

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0396797	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Adventhealth Durand	Street Address, City, State 1220 3rd Ave West, Durand, WI	
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
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with the laboratory manager, the laboratory did not specify the required external quality control (QC) materials in two of six procedures reviewed. Findings include: 1. Review of six test procedures revealed the ePlex RP2 (Respiratory Panel 2) and the DAT (Direct Antiglobulin Test) procedures did not specify the external control material. A. The ePlex Respiratory Pathogen 2 procedure stated, "Positive and negative external controls should be tested with each new lot of reagents or monthly, whichever occurs first. Viral transport medium can be used as the negative control. Previously characterized positive samples or viral transport medium spiked with well characterized organisms can be used as the external positive control. External controls should be run in accordance with laboratory protocols and accrediting organizations, as applicable." The Quality Control Plan of the ePlex IQCP (Individualized Quality Control Plan) included, "External Controls / Perform each month and/or on each new lot of cartridges". Neither the procedure nor the IQCP specified what controls personnel should use. B. In the Quality Control section, the Direct Antiglobulin Testing procedure stated, "To</p>

confirm the specificity and reactivity of the MTS Anti-IgG, -C3d Card, it is recommended that each lot be tested each day of use with known positive and negative samples. Reactivity must be present with the positive sample only. The anti-complement reactivity of the reagent can be assessed by using complement coated cells." The procedure did not show what controls the laboratory used and did not identify how the laboratory evaluated the anti-complement reactivity of the reagent. 2. Interview with the laboratory manager (staff A) on May 24, 2022 at 3:00 PM confirmed the ePlex and DAT procedures did not specify what controls the laboratory used to monitor the accuracy and precision of the complete analytic process for these two test systems.