| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D0279395 | 03/20/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Uhealth Pathology At Mailman | 1601 Nw 12th Ave Room 7002, Miami, FL | |

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 |
|---|---|
| **D0000** | A recertification survey was conducted on 02/22/2023 to 03/20/2023 at UHealth Pathology at Mailman. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 1:45 PM on 03/20 /2023. The following Condition was not met: D5400 - Analytic System 493.1250 |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the procedure manual and quality control (QC) records, and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and identify problems from 04/16/21 to 02/22 /23. Findings Included: Based on review of the procedure manual and quality control (QC) records and interview, the laboratory failed to run a negative control each day testing was performed on the Beckman Coulter Navios EX Flow Cytometer from 04 /16/21 to 02/22/23. (Cross Reference D5475) |
| **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 observation and interview, the laboratory failed to follow manufacturer instructions for storage temperature of seven out of seven Biomerieux products used in the ETESTfrom 02/01/2023 to 02/22/2023. Findings included: During the laboratory tour on 02/22/2023 at 10:30 AM, the surveyor found reagents stored in a minus 20 Celsius Degree freezer in the Microbiology Department. The following reagents were used for the Minimum Inhibitory Concentration test (ETEST) from Biomerioeux: One box of Vancomycin lot 1009755230, one box Ceftriaxone lot 1009598200, two boxes Imipemen lot 1009371780, one box Imipenem - relebactam MIC Test Strip lot 112222039, one box Ceftaroline lot 1009747600, eight boxes Levofloxacine lot 1009399100 and one box Linezolid lot 1008695870. Reviewed of the required storage temperatures as per manufacturer showed the following storage requirements: -Vancomycin, Ceftriaxone, Imipemen and Linezolid to be stored at -20 to +8 Celsius (C) Degrees. -Imipemem-relebactan and Ceftaroline to be stored at temperatures from -20 C and below. -Levofloxacine to be stored at +2 to +8 C. -Review of the temperature log revealed an acceptable temperature range of -10 to -30 C. -See below the temperatures documented: 02/01/2023: -22.7 C 02/02/2023: -24.4 C 02/03/2023: -25.2 C 02/04/2023: -16.9 C 02/05/2023: -16.8 C 02/06/2023: -23.7 C 02 /07/2023: -22.8 C 02/08/2023: -24.8 C 02/09/2023: -23.2 C 02/10/2023: -13.7 C 02/11 /2023: -23.0 C 02/12/2023: -22.6 C 02/13/2023: -22.0 C 02/14/2023: -22.0 C 02/15 /2023: -22.9 C 02/16/2023: -23.7 C 02/17/2023: -25.3 C 02/18/2023: -22.8 C 02/19 /2023: -23.3 C 02/20/2023: -23.2 C 02/21/2023: -18.3 C 02/22/2023: -25.3 C Review of the recorded temperatures revealed the following: -Vancomycin, Ceftriaxone, Imipemen and Linezolid the documented storage temperatures were outside of the acceptable range on: 02/01/2023, 02/02/2023, 02/03/2023, 02/06/2023, 02/07/2023, 02 /08/2023, 02/09/2023, 02/11/2023, 02/12/2023, 02/13/2023, 02/14/2023, 02/15/2023, 02/16/2023, 02/17/2023, 02/18/2023, 02/19/2023, 02/20/2023, 02/22/2023. -Imipemen-relebactan and Ceftaroline, the documented storage temperatures were outside of the acceptable range in the following dates: 02/04/2023, 02/05/2023, 02/10 /2023 and 02/21/2023. -Levofloxacine the documented storage temperatures were outside of the acceptable range from 02/01/2023 to 02/22/2023. During an interview on 02/24/2023 at 12:30 PM, the Microbiology Supervisor confirmed that the reagents listed above were stored outside of the acceptable range as per manufacturer instructions in the days of reference. |
| **D5475** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(3)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the procedure manual and quality control (QC) records and |

