

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0068958	(X3) Date Survey Completed 11/01/2022
Name of Provider or Supplier Child Health Associates	Street Address, City, State 604 Main St, Shrewsbury, MA	
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	A CLIA recertification survey was conducted for the Child Health Associates laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing review and interview, the laboratory failed to maintain a copy of all proficiency testing records as evidenced by the following: a) A review of proficiency testing records for calendar years 2020, 2021, and 2022 (6 testing events) revealed the fact that the attestation statements provided by the proficiency testing program were not signed by the analyst and the laboratory director or designee for four (4) of the six (6) testing events reviewed (College of American Pathologists (CAP) proficiency testing for the third hematology testing events of 2020 as well as the three testing events of 2021. b) In addition, for two (2) of the six (6) testing events, the attestation and coding forms used to report the results to the proficiency testing company were not retained by the laboratory (the first and second testing</p>

events of 2022). c) Testing person #2 interviewed on 11/1/22 at 8:55 am confirmed that the above attestation statements were either not retained or signed by the analysts and laboratory director or designee.