| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 31D2039164 | 09/26/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Best Care Laboratory Llc | 14 Applegate Drive, #B, Robbinsville, NJ | |

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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| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>The laboratory must test samples the same number of times that it routinely tests patient samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to test Hematology PT samples received from The College of American Pathologists (CAP) the same number of times that it tests patient samples for 1 and 2 event of 2018. The finding includes: 1. The patient samples were tested on one analyzer but PT samples were tested on two analyzers before PT results were reported. 2. The TS stated on 9/25/18 at 11:00 am that she was checking correlation of analyzers too. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of the Competency Assessment (CA) records, review of the procedure manual and interview with the Technical Supervisor (TS), the laboratory failed to perform a CA annually on five of five testing personnel in 2017 and 2018 and new TS after six months in 2018. The finding includes: 1. The laboratory had a CA procedure but was not followed. 2. TS confirmed on 9/25/18 at 10:25 am that CA procedure was not followed. |

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| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Proficiency Testing records and interview with the Technical Supervisor (TS), the laboratory failed to evaluate coded results obtained in 1 of 2017 Hematology event performed with the College of American Pathologists (CAP). The finding includes: 1) The laboratory did not evaluate code 20 (No appropriate target) for Hematology tests. 2) The TS confirmed on 9/25/18 at 9:50 am that the laboratory failed to evaluate coded results. |
| **D5309** | TEST REQUEST<br>CFR(s): 493.1241(e)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on survyeor review of Test Requisition (TR), Laboratory Information System (LIS) and interview with the Technical Supervisor (TS) and data entry personnel, the laboratory failed to ensure that information from TR was transcribed accurately into the LIS from July 2017 to July 2018. The finding includes: 1. The laboratory had a review documentation sheet with all TR but there was no review documentation sheet included with TR from July 2017 to July 2018 2. The TS and data entry personnel confirmed on 9/26/18 at 1:15 pm that the laboratory did not ensure information was transcribed accurately from July 2017 to July 2018. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>a. Based on surveyor review of the Procedure Manual (PM), Laboratory Information System (LIS) verification data and interview with the Technical Supervisor (TS), the laboratory failed to follow LIS- Interfaced procedure from 11/16/16 to the date of survey. The findings include: 1. The procedure stated to perform verification bi-annually: a. There was no documentation of Manual test results verification. b. The interfaced was last verified March of 2017. 2. The TS confirmed on 9/25/18 at 2:00 pm that the procedure was not followed. b. Based on surveyor review of the PM and interview with the TS, the laboratory failed to establish a written procedure for Hematology and Urine Microscopic tests performed in the laboratory from 11/16/16 to the date of the survey. The findings include: 1. The laboratory did not have a |

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| | procedure for Cold Agglutinins and Flags received on the Beckman Coulter LH 750. 2. The laboratory did not establish an accurate time and speed for centrifugation of urine microscopic procedue. 3. The TS confirmed on 9/25/18 at 2:10 pm that the above procedures were not established. c. Based on surveyor review of the PM and interview with the TS, the laboratory failed to follow the procedure for Quality Control (QC) Material from 11/16/16 to the date of the survey". The finding includes: 1. The QC procedure stated "While running established control material, the new material is tested for each analyte for 10 to 20 replicates and the ranges are calculated before being put into service. 2. There was no documented evidence the QC procedure was followed for all QC material in the laboratory. 3. The TS confirmed on 9/25/18 at 2:20 pm that the QC procedure was not followed. d. Based on surveyor review of the PM and interview with the TS, the laboratory failed to follow the procedure to "Check for the quality of blood film" from 4/21/17 to the date of the survey. The TS confirmed on 9/25/18 at 2:30 pm that the procedure stated above was not followed. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>a. Based on surveyor review of the Manufacturers Package Insert (MPI) and interview with the Technical Supervisor (TS), the laboratory failed to follow the MPI for Coagulation testing performed on the IL ACL Elite analyzer from August 2018 to the date of the survey. The findings include: 1. The MPI stated to establish a Normal Patient Mean (NPM) with each new lot of reagent but the laboratory did not establish a NPM with the current lot. 2. Approximately 10 patients were run a day during the above time period. 3. This deficiency was corrected on site the day of the survey. 4. The TS confirmed on 9/25/18 at 2:35 pm that the MPI was not followed. b. Based on surveyor review of the Clinitek Atlas Quality Control (QC) Manufacture Package Insert (MPI) and interview with the Technical Supervisor (TS), the laboratory failed to follow the MPI instructions for stability of QC material from 11/16/16 to the date of survey. The findings include: 1. The MPI stated that controls were stable for 8 hours after preparation, except the positive control for bilirubin was stable for 4 hours. 2. The testing personnel stated after preparation controls were used for 1 week. 3. Approximately 15 - 20 patients were run a day. 4. The TS confirmed on 9/25/18 at 2: 40 pm that the MPI was not followed. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of Performance Specifications (PS) records and interview with the Technical Supervisor (TS), the laboratory failed to verify Reportable Range for Hemoglobin A1C performed on the Trinity Ab 9210 analyzer before reporting patient test results from April 2017 to the date of survey. The TS confirmed on 9/25 /18 at 2:40 pm that all PS were not done. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to verify the laboratory reportable range at least once every six months for Specific Allergen (SA) test from 11/16/2016 to the date of survey. The finding includes: 1. The review of QC records revealed that upper limit of SA test was not checked at all. 2. The deficiency was previously cited 11/16/2016. 3. The plan of corrections stated "No High QC available on market to cover upper limit range. Pooled samples with high reading to use as internal control for upper limit" 4. The TS confirmed on 9/25/18 at 11:00 AM that upper limit of test was not verified. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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 |

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| | laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the laboratory failed to perform and document a control on each day of patient testing for Urine Microscopic tests from 11/16/16 to the date of the survey. The TS confirmed on 9/25/18 at 1:20 pm that the laboratory did not perform QC each day of patient testing. |
| **D5451** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(iii)(g)<br><br>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-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS) and Testing Personnel (TP), the laboratory failed to titer positive control for Syphilis, Antistreptolysin O and Rheumatoid Factor tests from 11 /16/16 to the date of survey. The finding includes: 1. There was no documented evidence that each time titer test was performed positive control was titered. 2. The TP # 1 listed on CMS form 209 confirmed on 9/26/18 at 11:00 am that positive control was not titered every time test was done. |
| **D6074** | TESTING PERSONNEL RESPONSIBILITIES<br>CFR(s): 493.1425(b)(5)<br><br>Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS), the Testing Personnel (TP) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Diasorin Liason XL from 11/16/16 to the date of the survey. The TS confirmed on 9/25/18 at 2:45 pm that trends and shifts were not reviewed. |