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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 07D2094414 | (X3) Date Survey Completed 04/07/2022 |
| Name of Provider or Supplier Westchester Medical Group Pllc | Street Address, City, State 644 West Putnam Ave, Greenwich, 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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| D2006 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure proficiency testing (PT) samples were tested in the same manner and number of times as routine patient samples were tested prior to reporting to the PT program. Findings include: 1. Record review on 4/7/22 of the PT samples instrument printouts revealed the following: a. Event 1 of 2021 for Hematology was performed by Testing Personnel (TP) #1 on 3/12/2021 at 1:59 PM. b. Event 1 of 2021 for Hematology was repeated by TP #1 on 3/15/2021 at 4:06 PM. 2. Record review on 4/7/2022 of the American Proficiency Institute (API) PT comparative evaluation report revealed the results submitted to API were from testing performed on 3/15/2021. 3. Staff interview with technical consultant on 4/7/2022 at 12:05 PM confirmed the above findings.</p> |
| D2007 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> |

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to rotate proficiency testing (PT) samples amongst all routine testing personnel (TP) in the specialty of Hematology and Chemistry. Findings include: 1. Record review on 4/7/22 of the American Proficiency Institute PT testing records revealed the following: a. All three Chemistry PT events of 2021 were performed by TP# 1. b. Events 1 and 2 of three Hematology PT events of 2021 were performed by TP# 1. c. Events 1 and 2 of three Hematology PT events of 2020 were performed by TP# 2. d. Events 1 and 3 of three Chemistry PT events of 2020 were performed by TP# 2. e. Events 2 and 3 of three Chemistry PT events of 2019 were performed by TP# 1. f. All three Hematology PT events of 2019 were performed by TP# 2. 2. Staff interview with TP#1 on 4/7/2022 at 12:15 PM confirmed the above findings.

D2009

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to attest that proficiency testing (PT) samples were tested in the same manner as routine patient specimens. Findings include: 1. Record review on 4/7/22 of the American Proficiency Institute PT evaluation and corrective action documentation revealed the lack of signature of the Laboratory Director (LD)/Designee on the following PT attestation forms: a. All three Chemistry PT events of 2019. b. All three Chemistry PT events of 2020. c. Hematology PT event 1 of 2020. d. Event 1 and 3 of 2021 Hematology and Chemistry PT. 2. Staff interview with TP# 1 on 4/7/2022 at 1:00 PM confirmed the above findings.

D2128

HEMATOLOGY

CFR(s): 493.851(e)

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to take remedial action when unacceptable proficiency testing (PT) scores were received in the specialty of Hematology. Findings include: 1. Record review on 4/7/22 of the American Proficiency Institute (API) PT performance evaluation report revealed the laboratory did not take any remedial actions when the following unacceptable PT scores were obtained for the event 1 of 2020 Hematology: a. Sample ID-HEM-02:

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| | <p>Hemoglobin, Red Cell Count and Hematocrit: PT score of 80%. b. Sample ID-HEM-03: Granulocytes: PT score of 80%. The above API PT performance review and corrective action form reviewed by the Laboratory Director/Designee indicated: "100% no corrective action needed". 2. Staff interview with TP# 1 on 4/7/2022 at 1:00 PM confirmed the above findings.</p> |
| <p>D5309</p> | <p>TEST REQUEST CFR(s): 493.1241(e)</p> <p>If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to have an ongoing mechanism to ensure manually entered results were accurately transcribed by testing personnel (TP) in the laboratory information system (LIS). Findings include: 1. Record review on 4/7/2022 for the laboratory's Quality Assurance(QA) program revealed the lack of audits to verify the accuracy of manually transcribed results by the TP into the LIS for the following instruments: a. Cepheid GeneXpert for COVID 19 testing. b. Alere for D-Dimer and Troponin. c. BD Veritor for SARS-COV2 Antigen. d. Abaxis Piccolo for Chemistry tests. c. Siemens Clinitek for Urinalysis. 2. Staff interview with the TP# 3 from the Urgent Care on 4/7/2022 at 2:32 PM confirmed above findings. 3. The laboratory performs 878 manually transcribed tests annually.</p> |
| <p>D5407</p> | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure the laboratory's policies and procedure manuals were approved by the current laboratory director (LD). Findings include: 1. Record review on 4/7/22 of the laboratory's "Urgent Care Manual" contents listed 41 procedures were currently in use. All the 41 procedures approved by previous LD were not signed or approved by the current LD. The former LD was replaced by the current LD in 2019. 2. Staff interview with the technical consultant on 4/7/2022 at 2:20 PM confirmed the above findings. 3. The laboratory performs 4,248 tests annually.</p> |
| <p>D5891</p> | <p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on record review and staff interview the laboratory failed to monitor and ensure the normal ranges were reported accurately in the final test reports in the specialty of Hematology. Findings include: 1. Record review on 4/7/2022 of the laboratory's male and female patient test reports for Complete Blood Count (CBC) revealed the laboratory was reporting gender specific normal ranges for CBC analytes. 2. Record review on 4/7/2022 of the laboratory's procedure manual revealed the laboratory did not establish gender specific normal ranges for CBC analytes. 3. Record review on 4/7/2022 of the laboratory's procedure manual (PM) and patient test reports for CBC revealed the following discrepant ranges were listed: Analyte Male Female PM WBC 4.8-10.8 4.8-10. 3.4-8.7 10x3/mcL RBC 4.7-6.10 4.2-5.4 3.8-5.3 mil/mcL HGB 12.5-16.7 11.1-15.3 11.7-15.8 g/dL HCT 37.5-50.1 33.3-45.9 34.7-45.9 % MCV 80-94 81-99 78.7-96.0 fL MCH 27-31 27-31 26.2-33.1 pg MCHC 32-36 32-36 32.6-36.2 g/dL PLT 140-400 140-400 116.1-329.3 10x3/mcL 4. Staff interview with technical consultant on 4/7/2022 at 2:00 PM confirmed the above findings. 5. The Laboratory performs 3,370 tests in the speciality of Hematology.

D6064

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:
Based on record review, surveyor observation and staff interview the laboratory failed to document testing personnel (TP) were trained to perform moderate complexity testing independently in the specialty of Hematology. Findings include: 1. Record review on 4/7/22 of the laboratory's personnel form (CMS-209) revealed 6 of 13 TP were hired and started patient testing since the last onsite survey in 2019. 2. Surveyor observation on 4/7/22 at 10:30 AM of the TP training and competency records revealed 5 of 13 TP did not have training documentation in the specialty of Hematology. 3. Staff interview with the technical consultant on 4/7/22 at 10:45 AM confirmed the above findings. 4. The laboratory performs 3,370 tests annually in the specialty of Hematology.