Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D1065136	**(X3) Date Survey Completed** 11/06/2018
Name of Provider or Supplier Doctors Of Compassionate Services Incorporate	**Street Address, City, State** 18 Luckie St, Baxley, GA	
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 proficiency testing desk review was completed on November 6, 2018. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Report 155 and the laboratory's proficiency testing (PT) reports as well as telephone interviews with laboratory testing personnel and an administrative associate at the American Association of Bioanalysts (AAB), the laboratory failed to enroll in PT for white blood cell (WBC) and red blood cell (RBC) counts in the first two testing events of 2018. Findings include: 1. Review of the CMS 155 revealed no scores for WBC and RBC for events 1 and 2 of 2018. 2. Review of the laboratory's PT results from the American Association of Bioanalysts (AAB) also revealed no results for WBC and RBC. 3. Telephone interview on November 5, 2018 with an administrative associate for AAB at 2:17 pm and with a testing personnel from the laboratory at 2:30 pm confirmed the laboratory did not enroll in PT for WBC and RBC in 2018.

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: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (1st and 2nd events of 2018), resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: Refer to D 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 proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory failed to maintain satisfactory performance in two consecutive events (1st and 2nd events of 2018), resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #815 platelets on event 1 of 2018 with a score of 60% and event 2 of 2018 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports from the American Proficiency Institute (API) confirmed the laboratory failed platelets on events 1 and 2 of 2018 resulting in the first unsuccessful performance.
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: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two consecutive events (1st and 2nd events of 2018), resulting in the first unsuccessful occurrence for platelet (PLT) analyte # 815 and failed to ensure the laboratory was enrolled in PT for WBC and RBC in 2018. Findings include: Refer to D 6015 & D 6016
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Report 155 and the laboratory's proficiency testing (PT) reports as well as telephone interviews with laboratory testing personnel and an administrative associate at the American Association of Bioanalysts (AAB), the laboratory director failed to ensure the laboratory enrolled in PT for white blood cell (WBC) and red blood cell (RBC) counts in 2018. Findings include: 1. Review of the CMS 155 revealed no scores for WBC or RBC for events 1 and 2 of 2018. 2. Review of the laboratory's PT results from the American Association of Bioanalysts (AAB) also revealed no results for WBC and RBC. 3. Telephone interview on November 5, 2018 with an administrative associate for AAB at 2:17 pm and with a testing personnel from the laboratory at 2:30 pm confirmed the laboratory did not enroll in PT for WBC and RBC.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing desk review using the Centers for Medicare and Medicaid (CMS) Casper Reports 155 and 153 and review of the laboratory's proficiency testing (PT) reports, the laboratory director failed to ensure the laboratory maintained satisfactory performance in two consecutive events (1st and 2nd events of

	2018), resulting in the first unsuccessful occurrence for platelets (PLT) # 815. Findings include: 1. Desk review of Casper Reports 153 and 155 disclosed the laboratory failed analyte #815 platelets on event 1 of 2018 with a score of 60% and event 2 of 2018 with a score of 60%. 2. Desk review of the laboratory's proficiency testing reports from the American Proficiency Institute (API) confirmed the laboratory failed platelets on events 1 and 2 of 2018 resulting in the first unsuccessful performance.