

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 48D2115767	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier Delgiacco Medical Llc	Street Address, City, State Vi Medical Foundation Bldg, Charlotte Amalie, VI	
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	An off-site CLIA proficiency testing (PT) desk review for Delgiacco Medical LLC dba St. Thomas Cancer Specialists was conducted on August 15, 2023 by a federal surveyor from the Centers for Medicare and Medicaid Services, CLIA New York Operation Branch. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. The laboratory was found to be out of compliance with the following Condition level deficiency: Successful participation (proficiency testing) on August 15, 2023.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site review of the CASPER 0153D report (Unsuccessful proficiency</p>

testing report), CASPER 0155D report (Individual Laboratory Profile the laboratory) and performance evaluations from the proficiency testing (PT) organization American Association of Bioanalysts (AAB) - Medical Laboratory Evaluation (MLE), the laboratory failed to achieve satisfactory performance of at least 80% for two out of three (first and second) consecutive events for the analyte Hemoglobin (HGB) which is in the specialty of Hematology in 2023. Findings include: Please refer to D2130.

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 an off-site review of the CASPER 0153D report (Unsuccessful proficiency testing report), CASPER 0155D report (Individual Laboratory Profile the laboratory) and performance evaluations from the proficiency testing (PT) organization American Association of Bioanalysts (AAB) - Medical Laboratory Evaluation (MLE), the laboratory failed to achieve satisfactory performance of at least 80% for two out of three (first and second) consecutive events for the analyte Hemoglobin (HGB) which is in the specialty of Hematology in 2023. Findings include: 1. Based on an offsite PT desk review performed on August 15, 2021, at 10:30 am and review of the CASPER 0153D, 0155D, and AAB-MLE PT evaluation reports, the laboratory failed to achieve satisfactory scores for the following two out of three consecutive events in 2023: Analyte: 0795 HGB: AAB-MLE 2023 - 1st event - 60%. AAB-MLE 2023 - 2nd event - 60%. 2. The above results were confirmed by email with AAB-MLE on August 15, 2023 at 11:04 am.