Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 42D0251357	**(X3) Date Survey Completed** 08/08/2023
Name of Provider or Supplier Palmetto Primary Care Physicians-Central Lab	**Street Address, City, State** 2500 Elms Center Rd, North Charleston, SC	
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 Recertification Survey was initiated on 08/08/2023 and concluded on 08/08/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
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 interview and document reviews, the laboratory failed to maintain satisfactory performance in two consecutive proficiency testing (PT) events (1st event and 2nd event) of 2023. Findings included: A review of the "American Proficiency Institute Performance Summary," dated 02/20/2023, revealed, for the 2023 1st event, the "Bilirubin, Total" had an unsatisfactory performance of 60%. A review of the

	"American Proficiency Institute Performance Summary," dated 06/26/2023, revealed, for the 2023 2nd event, the "Bilirubin, Total" had an unsatisfactory performance of 40%. In an interview on 08/08/2023 at 2:00 PM, the Technical Consultant indicated corrective action was performed for both events and an internal PT confirmed corrective action was effective.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on interview and document reviews, the laboratory failed to maintain satisfactory performance in two consecutive proficiency testing (PT) events (1st event and 2nd event) of 2023. Findings included: A review of the "American Proficiency Institute Performance Summary," dated 02/20/2023, revealed, for the 2023 1st event, the "Bilirubin, Total" had an unsatisfactory performance of 60%. A review of the "American Proficiency Institute Performance Summary," dated 06/26/2023, revealed, for the 2023 2nd event, the "Bilirubin, Total" had an unsatisfactory performance of 40%. In an interview on 08/08/2023 at 2:00 PM, the Technical Consultant indicated corrective action was performed for both events and an internal PT confirmed corrective action was effective.