Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0692393	08/11/2026
Name of Provider or Supplier	**Street Address, City, State**	
Nc State Laboratory Of Public Health	4312 District Drive, Raleigh, NC	

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 the result of a desk review of proficiency testing scores obtained from the national database, verified with the proficiency testing company. The facility was found to be out of compliance with the CLIA program's conditions. The following condition level deficiencies were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]. D6076 - 42 C.F.R. 493.1403 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 a proficiency testing desk review of the Certification and Survey Provider

	Enhanced Reporting (CASPER) 0155 report, the Wisconsin State Laboratory of Hygiene (WSLH) 2025 and 2026 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three testing events (2025 Events 3 and 2026 Event 2) in the specialty of Toxicology for the Lead analyte. Refer to D2118.
D2118	TOXICOLOGY CFR(s): 493.845(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 a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, the Wisconsin State Laboratory of Hygiene (WSLH) 2025 and 2026 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two of three testing events (2025 Events 3 and 2026 Event 2) in the specialty of Toxicology for the Lead analyte. Findings: 1. A review of the CASPER 0155 report revealed the following results: a. WSLH 2025 - 3rd Event - The laboratory received an unsatisfactory score of 60% for Lead. b. WSLH 2026 - 2nd Event - The laboratory received an unsatisfactory score of 60% for Lead. 2. A review of the WSLH proficiency testing records on August 11, 2026 at 3:30 pm confirmed the laboratory received the above 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 a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, the Wisconsin State Laboratory of Hygiene (WSLH) 2025 and 2026 proficiency testing records, the laboratory failed to provide overall management and direction of the laboratory services. 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 a proficiency testing desk review of the certification and survey provider enhanced reporting (CASPER) 0155 report, the Wisconsin State Laboratory of Hygiene (WSLH) 2025 and 2026 proficiency testing records, the laboratory director failed to ensure the overall quality of the laboratory's services. The laboratory director

	failed to ensure successful participation in an HHS-approved proficiency testing program. Refer to: D2118