| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 14D2183279 | 03/31/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Radiance Diagnostics | 1240 Iroquois Ave - Ste 300, Naperville, IL | |

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 |
|---|---|
| **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 record review, the Laboratory Personnel Report (CMS 209), and an interview with the laboratory director (LD), the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing General immunology testing for 2 out of 2 testing personnel (TP). Findings: 1. The employee files, the CMS 209, and competency policies and procedures were reviewed. 2. The CMS 209 lists 2 employees (TP1 and TP2) performing the following COVID-19 testing in the laboratory: *COVID-19 PCR by TaqPath Combo Kit; *COVID-19 PCR by NxTagCoV- Extended Panel Assay; *Access SARS-CoV2 IgG Assay *Access SARS-CoV2 IgM Assay *Rapid Diagnostic Test for the Detection of SAR-CoV2 Antigen; and *Rapid COVID-19 IgM /IgG Combo Test Kit. 3. The personnel documents presented revealed 2 out of 2 TP were evaluated and trained with procedures that failed to met the required criteria for personnel assessment of competency to perform both the moderately and highly complex testing for COVID-19. 4. The laboratory's competency policy and step-by-step procedure failed to include the following criteria as specified in the personnel requirements in subpart M: *Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; *Monitoring the recording and reporting of test results; *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; *Direct observation of performance of instrument maintenance and function checks; *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or |

| | |
|---|---|
| | external proficiency testing samples; *Assessment of problem solving skills; and *Indicate whether the TP1 and TP2 assessment were "Satisfactory or Unsatisfactory"; and *Indicated whether the TP1 and TP2 required supervision or not. 5. On an Initial survey conducted on 03/31/2021 at 1:15 PM, the LD confirmed the above findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, record review, and an interview with the laboratory director (LD), the laboratory failed to ensure conditions that are essential for proper storage of reagents and specimens are performed as instructed by the manufacturer and in a manner that provides test results within the laboratory's stated performance specifications for coronavirus-19 (COVID-19) analysis, affecting all patients. "The laboratory failed to accurately monitor and document the laboratory's refrigerator temperature." Findings: 1. On 03/31/2021 at 11:00 AM during a tour of the laboratory, the surveyor observed in the refrigerator where patients' specimens were stored for digest. The thermometer used in the refrigerator did not indicate exact temperature readings but provided incremented ranges. 2. The procedure manual, temperature logs and calibration certifications were reviewed. 3. The procedure manual and the manufacturer's instructions revealed all refrigerators, freezers, and rooms temperatures are required to be monitored and documented to ensure optimal environmental conditions for patients specimens and testing. 4. Further review showed the laboratory failed to calibrate the above thermometer to ensure the accuracy of the color gradient ranges. 5. On an Initial survey conducted on 03/31 /2021 at 1:15PM, the LD confirmed the above findings. |