

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0389541	(X3) Date Survey Completed 12/01/2021
Name of Provider or Supplier Aurora Health Center Lake Geneva Acl Laboratory	Street Address, City, State 146 E Geneva Square, Lake Geneva, 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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of test records and interview with the technical consultant, the laboratory has not maintained a record system that recorded the identity of the testing person for any test results when hematology and chemistry test results met parameters that allowed the results to auto-file by an automatic transfer of the results to the electronic medical record (EMR) without review by the testing person. Findings include: 1. Review of testing records from the Sysmex analyzer and the laboratory information systems showed no record of the individual that operated the hematology analyzer to test specimens when results auto-filed from the Sysmex hematology analyzer through Sysmex WAM software to the EMR. Review of test records from testing performed on the Dimension Xpand chemistry analyzer showed no record of the individual that operated the analyzer when results auto-filed to the EMR. 2. Interview with the technical consultant (staff A) on December 1, 2021 at 12:15 PM confirmed the laboratory did not have a record system that retained the identity of the individuals performing hematology or chemistry testing when results auto-filed to the EMR.</p>