Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301999	07/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Drs Dabbs & Hyland P C	1513 Pediatric Drive, Jasper, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of Cold Agglutination Test records and an interview with Testing Personnel #1, the laboratory failed to verify the accuracy of Cold Agglutination Test at least twice annually. This was noted from February 2021 to June 2021. The findings include: 1. A review of the Cold Agglutination Test records revealed a lack of accuracy verification being performed at least twice annually. 2. During an interview on 07/06/2021 at 12:45 PM, Testing Personnel #1 confirmed the laboratory had not verified the accuracy of Cold Agglutination Test. [CLIA non-regulated analytes (not found in Table I of the manual) should be verified at least twice annually].
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Hematology maintenance records, a review of the Horiba Micros 60 Procedure, and an interview with Testing Personnel #1, the laboratory failed to document weekly maintenance. This was noted from February 2021 to May 2021. The findings include: 1. A review of the Hematology maintenance records

	revealed the weekly concentrated cleaning cycle was not documented as being performed, except for 04/26/2021 (February 2021 to May 2021). 2. A review of the Horiba Micros 60 Procedure revealed in section 7 page 48 under Maintenance and Service Menu "Weekly Maintenance: Concentrated Cleaning Cycle - a concentrated cleaning cycle must be performed with Minoclair solution once weekly..." 3. During an interview on 07/06/2021 at 1:30 PM, Testing Personnel #1 stated the weekly maintenance was being performed but not documented on the maintenance form.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Cold Agglutination Test quality control (QC) records, a review of the procedure manual, and an interview with Testing Personnel #1, the laboratory failed to document quality controls performed for Cold Agglutination Test. This was noted from February 2021 to June 2021. The findings include: 1. A review of the QC records for the Cold Agglutination Test revealed no quality control was being documented. 2. A review of the procedure manual revealed in step 5 of the Cold Agglutination Procedure "Use of a normal sample is used as a negative control and is useful for interpretation of test. A control should be performed each day a patient test is performed. A positive control is not required for for this test." 3. During an interview on 07/06/2021 at 12:45 PM, Testing Personnel #1 confirmed a negative control is run with a patient test but is not documented.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Urine Culture (screens for growth/no growth) and Dermatophyte Screen quality control (QC) records and an interview with Testing Personnel #1, the laboratory failed to performed checks of each batch of media for its ability to support growth and no growth for Urine Culture screens and Dermatophyte Screens. This was noted from February 2021 to June 2021. The findings include: 1. A review of the QC records for the Urine Culture (screens for growth/no growth) and Dermatophyte Screen revealed each batch of media was not being checked for its ability to support growth and inhibit specific organisms. A sterility check was being

	performed for Urine Cultures on the Uricult CLED/EMB. 2. During an interview on 07 /06/2021 at 12:45 PM, Testing Personnel #1 confirmed sterility checks are performed on Uricult CLED/EMB (Urine Cultures); but each batch of media is not checked for its ability to support growth and inhibit specific organisms. At 1:10 PM, Testing Personnel #1 confirmed each batch of Myosel Agar (Dermatophyte Screen) is not checked for its ability to support growth and inhibit specific organisms.