Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0673199	03/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ch Pc Med-Care Of Fairfield	150 Fairfield Rd, Fairfield, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to follow its policies and procedures for assessing the competency of two of two TP from 4/28/17 to the date of the survey. The findings include: 1. The CA form indicated all criteria for review were completed but there was no documented evidence category 2, 3, 4, 6, 7, 10 and 12 were performed. 2. The TP #1 listed on CMS form 209 confirmed on 3/28/19 at 10:25 am that the laboratory did not follow its CA procedure.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow the "Flag Procedure" for flags obtained on Hematology tests performed on the Sysmex XP-300 analyzer from 1/2/19 to the date of the survey. The finding includes: 1. The PM stated to "check smear" or

	perform plasma replacement for samples with flags but there was no documented evidence for ten of ten flagged samples the PM was followed. 2. The TP #1 listed on the CMS form 209 confirmed on 3/28/19 at 1:50 pm that the Flag Procedure was not followed. b. Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the "Flag Procedure" for flags obtained on Urine Microalbumin (UM) tests performed on the Beckman Coulter AU 480 from 1/2/19 to the date of the survey. The finding includes: 1. A review of the UM test results revealed ten of ten samples had flags but there was no documented evidence the laboratory had attempted to correct the flag. 2. The TP #1 listed on the CMS form 209 confirmed on 3/28/19 at 2:20 pm that the Flag Procedure was not followed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures were performed on the Sysmex XP 300 analyzer were adequate from 4/11/17 to the date of survey. The finding includes: 1. There was no documented evidence Reportable Range Verification was performed. 2. The TP #1 listed on the CMS form 209 confirmed on 3/28/19 at 11:15 am that PS records were not adequate.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records, Levy Jennings (LJ) charts and interview with the Testing Personnel (TP), the laboratory did not document Corrective Action (CA) taken when laboratory QC showed negative or positive bias from September 2018 to the date of survey. The findings include: 1. There was no evidence of review or documented CA when the laboratory had a negative bias for Folate, Thyroid peroxidase and Prostate-specific antigen tests performed on the Beckman Coulter AU 480 and Abbott Architect Plus from September 2018 to January 2019. 2, There was no evidence of review or documented CA when the laboratory had

	a Positive bias for Hemoglobin A1C tests preformed on the BioRad D10 from January 2019 to the date of the survey. 3. The TP #1 listed on CMS form 209 confirmed on 3 /28/19 at 2:00 pm that laboratory failed to document CA.
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 surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 4/11/17 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 3/28/19 at 2:55 pm that the TRD was not on the FR.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Intervals (RI) used for Hematology test from 4/11/17 to the date of survey. The TP #1 listed on the CMS form 209 confirmed on 3/28/19 at 1:00 pm that the source of the RI was unknown. b. Based on surveyor review of the FR, Procedure Manual (PM) and interview with the TP, the laboratory failed to use the RI from the source specified in the PM for Chemistry tests performe on the Beckman Coulter AU 480 from 4/11/17 to the date of the survey. 1. The TP stated the laboratory used the RI in the Procedure Manual (PM). 2. The RI on the FR did not match the PM for: a. Triglycerides b. Very Low Density Lipoprotein (VLDL) c. High Density Lipoprotein (HDL) d. Hemoglobin A1C 3. The TP #1 listed on the CMS form 209 confirmed on 3/28/19 at 1:10 pm that the source of the RI on the FR was unknown. c. Based on the surveyor review of the FR and interview with the TP the laboratory failed to have a RI for all laboratory tests performed in the laboratory from 4/11/17 to the date of the survey. The findings include: 1. RI were not on the FR for: a. Mean Platelet Volume b. Color for Urinalysis c. Specific Gravity d. pH 2. The TP #1 listed on the CMS form 209 confirmed on 3/28 /19 at 2:20 pm that the above tests did not have a RI on the FR.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)

	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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files and interview with the Testing Personnel (TP), the Laboratory Director failed to have training documented for one out of two TP from 4/11/17 to the date of survey. The TP #1 on CMS from 209 confirmed on 3/28/19 at 10:50 am that all TP did not have education documented.