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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D2038083 | (X3) Date Survey Completed 06/29/2022 |
| Name of Provider or Supplier Varmed Health Center Llc | Street Address, City, State Manuel Rossy Street Corner To Isabel Segunda, Bayamon, PR | |
| 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 |
|---------------------------|---|
| D5445 | <p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the Urinalysis microscopic quality control review and laboratory director interview; it was determined that the laboratory did not include and not document the negative microscopic control material when 7,000 patient were processed and reported from January 2022 to June 2022. The findings include: 1. The Urinalysis quality control was review on June 28, 2022 at 11:01 am. No negative quality control material was documented. 2. The laboratory supervisor confirmed on June 28, 2022 at 11:10 am that no microcopy negative control was included from January 2022 to June 2022 when 7,000 patient were processed and reported under the microscope.</p> |
| D6093 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> |

This STANDARD is not met as evidenced by:
Based on Urinalysis microscopy quality control records review from January 2022 to June 2022 and laboratory director interview on June 29, 2022 at 11:25am, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5445

D6177

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on Urinalysis microscopic quality control records review from January 2022 to June 2022 and laboratory director interview on June 29, 2022 at 11:30 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D5445.