Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0641549	07/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Uab Ob/Gyn Research And Diagnostic Laboratory	618 20th Street South, Ohb 365, 360, & 537, Birmingham, 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 by the Laboratory Supervisor. 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 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 verified by a telephone interview with the Laboratory Supervisor, the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing for Hepatitis B Surface Antigen (HBS AG), an analyte in the specialty of General Immunology. The laboratory failed two out of three PT events in 2024-2025, resulting in initial unsuccessful proficiency testing performance. Refer to D2084. .
D2084	GENERAL IMMUNOLOGY CFR(s): 493.837(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 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 verified by interview with the Laboratory Supervisor, the laboratory failed to successfully participate (achieve scores of 80% or greater) in proficiency testing for Hepatitis B Surface Antigen (HBS AG). The laboratory failed two out of three PT events in 2024-2025, resulting in initial unsuccessful proficiency testing performance. The findings include: 1. A review of the CASPER Reports revealed the laboratory received failing scores for HBS AG in two out of three CAP PT events, as follows: A) 2024 Immunology Event #3: 60 % B) 2025 Immunology Event #2: 60 % 2. During a telephone interview on 7/9/2025 at 2:12 PM, the Laboratory Supervisor confirmed these 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 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 verified by interview with the Laboratory Supervisor, 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 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 verified by interview with the Laboratory Supervisor, the laboratory director failed to ensure the laboratory had successful participation in an HHS approved proficiency testing program for Hepatitis B Surface Antigen (HBS AG) in two out of three 2024-2025 CAP PT events. Refer to D2084.