

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0715589	(X3) Date Survey Completed 12/06/2021
Name of Provider or Supplier Childhood Health Assoc Of Salem	Street Address, City, State 891 23rd St Ne, Salem, OR	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records from The College of American Pathologists (CAP) for Microbiology in the years 2020 and 2021 and discussion and interview with the Technical Supervisors (TS) for Microbiology at this facility on 12/6 /2021, the laboratory failed to ensure that the attestation forms for 2020 and 2021 (to date) were signed by the testing personnel (TP) and the Laboratory Director (LD). Findings include: 1. Upon review of the attestation forms (3 of them) for the year 2020, none of them had the requisite signature of the TP or the LD. 2. Upon review of the attestation forms (2 of them) for the year 2021, none of them had the requisite signature of the TP or the LD.</p>
D2026	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of Microbiology Proficiency Testing (PT) records for event #3 in 2020 and discussion with two (2) Microbiology Technical Supervisors (TS), the laboratory failed to ensure corrective action (CA) was performed on the mis-identification of an organism in 2020. Findings include: 1. For event #3 of PT in 2020, specimen UC-12 was mis-identified as *Klebsiella aerogenes*. The correct identification was *Enterobacter cloacae*. No corrective action or follow up was performed for this error by the TS's or the Laboratory Director (LD). 2. Upon interview of the TS's (2) during survey 12/6/2021, it was confirmed that no CA was performed or documented in writing or otherwise.