

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0038249	(X3) Date Survey Completed 11/05/2024
Name of Provider or Supplier Unitypoint Health Marshalltown	Street Address, City, State 55 Unitypoint Health-Marshalltown, Marshalltown, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing records, the Laboratory Test List & Annual Volume form, observations made during the survey, and confirmed by interview with General Supervisor (GS) #2 at 8:40 am on 11/05/2024, the laboratory failed to enroll in an HHS approved proficiency testing program for the analyte, human immunodeficiency virus (HIV) 1/2 antibody/antigen, for two out of two years from 1/1/2023 - 11/05/2024. The findings include: 1. The Laboratory Test List & Annual Volume form stated the laboratory performed HIV 1/2 antibody/antigen testing using the Abbott Determine HIV-1/2 Ag/Ab combo kit. 2. A tour of the laboratory confirmed the presence of Abbott Determine HIV-1/2 Ag/Ab combo kits on the shelves. 3. At the time of the survey, GS #2 confirmed the laboratory did not enroll in proficiency testing for the analyte, HIV 1/2 antibody/antigen, in 2023 or 2024.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</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 for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

A. Based on review of American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing records and confirmed by interview with General Supervisor (GS) #2 at 8:40 am on 11/05/2024, the laboratory failed to perform a self evaluation when the laboratory received 10 ungraded PT scores from three out of six testing events from 01/01/2023- 11/05/2024. The findings include: 1. For 2023 2nd event, the laboratory received ungraded PT test scores for the following: *CAP C-B 2023 General Chemistry/Therapeutic Drugs: alanine aminotransferase (ALT)- specimens CHM-06, CHM-07, CHM-08, CHM-09, and CHM-10. 2. For 2023 3rd event, the laboratory received ungraded PT test scores for the following: *CAP C-C 2023 General Chemistry/Therapeutic Drugs: ALT- specimens CHM-11, CHM-12, CHM-13, CHM-14, and CHM-15. 3. At the time of the survey, GS #2 confirmed the laboratory did not perform a self evaluation for the ungraded PT test scores listed above. B. Based on review of American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing (PT) records and confirmed by interview with General Supervisor (GS) #2 at 8:40 am on 11/05/2024, the laboratory failed to perform a self evaluation when the laboratory received a score of zero for one out of six testing events from 01/01/2023- 11/05/2024. The findings include: 1. For 2024 testing event 2, the laboratory received a score of zero for failure to submit PT results before the submission deadline for the following: CAP C-B 2024 General Chemistry/Therapeutic Drugs: blood urea nitrogen (BUN) (specimens CHM-06, CHM-07, CHM-08, CHM-09, and CHM-10). 2. At the time of the survey, GS #2 confirmed the laboratory did not perform a self-evaluation for the failed PT scores.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing (PT) records and confirmed by interview with General Supervisor (GS) #2 at 8:40 am on 11/05/2024, the laboratory failed to take and document corrective action for 12 unacceptable PT scores from four out of six PT testing events from 01/01/2023- 11/05/2024. The findings include: 1. For 2023 testing event 1, the laboratory received unacceptable PT test scores for the following: *API 2023 Core Chemistry 1st event- D-dimer (specimen CM-04) 2. For 2023 testing event 2, the laboratory received unacceptable PT scores for the following: *CAP C-B 2023 General Chemistry/Therapeutic Drugs- direct bilirubin (specimens CHM-06 and CHM-10); human chorionic gonadotropin (HCG) quantitative (specimen CHM-10); and blood urea nitrogen (BUN) (specimens CHM-06, CHM-07, CHM-08, CHM-09, and CHM-10) *CAP UDS6-B 2023 Urine Drug Testing (Screen), Limited- opiate group (specimen UDS-13) 3. For 2023 testing event 3, the laboratory received unacceptable PT test scores for the following: *CAP C-C 2023 General Chemistry /Therapeutic Drugs- direct bilirubin (specimens CHM-12) 4. For 2024 testing event 1,

the laboratory received unacceptable PT test scores for the following: *API 2024 Core Chemistry 1st event- D-dimer (specimen CM-01) 5. At the time of the survey, GS #1 confirmed the laboratory did not take and document corrective action for the unacceptable PT test scores listed above.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on lack of quality control records, review of patient test reports, and confirmed by the laboratory director on 11/5/2024 at 10:16 am, the laboratory failed to document the Hematoxylin and Eosin (H&E) stain quality each day of patient testing for one out of one patient who had a frozen section performed 6/19/2024. The findings include: 1. Patient identifier A had a frozen section stained with H&E stain on 6/19/2024. 2. At the time of the survey, the laboratory director confirmed the laboratory did not document the Hematoxylin and Eosin stain quality on 6/19/2024.

D5555

IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's immunohematology policies, blood bank system alarm check records, and confirmed by General Supervisor (GS) #2 at 11:03 am on 11/05/2024, the laboratory failed to inspect, perform, and document quarterly alarm system checks for the blood bank freezer for eight out of eight time periods from 01/01/2023- 11/05/2024. The findings include: 1. The laboratory's "Testing Blood Bank Refrigerator/Freezer/Plasma Thawing System Alarms" policy stated that the alarms on the fresh frozen freezer would be checked quarterly. 2. At the time of the survey, GS #2 confirmed that the laboratory did not perform quarterly alarm checks on the fresh frozen freezer from 01/01/2023- 11/05/2024.