Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0920891	10/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Comprehensive Medical Care	409 Dodds Ave, Chattanooga, TN	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: The laboratory failed to maintain successful participation in 2 out of 2 events for the analyte red blood cell (RBC), events one and two of 2018, resulting in the first unsuccessful PT occurrence for the analyte RBC. (Refer to 2130)
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

	This STANDARD is not met as evidenced by: Based on a review of the CMS CASPER Report 0155D, phone interview with the American Association of Family Physicians (AAFP) official, and an interview with lead lab nurse, the laboratory failed to maintain satisfactory performance in two of two events for the red blood cell (RBC) analyte, events one and two of 2018, resulting in the first unsuccessful occurrence. Findings include: 1. Review of the CMS Report 0155D for Proficiency Testing (PT) scores revealed the RBC score for event one of 2018 = 60% and event two of 2018 = 40%. 2. A phone interview on October 2, 2018, at 1:30pm EST, with the AAFP PT agency official confirmed the laboratory's unsuccessful performance for the RBC score for event one of 2018 = 60% and event two of 2018 = 40%. 3. An interview on October 2, 2018, at 1:30pm EST, with the lead lab nurse confirmed the laboratory's unsuccessful performance for the RBC score for event one of 2018 = 60% and event two of 2018 = 40% and the lab received another lab's PT results for events one and two of 2018 from AAFP PT officials.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on a lack of the proficiency testing (PT) records and an interview with the lead lab nurse, the laboratory failed to receive and retain the correct PT records from the PT agency for events one and two of 2018 for hematology complete blood count (CBC). Findings include: 1. Review of the 2018 PT book revealed the wrong laboratory's PT results located at 6918 Shallowford Road, Suite 226, Chattanooga, Tennessee. The lab missing the correct PT records from the PT agency for events one and two of 2018 for hematology complete blood count (CBC). 2. An interview on October 2, 2018, at 1:15pm, with the lead lab nurse confirmed the wrong laboratory's PT results and the lab missing the correct PT records from the PT agency for events one and two of 2018 for hematology complete blood count (CBC).
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) plan, lack of quarterly QA meeting documents and an interview with the lead lab nurse, the laboratory failed to conduct and retain any of the required quarterly QA meeting records from 2016-2018. Findings include: 1. Review of the QA plan revealed the requirement to hold quarterly review meetings with the lab staff and the clinical consultant (CC- who is also the lab director-LD) with written minutes kept for two years. 2. Review determined a lack of any documented quarterly QA meetings or minutes for 2 years. 3. An interview on October 2, 2018, at 1:15pm, with the lead lab nurse confirmed the laboratory did not conduct and retain any of the required quarterly QA meeting records from 2016-2018.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure manual and interview with lead lab nurse, the laboratory failed to include panic or alert values for hematology complete blood count (CBC) for 2016-2018. Findings include: 1. Review of the laboratory's manual (dated May 2015 by laboratory director - LD) revealed on panic or alert values for CBC testing. 2. An interview on October 2, 2018, at 1:15pm, with the lead lab nurse confirmed the laboratory did not have any panic or alert values for CBC testing from 2016-2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Laboratory Director (LD) failed to ensure all proficiency testing (PT) records are reviewed and evaluated to identify problems that require corrective actions (Refer to D6018); LD failed to have a corrective action plan when PT results are unsatisfactory or unacceptable (Refer to D6019); LD failed to ensure quality assessment programs are established and maintained (Refer to D6021); and the LD failed to ensure prior to testing patient specimens all testing personnel have the appropriate education, experience, training and can perform and report accurate results for 2016-2018. (Refer to D6029).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a lack of 2018 proficiency testing (PT) and quality assurance (QA) records, observation of lab staff logging into the PT agency website, and an interview with the lead lab nurse, the laboratory director (LD) failed to ensure all proficiency testing (PT) records are reviewed and evaluated to identify problems that require corrective actions for 2018. Findings include: 1. Review of the lab's 2018 PT and QA records for the first and second events for CBC revealed the results were actually for a different lab which is located at 6918 Shallowford Road, Suite 2016, Chattanooga, Tennessee. 2. An observation on October 2, 2018, at 3:00pm, of the lead lab nurse logging into the American Academy of Family Physicians (AAFP) for PT results verified the lab staff only had access to a different lab's PT results which is located at 6918 Shallowford Road, Suite 206, Chattanooga, Tennessee. 3. An interview on October 2, 2018, at 1:15pm, with the lead lab nurse confirmed the lab's 2018 PT and QA records for the first and second events for CBC revealed the results were actually for a different lab which is located at 6918 Shallowford Road, Suite 2016, Chattanooga, Tennessee.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of unsatisfactory scores for proficiency testing (PT) results for the first and second events of 2018 for red blood cells (RBC) and an interview with the lead lab nurse, the laboratory director (LD) failed to have a corrective action plan in place plan when PT results are unsatisfactory or unacceptable. Findings include: 1. Review of the CMS Report 0155D for Proficiency Testing (PT) scores revealed the 2018 RBC scores for the first and second events without any corrective action plan available for review. 2. An interview on October 2, 2018, at 1:30pm EST, with the lead lab nurse confirmed the 2018 RBC scores for the first and second events without any corrective action plan available for review.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assurance (QA) Plan, lack of QA documentation for 2016-2018 and an interview with the lead lab nurse, the laboratory director failed to ensure the QA program was maintained for 2016-2018. Findings include: 1. Review of the laboratory's QA revealed the requirement to hold quarterly review meetings with the lab staff and the clinical consultant (CC- who is also the lab director-LD) with written minutes kept for two years. 2. Review of the QA documentation revealed no review meeting/minutes for 2016-2018. 3. An interview on October 2, 2018, at 1:15pm, with the lead lab nurse confirmed the laboratory did not conduct any of the required quarterly QA meeting records from 2016-2018.
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 a review of the CMS 209 personnel form, testing person (TP) records and an interview with the lead lab nurse, the laboratory director failed to ensure TP education verification documents for four of four TP were available for 2016-2018. Findings include: 1. Review of the CMS 209 personnel form revealed four testing persons performing moderate complexity testing (MCT) for 2016-2018. 2. Review of 4 of 4 TP records revealed no education documents (i.e. high school diploma/transcript) for 2016-2018. 3. An interview on October 2, 2018, at 2:15pm, with the lead lab nurse confirmed the laboratory did not have any education documents available for review for 2016-2018.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of 2016-2018 personnel records and an interview with the lead lab nurse, the laboratory's technical consultant (TC) failed to document signed reviews for four of four testing personnel training and competencies. Findings include: 1. There were no signed competency reviews by the technical consultant documented for 4 of 4

	testing persons for 2016-2018 available for review. 2. In an interview, October 2, 2018, at approximately 2:30 PM, the lead lab nurse confirmed the technical consultant failed to sign and review all 4 of 4 of the testing persons' competencies in 2016-2018.