Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D1096223	04/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mississippi Public Health Laboratory	570 East Woodrow Wilson, Jackson, MS	

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 an onsite survey conducted 3-29-2021 to 4-2-2021 the laboratory was found NOT to be in compliance with the CLIA regulations at 42 CFR: 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 review of the laboratory's proficiency testing (PT) records from WSLH, CLIA database, and interview with the chemistry department head, the laboratory failed to demonstrate successful performance for Sodium (Na) with two of three

	consecutive testing events for 2nd event 2020 and 1st event 2021, as evidenced by: 1. The laboratory failed to achieve satisfactory performance for Sodium (Na) with two of three consecutive testing events for 2nd event 2020 and 1st event 2021 (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 review of the laboratory's proficiency testing (PT) records from WSLH, CLIA database, and interview with the chemistry department head, the laboratory failed to achieve satisfactory performance for Sodium (Na) with two of three consecutive testing events for 2nd event 2020 and 1st event 2021, demonstrating unsuccessful performance as evidenced by: 1. In review of the laboratory's PT records from WSLH and confirmed with the CLIA database, the laboratory had received the following scores with Sodium: 2nd event 2020 - Na = 20% 1st event 2021 - Na = 60% 2. In interview with the chemistry department head on 3-29-2021 @1505 she was aware they failed both proficiency testing events and confirmed that they had received those scores. The Laboratory Director @1506 also confirmed that they had received those scores.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's package insert, and interview with the CBC (complete blood count) supervisor, the laboratory failed to label new open vial stability expiration dates on their Beckman Coulter hematology controls on 3-31-2021 as evidenced by: 1. In review of the manufacturer's package insert (Beckman Coulter) table of expected results states, "16 open vial days." 2. In direct observation on 3-31-2021 @1020 in the QC refrigerator, the following Beckman coulter controls did not have the open vial stability dates labeled on the control materials: 1 vial of open QC Level 1 lot# 123173620 opened 3/16/2021 1 vial of open QC level 2 lot# 133183520 opened 3/16/2021 1 vial of open QC leve 3 lot# 143193620 opened 3/16/2021 3. In interview with the CBC section supervisor on 3-31-2021 @1024 she states that she did not know how long the control were good for after they were opened. She was unaware that the control did have a new expiration date after opening.