11/5/2020 4:21 AM NEC2 CONTROL 22. 11/5/2020 9:03 AM NEC1 CONTROL 23. 11/6/2020 8:20 PM NTC CONTROL 24. 11/6/2020 9:13 PM NTC CONTROL 25. 11/6/2020 7:58 PM POS NTC CONTROLS 26. 11/6/2020 6:33 PM NTC CONTROL 27. 11/6/2020 7:59 PM NTC CONTROL 28. 11/6/2020 3:10 PM POS NTC CONTROLS 29. 11/6/2020 4:05 PM NTC CONTROL 30. 11/6/2020 6:58 PM NTC CONTROL 31. 11/6/2020 2:43 PM NTC CONTROL 32. 11/6/2020 6:57 PM POS NTC CONTROLS 33. 11/6/2020 12:53 PM POS CONTROL 34. 11/6/2020 3:50 PM POS NTC CONTROLS 35. 11/6/2020 4:22 PM NTC CONTROL 36. 11/6/2020 9:44 AM NEC2 CONTROL 37. 11/6/2020 2:19 AM NTC CONTROL 38. 11/6/2020 8:41 AM NTC CONTROL 39. 11/6/2020 10:27 PM NTC CONTROL 40. 11/6/2020 9:40 PM NEC1 CONTROL 41. 11/6/2020 3:19 AM NTC CONTROL 42. 11/6/2020 10:36 AM NTC CONTROL 43. 12/8/2020 3:24 PM POS CONTROL 44. 12/31/2020 2:50 AM POS CONTROL 45. 12/31/2020 3:02 AM POS CONTROL 46. 12/31/2020 3:02 AM NTC POS CONTROLS 47. 12/31/2020 3:54 AM POS CONTROL 48. 12/31/2020 3:54 AM POS CONTROL 49. 12/31/2020 7:37 AM POS CONTROL 50. 12/31/2020 7:57 AM POS CONTROL 51. 12/31/2020 9:

29 AM POS CONTROL 52. 12/31/2020 2:06 PM POS CONTROL 53. 12/31/2020 2:51 PM NTC CONTROL 54. 12/31/2020 3:26 PM NTC CONTROL 55. 12/31/2020 3:30 PM NTC CONTROL 56. 12/31/2020 2:27 PM NTC NEC1 POS CONTROLS 57. 12/31/2020 2:09 PM NTC POS CONTROLS 58. 12/31/2020 12:31 PM POS NEC1 CONTROLS 59. 12/31/2020 1:09 PM NTC POS CONTROLS 60. 12/31/2020 11:55 AM NTC CONTROLS 61. 12/31/2020 11:13 AM NEC2 NTC CONTROLS 62. 12/31/2020 3:28 PM POS NTC CONTROLS 63. 12/31/2020 2:51 PM NEC2 POS CONTROLS 64. 12/31/2020 4:10 PM NTC CONTROL 65. 12/31/2020 5:49 PM POS CONTROL 66. 12/31/2020 8:04 PM POS NTC CONTROLS 67. 12/31/2020 6:36 PM NTC CONTROL 68. 12/31/2020 8:04 PM NTC CONTROL 69. 12/31/2020 8:46 PM NTC CONTROL 70. 12/31/2020 7:17 PM NTC CONTROL 71. 1/1/2021 2:20 PM NTC CONTROL 72. 1/1/2021 1:07 AM NTC CONTROL 73. 1/2/2021 1:20 AM NTC CONTROL 74. 1/27/2021 6:02 POS CONTROL 75. 02/5/2021 9:07 AM NTC CONTROL 76. 02/26/2021 5:18 PM NEC1 NEC2 CONTROLS

2. During an interview with the laboratory director on 4/15/2021 when asked about quality control failures, the laboratory director said: "In order for us to get better clarity we had to print data directly from the machine, the LIS (laboratory information system) is not attached to them, see the plates, and noticed some had potential for contamination because they weren't as clean as the result should have been, not exactly clear or clean. There are many reasons why that can occur, reagents, water, not changing gloves, too close, didn't decontaminate, one sample effects the next. We don't know why that occurs." The laboratory determined that the quality control failures were isolated from February 10, 2021 until March 15, 2021. 3. Documentation for corrective action of quality control, number of patients found to be affected, and corrected reports of patients was requested from the laboratory director by the surveyor on 4/15/2021 at about 4:30 PM and again via email on 4/15/2021 at 6:52 PM. The requested documents were not provided to the surveyor. 4. The laboratory's SOP "Rapid Real-time PCR-based Screening for SARS-CoV-2 (COVID-19) on BioRad CFX384" shows that 188 patient samples can be tested for each plate under the image titled "384 Plate Layout".

D6143

GENERAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have

served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on interview and record review, the laboratory failed to evaluate and designate one individual as a General Supervisor. 1. In a review of the laboratory's plan of correction under "Laboratory Director Investigative Report cited deficiency D5400 /D5401" the document says: "To ensure testing personnel follow SOP, the supervisor and/or QA (quality assurance) manager observes each testing personnel at any point of the process, in addition to employee competency evaluations." It is signed by the laboratory director on 3/29/2021. 2. In a review of the laboratory's plan of correction under "Laboratory Director Investigative Report cited deficiency D6079" the document titled "Medical Director Delegation of Duties" for the Quality Management department indicates TP#14 as an authorized person for the delegated function of: "day-to-day supervision and oversight of the laboratory sections operation and personnel performing testing." 3. In an interview with TP#14 on 4/14/2021 at 10:15 am, she identified herself as the "QA manager." When asked about her duties she said: that she updated procedure, checks quality control, and observes all employees at least 1-2 times a week, including night shift at least 1 time a week to ensure they are following the SOP. She said if an individual misses a training of a change in SOP that she will go over it with them before they begin testing again. 4. In an interview with the laboratory director on 4/15/2021 at around 3:15 PM when asked what the QA manager's duties were the laboratory director said: "She's my eyes and ears, she works on all the projects I give her and any time she has a question she calls. She follows

what was written, follows all the rules and regulations with what we wrote. " When asked does she act as a laboratory supervisor, he said "No supervisor not a supervisor." When asked does she train other personnel, he said "No she doesn't have that skillset." 5. The QA manager's personnel qualifications were requested during an interview with the laboratory director on 4/15/2021 around 3:15 PM and in an email sent on 4/15/2021 around 6:50 PM. The laboratory's response received in an email on 4/16/2021 from the laboratory's attorney said: "RESPONSE: THE DELEGATION TO THE QA MANAGER IS SET FORTH IN WRITING, AND A COPY OF THIS DOCUMENTATION WAS SUBMITTED ON MARCH 29TH UNDER TAG 6107. THE QA MANAGER IS NOT TESTING PERSONNEL, SO NO QUALIFICATIONS ARE DEFINED UNDER CLIA REGULATIONS THAT REQUIRE COMPLIANCE."