

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0383858	(X3) Date Survey Completed 10/11/2022
Name of Provider or Supplier Mercyone Pleasant Hill Llc	Street Address, City, State 5900 East University Avenue, Suite 100, Pleasant Hill, 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
D6055	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records, hematology and chemistry instrument performance specification records, and confirmed by personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 2:15 pm on 10/11/2022, the technical consultant failed to document training for six out of ten testing personnel (personnel identifiers #3- #7 and #12) using the Sysmex XN430 hematology instrument and one out of one testing personnel (personnel identifier #3) using the Siemens EPOC chemistry instrument prior to reporting patient test results. The findings include: 1. The laboratory began using the Sysmex XN430 hematology instrument to perform patient testing in August 2021. 2. The laboratory began using the Siemens EPOC chemistry instrument to perform patient testing in March 2022. 3. At the time of the survey, personnel identifier #3 confirmed that the laboratory did not have documented training on the Sysmex XN430 hematology instrument for personnel identifiers #3- #7 and #12 or documented training on the Siemens EPOC chemistry instrument for personnel identifier #3.</p>