Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D1039229	**(X3) Date Survey Completed** 08/21/2024
Name of Provider or Supplier Wellmont Health System	**Street Address, City, State** 1519 Main Street, Sneedville, TN	
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	Based on a proficiency testing desk review survey performed on 08.21.2024, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D2016 - 42 C.F.R. 493.803 Condition: Successful participation
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 review of the Centers for Medicare and Medicaid Services CASPER Report 155 (CMS 155) and the laboratory's proficiency testing (PT) evaluation

	reports, the laboratory failed to maintain satisfactory participation for two consecutive proficiency testing events in 2023 and 2024, resulting in initial unsuccessful participation for the Creatine Kinase (CK) Isoenzyme. (See D2096)
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 a desk review of the CMS 155 and the laboratory's PT evaluation reports, the laboratory failed to maintain satisfactory performance for two consecutive test events for the Creatine Kinase (CK) Isoenzyme analyte, resulting in an initial unsuccessful PT occurrence. The findings include: 1. A review of the CMS 155 report revealed the following unsatisfactory CK Isoenzyme scores: - 2023 Event three: 0% - 2024 Event one: 0% 2. A review of the laboratory's College of American Pathologists (CAP) PT evaluation report revealed the following unsatisfactory CK Isoenzyme scores: - 2023 Event three: 0% - 2024 Event one: 0%