Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2076584	01/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Capital Diagnostics	14201 Park Center Drive Ste 403, 405 & 407, Laurel, MD	

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	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the proficiency testing provider. The facility was found to be out of compliance with the following conditions of the CLIA program: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
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 desk review of proficiency testing (PT) records from the Certification and

	Survey Provider Enhanced Reporting 0155D report and College of American Pathologists, the laboratory failed to successfully participate in an approved PT program for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the subspecialty of routine chemistry for the analyte albumin and the subspecialty of toxicology. Refer to D2096 and D2110.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (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 desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and the proficiency testing (PT) original evaluation reports from College of American Pathologists (CAP), the laboratory failed to achieve satisfactory performance for the analyte albumin in two consecutive PT events. Findings: 1. Review of the CASPER 0155D report revealed that the laboratory received the following unsatisfactory scores for albumin: a. 40% in the 2025 2nd PT event b. 20% in the 2025 3rd PT event 2. Review of the CAP original evaluation reports confirmed the CASPER 0155D report results.
D2110	TOXICOLOGY CFR(s): 493.845(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D report and the proficiency testing (PT) original evaluation reports from College of American Pathologists (CAP), the laboratory failed to achieve satisfactory performance for the subspeciality of toxicology in two consecutive PT events. Findings: 1. Review of the CASPER 0155D report revealed that the laboratory received the following unsatisfactory scores for overall toxicology: a. 40% in the 2025 2nd PT event b. 73% in the 2025 3rd PT event 2. Review of the CAP original evaluation reports confirmed the CASPER 0155D report results.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting 0155D report and College of American

	Pathologists, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure PT samples were tested as required. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting 0155D report and College of American Pathologists, the laboratory director failed to ensure PT samples were tested as required. The laboratory director failed to ensure successful participation in an approved PT program. Refer to D2096 and D2110.