| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 33D2005935 | 02/29/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Wadsworth Center - Griffin Laboratory | New York State Department Of Health, Slingerlands, NY | |

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** | The Centers for Medicare & Medicaid Services (CMS) CLIA federal surveyors conducted an announced CLIA recertification survey at Wadsworth Center - Griffin Laboratory on February 29, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiencies were found during the announced routine CLIA recertification survey completed on February 29, 2024 around 12:00 pm. |
| **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 and interview with the Quality Assurance (QA) Officer, the laboratory failed to have a written Clinical Consultant competency policy based on the job responsibilities for one of one Clinical Consultant. Findings include: 1. The Laboratory Personnel Report (Form CMS-209) signed by the Laboratory Director on 02/14/2024 lists one Clinical Consultant for the laboratory. 2. Record review on 02/29 /2024 of 2023 and 2024 personnel competency records revealed no documentation for one of one Clinical Consultant competency based on job responsibilities. 3. Review of the competency assessment policy on 02/29/2024 revealed the laboratory did not establish a written policy to assess the Clinical Consultant based on job responsibilities. 4. Interview on 2/29/24 at 09:30 am with the QA Officer confirmed the findings above. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a) |

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| | 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 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>A. Based on a review of laboratory procedures, lack of received specimen documentation, and interview with laboratory staff, the laboratory failed to establish and document specimen acceptability temperatures for received rabies specimens from 2022 to 2024. 1. Review of the RAB 037 SOP Ante-Mortem Sample Receipt, Accessioning, Resulting procedure, %. Sample Requirements/shipping/labeling procedure revealed, 5.1 "All samples other than whole blood or serum should be quickly frozen after collection, stored at minimum -70 degrees Celsius and shipped on cold pack if sent by local carrier or on dry ice if sent overnight". 2. The rabies specimen, collection, storage, and shipping process states, "ship at room temperature". 3. On the day of the survey, February 29, 2024, the laboratory was unable to provide documentation of the temperatures of received rabies specimens from 2022 to 2024. 4. Laboratory staff stated that they check to see if the specimen is received with dry ice in the box, or if at room temperature, but they do not check and document the exact temperature of the specimen received. 5. Per the CMS 116 form, signed by the laboratory director on February 14, 2024, two virology specimens and 575 general immunology specimen tests have been performed annually. 6. The laboratory staff confirmed the temperature are not taken when samples specimens are received on February 29, 2024, around 11:00 am. 47272 B. Based on a review of laboratory procedures, lack of received specimen documentation, and interview with Technical Supervisor #2 (TS #2), the laboratory failed to document specimen acceptability for received Plaque Reducing Neutralization Testing (PRNT) specimens in 2023 and 2024. Findings include: 1. Review of "SOP VI-004 Plaque Reduction Neutralization Test" under "4.0 SAMPLE REQUIREMENTS" stated, "Samples are shipped by intra agency mail frozen, on cooler packs, or at ambient temperature." 2. Review of the laboratory's specimen receipt log revealed no documentation of the specimen disposition upon receipt into the laboratory. 3. Interview on 2/29/2024 with TS #2 confirmed the findings. 4. Per the CMS 116 form, signed by the Laboratory Director on 02/14/2024, two virology specimens were performed annually. |
| **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 the review of laboratory humidity records and interviews with laboratory |

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| | staff, the laboratory failed to monitor and document humidity conditions of the rabies laboratories from 2022 to 2024. Finding Include: 1. The Rabies laboratory uses two Thermo Fisher Scientific 3500 Genetic Analyzers for Ante-mortem Rabies Virus testing. 2. The Thermo Fisher Scientific 3500 Genetic Analyzers user guide stated, Environmental requirements, operating conditions of 20% to 80% relative humidity, noncondensing. 3. On the day of survey, February 29, 2024, the laboratory could not provide documentation of humidity conditions monitored in the rabies laboratories from 2022 to 2024. 4. Laboratory staff confirmed humidity was not monitored or documented in the rabies laboratory on February 29, 2024, around 12:00 pm. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory temperature records and an interview with general supervisor (GS) #1. the laboratory failed to document corrective actions for out-of-range temperatures (-10 to -30 degrees Celsius) from 2022 to 2024. Findings Include: 1. A review of the temperature monitoring FA prep room 117 revealed the acceptable temperature range is from -10 to -30 degrees Celsius. 2. On the day of the survey, February 29, 2024, a review of rabies temperature records from 2022 and 2024 revealed, in 2023, temperatures were found outside of the acceptable temperature range in 8 of 12 months (February, March, April, May, July August, September, and October) for the thermos flammable freezer in Room 117. 3. The laboratory could not provide documented corrective actions for each day temperatures were out of range in 2023 for the freezer in room 117. 4. GS#1 confirmed the findings above on February 29, 2024, at 12:00 pm. |