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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 07D2021994 | (X3) Date Survey Completed 11/29/2018 |
| Name of Provider or Supplier Westmed Medical Group Immediate Care | Street Address, City, State 1281 East Main St, Stamford, CT | |
| 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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| D6045 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the technical consultant (TC) failed to ensure all testing personnel (TP) are adequately trained before testing patient samples. Findings include: 1. Record review of laboratory's proficiency testing (PT) records from American Proficiency Institute (API) on 11/29/18 revealed the following: a. One of two TP attested the 2018 Chemistry core third event PT document was not listed on the CMS-209 form. b. One of two TP listed in the above PT attestation form did not have training or competency evaluation records. c. The above listed TP performed 2 moderate complexity tests and one CLIA waived test in this PT event. 2. Staff interview the TC on 11/29/18 at 11:30 AM confirmed the above findings. The TC stated urgent care staff were trained to perform CLIA waived tests. The TC further stated he/she was not aware the urgent care staff performed moderate complexity tests.</p> |
| D6049 | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> |

This STANDARD is not met as evidenced by:
Based on record review and staff interview the technical consultant (TC) failed to review the laboratory's instrument maintenance and function checks. Findings include: 1. Record review of the laboratory's hematology analyzer (Beckman AcTDiff) maintenance records on 11/29/18 revealed: a. The TC did not review and document any maintenance or function checks from July 2018 till to-date. b. Instrument maintenance review was performed by an individual not listed on the CMS-209 form. 2. Staff interview with the TC on 11/29/18 at 11:30 AM confirmed the above findings.

D6055

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to evaluate testing personnel (TP) to ensure competency to perform and report accurate test results before testing patient samples independently. Findings include: 1. Record review of TP competency records on 11/29/18 revealed the following: a. Three of three TP listed on the CMS-209 form were retrained in July 2018 when they were hired at this laboratory. b. The TP listed above did not have a competency assessment before they were independently testing patient samples at this laboratory. c. The TP listed above were testing patient samples since July of 2018 immediately after their training at this laboratory. d. The TP listed above have had a competency evaluation performed elsewhere in February 2018 by an individual not listed on the CMS-209 form. 2. Staff interview with the technical consultant (TC) on 11/29/18 at 11:00 AM confirmed the above findings. The TC further stated the individual listed in line item (d) above had no responsibility with sample analysis at this laboratory. 4. The laboratory performs approximately 1500 moderate complexity tests annually.