

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2155110	(X3) Date Survey Completed 01/05/2023
Name of Provider or Supplier Baebies, Inc	Street Address, City, State 25 Alexandria Way, Durham, NC	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview with the TS (technical supervisor) 1/5/23, procedures had not been reviewed by the current laboratory director. Review of the laboratory's policies and procedures revealed they were not signed and dated by the current laboratory director to indicate review and approval. During interview at approximately 12:15 p.m., the TS confirmed that the policies and procedures had not been signed and dated by the current laboratory director. She stated the policies and procedures were approved by the previous laboratory director, so the current laboratory director did not realize he needed to approve them.</p>
D6179	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(5)</p> <p>Each individual performing high complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, clinical consultant, or director.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the TS (technical supervisor) and TP (testing personnel) #2 on 1/5/23, the testing personnel failed to recognize that supplies were improperly stored and used the supplies for patient testing. During a tour of the</p>

laboratory at approximately 2:20 p.m., the surveyor observed the following supplies stored at room temperature in a drawer in the laboratory, available for use: 1. One Thermo Fisher Scientific invitrogen Quant-iT dsDNA Assay kit, High Sensitivity (lot #2495479). Instructions on box state to store at -25 to 8 degrees Celsius; 2. One Thermo Fisher Scientific invitrogen Quant-iT dsDNA Assay kit, Broad Range (lot #2415747). Instructions on box state to store at -25 to 8 degrees Celsius. During interview at approximately 2:25 p.m., the TS and TP #2 confirmed that the assay kits were used for patient testing. TP #2 stated that manufacturer's instructions for previous kits indicated room temperature storage, so they did not realize the kits were not stored properly. She stated manufacturer's storage instructions might have changed.