Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2040472	05/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mary F Holley Md Pc	2001 Gunter Ave, Guntersville, AL	

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
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 CMS (Centers for Medicare and Medicaid) CASPER reports and a review of the API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to successfully participate in two consecutive testing events for Hemoglobin (Hematology testing). These failures of Hemoglobin for Event #3, 2019 and Event #1, 2020 resulted in an initial unsuccessful proficiency testing for the laboratory. The findings include: 1. A review of the CASPER reports revealed the laboratory scored sixty percent (60 %) for Hemoglobin for Event #3, 2019 and Event #1, 2020. These consecutive failures of the same analyte constitutes an initial unsuccessful proficiency testing participation. 2. A

	review of the API proficiency testing evaluations for the above mentioned events confirmed the sixty percent scores for the Hemoglobin for Event #3, 2019 and Event #1, 2020.
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 a review of the CMS (Centers for Medicare and Medicaid) CASPER reports and a review of the API (American Proficiency Institute) proficiency testing evaluations, the surveyor determined the laboratory failed to perform satisfactorily in Hemoglobin testing for Event #3, 2019 and Event #1, 2020. The laboratory scored sixty percent (60 %) for the two consecutive testing events for Hemoglobin (Hematology testing), resulting in unsuccessful proficiency testing participation. The findings include: Refer to D2016.