

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2107944	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Right Choice Health Group, Llc	Street Address, City, State 125 Liberty St, Suite 205, Springfield, 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 recertification survey was conducted for the Right Choice Health Group, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory failed to perform and document function checks at the frequency the laboratory established. Review of calendar years 2018 and 2019 maintenance records revealed that the the laboratory failed to document maintenance performed as evidenced by the following: a) Interview with the technical supervisor on 12/17/19 at 11:53 AM confirmed that the eight (8) Eppendorf pipets had been checked for calibration during calendar year 2019. b) Documentation could not be provided during the time of the survey to confirm that calibration checks of the eight (8) pipets had been performed. .</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to perform calibration verification as appropriate as evidenced by the following: a) A review of quality control records for calendar years 2018 and 2019 was performed. The review revealed that calibration verifications of at least 3 points were not performed once every six months for one (1) of one (1) quantitative chemistry analytes performed. Calibration verification was not being performed at least once every six months for urine creatinine. b) The technical supervisor interviewed on 12/17/19 at 9:35 AM confirmed that calibration verifications of at least 3 points had not been performed at least once every six months for urine creatinine. .

D5805

TEST REPORT
 CFR(s): 493.1291(c)

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) 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 staff interview, the laboratory failed to ensure that the final report contained all required information for interpretation as evidenced by the following: a) Record review conducted on 12/17/19 of twenty (20) final patient test reports for testing performed between 9/5/18 and 12/9/19 revealed that all twenty (20) of the final reports did not include the test report date. b) The laboratory technical supervisor confirmed in an interview on 12/17/19 at 11:40 AM that the final report in the patient's electronic medical record did not include the above information. .

D5821

TEST REPORT

CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to maintain a suitable copy of the corrected report when errors in the reported patient test results were detected as evidenced by the following: a) In April of 2019 the laboratory had to correct eleven (11) test reports for testing performed between 4/1/19 and 4/5/19 (accession numbers 190405039, 190404018, 190402036, 190402060, 190401100, 190401067, 190401084, 190401093, 190401017, and 190402023). b) A review of the eleven (11) corrected reports revealed that the reports failed to indicate that they were, in fact, corrected results. c) Interview with the technical supervisor on 10/24/18 at 11:45 AM confirmed that the corrected reports, did not indicate that they had been corrected. d) Based on this evidence there was no assurance the medical care providers were provided with most updated test results to ensure proper diagnosis and care. The laboratory performs approximately 269,800 toxicology tests annually.