

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2226722	(X3) Date Survey Completed 09/12/2023
Name of Provider or Supplier Quest Diagnostics Mary Bird Perkins Cancer Center	Street Address, City, State 1203 S Tyler Street, Suite #110, Covington, LA	
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
D0000	A Certification survey was performed on September 12, 2023 at Quest Diagnostics Mary Bird Perkins Cancer Center, CLIA ID # 19D2226722. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CASPER 155D report, proficiency testing records, and interview with personnel, the laboratory failed to report the proficiency testing results to the state of Louisiana's CLIA program for four (4) of four (4) events reviewed. Findings: 1. Review of the CASPER 155D report revealed the laboratory's proficiency testing results were not accessible. 2. Review of the laboratory's 2022 and 2023 proficiency testing records revealed the laboratory was enrolled and participated in the College of American Pathologists (CAP) proficiency testing program for Chemistry and Hematology; however, the results were not released/reported to the CMS CLIA program for the state of Louisiana. 3. In interview on September 12, 2023 at 12:23 pm, the Technical Consultant confirmed the laboratory did not release their proficiency testing results to the state of Louisiana's CLIA program.</p>
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</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish a complete written competency assessment policy for Technical Consultants. Findings: 1. Review of the laboratory's "Policy for Delegation of Responsibilities" revealed the laboratory not include frequency of performance of competency assessments for the Technical Consultants. 2. In interview on September 12, 2023 at 4:35 pm, the Technical Consultant confirmed the laboratory's policy did not include the frequency of performance of competency assessments for Technical Consultants.

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have Chemistry quality control range establishment policies approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's policy for quality control range establishment for Chemistry testing revealed the Laboratory Director did not approve/sign the policy. 2. In interview on September 12, 2023 at 3:50 pm, the Technical Consultant confirmed the Laboratory Director did not approve/sign the identified policy.

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 observation and interview with laboratory personnel, the laboratory failed to ensure blood collection supplies were not used beyond their expiration date. Findings: 1. Observation by surveyors on September 12, 2023 at 9:52 a.m. revealed the following expired blood collection tubes in the phlebotomy room: - BD Vacutainer Sodium heparin; reference 367871; Lot 2109090; Expiration date: August 31, 2023; Quantity: nine (9) tubes 2. In interview on September 12, 2023 at 10:12 a.m., Testing Personnel 1 confirmed the items identified above were expired.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on observation by surveyors, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on review of the laboratory's CASPER 155D report, proficiency testing records, and interview with personnel, the Laboratory Director failed to ensure proficiency testing results were reported as required. Refer to D2005.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's personnel records and interview with personnel, the Laboratory Director failed to ensure two (2) of two (2) Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of personnel records for Testing Personnel 1 and Testing Personnel 2 revealed the Laboratory Director did not sign off on the initial Beckman Coulter AU 480 Chemistry analyzer training documents approving the identified personnel for patient testing. 2. In interview on September 12, 2023 at 2:00 pm, the Technical Consultant confirmed the Laboratory Director did not sign the training documents for Testing Personnel 1 and Testing Personnel 2.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Refer to D5209.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(13)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5407.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:
Based on observation by surveyors, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5417.

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CASPER 155D report, proficiency testing records, and interview with personnel, the Technical Consultants failed to ensure proficiency testing results were reported as required. Refer to D2005.