

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0383858	(X3) Date Survey Completed 09/26/2024
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, personnel records, and confirmed by interview with Testing Personnel (TP) identifier #3 at 9:57 am on 09/26 /2024, the laboratory failed to follow written policies and procedures for assessing competency for one out of four new testing personnel (TP #10) hired since the last survey on 10/11/2022. The findings include: 1. The laboratory's Clinical Laboratory Personnel Training and Competency Policy stated the following: "The competency of testing personnel is assessed and documented within the first six months of employment and on an annual basis thereafter." 2. The laboratory hired and documented training for TP #10 in June 2023. 3. Review of personnel records for TP #10 did not include documentation of competency assessment performance within the first six months of employment. 4. At the time of the survey, TP #3 confirmed the laboratory did not assess and document competency for TP #10 within the first six months of employment.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score</p>

for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records and confirmed by interview with Testing Personnel (TP) identifier #3 at 10:25 am on 09/26/2024, the laboratory failed to perform a self evaluation when the laboratory received two ungraded PT scores from two out of five testing events from 01/01/2023- 09/26/2024. The findings include: 1. For 2023 Hematology/Coagulation 3rd event, the laboratory received ungraded PT test scores for the following: * Vaginal Wet Prep- specimen VA-03 2. For 2024 Hematology/Coagulation 2nd event, the laboratory received ungraded PT test scores for the following: * Vaginal Wet Prep- specimen VA-02 3. At the time of the survey, TP #3 confirmed the laboratory did not perform a self evaluation for the ungraded PT test scores listed above.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observations made during the survey and confirmed by interview with Testing Personnel (TP) identifier #3 at 11:13 am on 09/26/2024, the laboratory failed to ensure it did not use the potassium hydroxide (KOH) reagent beyond its expiration date when used for 88 out of 88 patients tested from 12/01/2023- 09/26/2024. The findings include: 1. Observations made during the survey revealed that the laboratory had in use KOH reagent lot # B02E063M, expiration 11/30/2023. 2. At the time of the survey, TP #3 confirmed the laboratory used the expired reagent for 88 patient tests.

D6045

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Test List & Annual Volume form, observations made during the survey, personnel records, and confirmed by interview with Testing Personnel (TP) identifier #3 at 9:57 am on 09/26/2024, the technical consultant failed to document training of testing personnel for each test system for one out of four new testing personnel (TP #12) hired since the last survey on 10/11/2022. The findings include: 1. Review of the Laboratory Test List & Annual Volume form and observations made during the survey indicated the laboratory performs the following non-waived testing: complete blood count (CBC) with differential on the Sysmex XN-430 instrument; serum human chorionic gonadotropin (HCG) qualitative on the Henry Schein combo kit; D-dimer on the Triage MeterPro; and manual potassium hydroxide (KOH), vaginal wet prep, and urine sediment examinations on a microscope. 2. The

laboratory hired and trained TP #12 to perform non-waived testing in May 2024. 3. The training records for TP #12 were not complete for the Sysmex XN-430 test system. 4. An interview with TP #3 confirmed TP #12 performed and reported CBC test results independent of supervision from other trained testing personnel. 5. At the time of the survey, TP #3 confirmed the technical consultant failed to ensure documented training for the Sysmex XN-430 test system for TP #12.