| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 13D2241674 | 06/26/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| D&G Medical Associates Pllc | 1430 W Ustick Rd Ste 100, Meridian, ID | |

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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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the Laboratory Director (LD) on 6/26/2024, the laboratory failed to establish and follow written policies and procedures to assess testing personnel (TP) competency in 2023 and 2024. The findings include: 1. A review of the CMS 209 identified three (3) TP performing moderate complexity testing. 2. A review of laboratory procedures identified that the laboratory failed to establish policies or procedures to assess TP initial training, semiannual and annual competency. 3. A review of training and competency assessment records identified that the laboratory failed to have a six month competency assessment for one (1) of one (1) TP in 2023 and for one (1) of one (1) TP in 2024. 4. A review of training and competency assessment records identified that the laboratory failed to have an annual competency assessments for one (1) of one (1) TP in 2024. 5. An interview with the LD on 6/26/2024 at 1:20 pm confirmed the above findings. 6. The laboratory reports performing 2,100 tests annually. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when |

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| | appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of patient records, the QIAstat-DX respiratory panel instructions for use (IFU), the laboratory's procedures and an interview with the Laboratory Director (LD) on 6/26/2024, the laboratory failed to have a procedure for monitoring stability of patient specimens received to ensure they are within the manufacturer requirements. The findings include: 1. A review of the patient records identified that the laboratory failed to verify patient requisitions contained the correct date and time of collection. One patient requisition had a collection date and time of 3/13/2024 12: 50 pm and the corresponding test report had a testing date and time of 3/13/2024 12: 16 pm. 2. A review of the QIAstat-DX respiratory panel IFU identified that respiratory samples are stable at room temperature (15-25 C) for four (4) hours and refrigerated for three (3) days in universal transport medium (UTM). 3. A review of the laboratory's procedures identified that the laboratory failed to have a procedure that included conditions of specimen transport, storage and verification and documentation of patient respiratory sample room temperature stability prior to testing. 4. An interview with the LD on 6/26/2024 at 1:40 pm confirmed that they did not confirm and document sample collection date, time and stability for respiratory panel testing samples prior to testing and reporting results. 5. The laboratory report performing 2,100 respiratory tests annually. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of patient laboratory test reports and an interview with the Laboratory Director (LD) on 6/26/2024, the laboratory failed to indicate the name and address of the performing laboratory, patients full name and specimen source for QIAstat respiratory panel testing. The findings include: 1. A review of patient laboratory test reports for the QIAstat respiratory panel identified that the laboratory failed to indicate the name and address of the performing laboratory, the patients full name for positive identification and the specimen source. 2. An interview with the LD on 6/26/2024 at 1:53 pm confirmed the above findings. 3. The laboratory reports performing 2,100 respiratory tests annually. 4. This is a repeat deficiency for not indicating the name and address of the facility, patients full name and the specimen source from the last inspection on 9/26/2022. |