| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D2072132 | 06/26/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Fnlcr Viral Oncology Section | Bldg 535 Sultan Street Room 428, Frederick, MD | |

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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| **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 record review, observation and interview, the laboratory failed to define a room temperature range consistent with the manufacturer's instructions and failed to monitor the room temperature. Findings include: 1. During a tour of the laboratory on 6/26/19 at approximately 9:45 am, the surveyor observed the Invitrogen TE Buffer, pH 7.0, was stored at room temperature (RT) in the Reagent Prep Room. 2. The Invitrogen manufacturer's instructions required that the TE Buffer be stored at 15-25 C (59-77 F). 3. A wall-mounted thermostat was observed by the door. 4. Interview with the technical supervisor (TS2) at approximately 10:15 revealed that the RT is controlled and monitored by the building facility department (BFD) rather than the laboratory. 5. The laboratory was unaware of the acceptable RT range determined by the BFD. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory director failed to ensure that a procedure was available to the laboratory personnel for the twice annual verification of accuracy for two of two test procedures. Findings include: 1. The laboratory performed Kaposi's Sarcoma Associated Herpes Virus (KSHV) and Endogenous Retrovirus (ERV-3) testing. 2. Review of the procedure, ERV-3 and KSHV PCR Assay Employee Training, Competency Assessment, and Bi-Annual Assay Verification, Version 1.7, revealed on page 5 that the procedure for the twice annual verification of accuracy was incomplete. 3. The procedure did not include instructions on how to perform the bi-annual verification. 4. The above findings were confirmed on 6/26/19 at approximately 11:30 am by the technical supervisor (TS1). |