Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0871507	(X3) Date Survey Completed 05/21/2025
Name of Provider or Supplier Kevin G Kelly Md	Street Address, City, State 13150 Hwy 43 South Suite 10, Russellville, 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
D0000	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified with the laboratory's proficiency testing provider, AAB - Medical Laboratory Evaluation (AAB-MLE). The laboratory was found to be out of compliance with CONDITION LEVEL DEFICIENCIES, as follows: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate 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 off-site proficiency testing (PT) desk reviews of the CASPER Reports

	0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from the AAB-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing in the Specialty of Hematology and White Blood Cell (WBC) Count. The laboratory failed two consecutive PT events in 2024 and 2025, resulting in initial unsuccessful proficiency testing performance. Refer to D2130 and D2131.
D2130	HEMATOLOGY CFR(s): 493.851(f) (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 off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from the AAB-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing for White Blood Cell (WBC) Count resulting in initial unsuccessful performance. The findings included: 1. Based on review of the CASPER Reports 153D and 155D, Individual Laboratory Profile reports, the laboratory received the following failing scores, resulting in unsatisfactory performances for two consecutive events, as follows: A. 2024-Event M3: WBC 60% B. 2025-Event M1: WBC 60% 2. A review of the laboratory's proficiency testing results from AAB-MLE confirmed the above findings.
D2131	HEMATOLOGY CFR(s): 493.851(g) (g) Failure to achieve an overall testing event score of satisfactory performance for 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 off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from AAB-Medical Laboratory Evaluation (AAB-MLE), the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing in the Specialty of Hematology, resulting in initial unsuccessful performance. The findings included: 1. Based on review of the CASPER Reports 153D and 155D, Individual Laboratory Profile reports, the laboratory received the following failing scores, resulting in unsatisfactory performances for the Specialty of Hematology for two consecutive events, as follows: A. 2024-Event M3: 60% C. 2025-Event M1: 66% 2. A review of the laboratory's proficiency testing results from AAB-MLE confirmed the above findings. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and proficiency testing evaluation reports from AAB-Medical Laboratory Evaluation (AAB-MLE), the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 off-site proficiency testing (PT) desk reviews of the CASPER Reports 0153D and 0155D (Individual Laboratory Profiles from the Centers of Medicare and Medicaid Services [CMS]), and PT evaluation reports from AAB-Medical Laboratory Evaluation (AAB-MLE), the laboratory director failed to ensure the laboratory had successful participation in an HHS approved proficiency testing program in the Specialty of Hematology and White Blood Cell (WBC) Count in two consecutive 2024-2025 AAB-MLE PT events, resulting in initial unsuccessful participation. Refer to D2130 and D2031.