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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 22D1034535 | (X3) Date Survey Completed 06/18/2019 |
| Name of Provider or Supplier New England Hospitalists, Pc | Street Address, City, State 475 Pleasant Street, Worcester, MA | |
| 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 CLIA COLA validation survey was conducted for New England Hospitalists, PC pursuant to the Clinical Laboratory Improvement Ammendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. . |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of urine drug screens twice annually as evidenced by the following: a) The laboratory has been enrolled in the American Association of Bioanalysis (AAB) proficiency testing as a means of verifying accuracy of urine drug screen test results twice annually. b) A review of 2017, 2018, and 2019 AAB proficiency testing results revealed that for calendar year 2018 the laboratory failed to enroll in a timely way missing two of the three scheduled events for that year. In addition the laboratory received a score of 60% for the last off cycle event due to mistranscription of the results entered for cocaine and opiates. c) The laboratory technologist confirmed in an interview of 6/18/19 at 8:45 AM that the laboratory had enrolled late in 2018 resulting in only one testing event being completed for that year. .</p> |
| D5805 | <p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5)</p> |

Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to clearly indicate the test results on the final report as evidenced by the following: a) The laboratory performs urine qualitative drug screening for five drugs of abuse b) A review of eighteen (18) final reports for testing completed between 6/19/18 and 3/27/19 was performed. c) The review revealed that the report under the result column indicated the drug analyzer absorbance value, for the analyte, not an actual qualitative result of positive or negative. In addition, where a drug was detected the result was flagged with an "H" for high (patient ID 47 - positive for benzodiazepines on 6/25/18, patient ID 484 - positive for amphetamine, benzodiazepines and opiates on 8/20/18, and patient ID 85 - positive for cocaine on 1/14/19) under the Flag column. d) The laboratory director and laboratory technologist confirmed in an interview on 6/18/19 at 10:15 AM that qualitative test results of positive or negative for the drugs tested were not available on the final report.

D6011

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(2)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(2) and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to provide a safe environment in which employees are protected from physical, chemical, and biological hazards as evidenced by the following: a) The laboratory eyewash system consists of a large 6.0 gallon plastic container. b) The instructions for maintenance of the eyewash indicate that the water should be changed out every 90 days. c) Interview with the laboratory technologist on 6/18/19 at 10:05 AM revealed that there was no documentation maintained to verify that the water was changed every 90 days according to the manufacturer's requirements.