| | |
|---|---|
| | interview, the laboratory failed to run a negative control each day patient testing was performed on the Beckman Coulter Navios EX Flow Cytometer for 2 of 2 (October 2021 and April 2022) months reviewed. Findings included: Review of the daily alignment check, detector standardization, color compensation and verification QC records for October 2021 and April 2022, revealed there was no negative control run. A total of 7,839 Leukemia/Lymphoma panels were tested using the Beckman Coulter Navios EX Flow Cytometers from 04/16/21 to 02/22/23. The laboratory used the all three Flow Cytometer to diagnose and monitor leukemia and lymphoma. The laboratory evaluated the following antibodies: CD 2 (T cell lymphocytic marker), CD3 (T cell lymphocytic marker), CD4 (T cell lymphocytic marker), CD5 (T cell lymphocytic marker), CD7 (T cell lymphocytic marker), CD8 (T cells marker), CD9 (leukocyte marker), CD10 (follicle center cells marker), CD11c (dendritic cell marker), CD13 (myeloid cells marker), CD14 (monocytes and macrophages marker), CD15 (myeloid cells marker), CD16 (granulocytes and natural killer cell marker), CD19 (B cell marker), CD20 (B cell marker), CD22 (B cell lymphocytic marker), CD27 (B cell lymphocytic marker), CD33 (monocytes and macrophages marker), CD34 (hematopoetic stem cells marker), CD38 (plasma cells and activated T and B cells marker), CD45 (leukocyte marker), CD56 (natural killer cells marker), CD58 (lymphocytic marker), CD64 (monocytes and macrophages marker), CD71 (erythroid marker), CD79a (B cell lymphocytic marker), CD81 (plasma cell marker), CD103 (alloantigen-induced regulatory T cells marker), CD117 (stem cell and plasma cells marker), CD123 (hematopoietic progenitor cell marker), CD 138 (plasma cell marker), CD200 (lymphocytic marker), CD229 (plasma cell marker), CD319 (lymphocytic marker), HLA-DR (Human Leukocyte Antigen - DR isotype T cell marker), Kappa (light chain B cell markers), and Lambda (light chain B cell markers), MPO (myeloperoxidase marker), and TdT (Terminal deoxynucleotidyl transferase marker). On 02/24/2023 at 11:02 AM, the Technical Supervisor A stated that they only ran a positive verify control for the last 23 months and that the laboratory did not have an IQCP (Individualized Quality Control Plan). |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, review of the procedure manual and interview, the laboratory failed to have a step-by-step procedure that explained how they performed the instrument to instrument comparison and how they defined the acceptability between test results for the Beckman Coulter Navies Flow Cyclometer instrument to instrument comparisons from 11/18/2022 to 02/22/2023. Findings Included: A tour of the laboratory on 02/22/2023 at 9:45 AM revealed there were three flow cyclometers (serial numbers A50, BE 28603, BE 32611). Review of the flow cytometry procedure manuals showed there was no procedure for the performance of the instrument to instrument comparison for the flow cytometers. The last annual review of the flow cytometry procedures by the Laboratory Director was signed and dated on 11/18 /2022. The laboratory used all three Flow Cytometers to diagnose and monitor leukemia and lymphoma. The laboratory evaluated the following antibodies: CD 2 (T |

| | |
|---|---|
| | cell lymphocytic marker), CD3 (T cell lymphocytic marker), CD4 (T cell lymphocytic marker), CD5 (T cell lymphocytic marker), CD7 (T cell lymphocytic marker), CD8 (T cells marker), CD9 (leukocyte marker), CD10 (follicle center cells marker), CD11c (dendritic cell marker), CD13 (myeloid cells marker), CD14 (monocytes and macrophages marker), CD15 (myeloid cells marker), CD16 (granulocytes and natural killer cell marker), CD19 (B cell marker), CD20 (B cell marker), CD22 (B cell lymphocytic marker), CD27 (B cell lymphocytic marker), CD33 (monocytes and macrophages marker), CD34 (hematopoetic stem cells marker), CD38 (plasma cells and activated T and B cells marker), CD45 (leukocyte marker), CD56 (natural killer cells marker), CD58 (lymphocytic marker), CD64 (monocytes and macrophages marker), CD71 (erythroid marker), CD79a (B cell lymphocytic marker), CD81 (plasma cell marker), CD103 (alloantigen-induced regulatory T cells marker), CD117 (stem cell and plasma cells marker), CD123 (hematopoietic progenitor cell marker), CD 138 (plasma cell marker), CD200 (lymphocytic marker), CD229 (plasma cell marker), CD319 (lymphocytic marker), HLA-DR (Human Leukocyte Antigen - DR isotype T cell marker), Kappa (light chain B cell markers), and Lambda (light chain B cell markers), MPO (myeloperoxidase marker), and TdT (Terminal deoxynucleotidyl transferase marker). On 02/23/2023 at 10:56 AM, Technical Supervisor A stated they did not have a policy for instrument to instrument comparison. |