

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2125750	(X3) Date Survey Completed 05/23/2023
Name of Provider or Supplier Mercyone Comfort Health Center For Women	Street Address, City, State 1601 Nw 114th Street, Suite 151, Clive, IA	
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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 10:15 am on 5/23/23, the laboratory failed to retain proficiency testing attestation statements for three out of six testing events from 5/23/2021 - 5/23/2023. The findings include: 1. The laboratory did not retain the proficiency testing attestation statement for 2023 testing event 1. 2. The laboratory did not retain the proficiency testing attestation statement for 2022 testing event 3. 3. The laboratory did not retain the proficiency testing attestation statement for 2022 testing event 2.</p>
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 Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (CMS-116 form) and the laboratory procedure manual and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 5/23/23, the laboratory director failed to approve, sign and date all laboratory procedures. The findings include: 1. The Iowa State Agency received a CLIA Application for Certification (CMS-116 form) on 9/9 /2022 requesting a change to a new laboratory director. 2. At the time of the survey,</p>

the new laboratory director did not approve, sign or date any of the laboratory procedures.