

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2226722	(X3) Date Survey Completed 02/14/2022
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	An Initial survey was performed on February 14, 2022 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.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of the laboratory's performance verification studies, test menu, and interview with personnel, the laboratory failed to include raw data that matched the values utilized for precision studies for Complete Blood Count (CBC) testing. Findings: 1. Observation by surveyor during the laboratory tour on February 14, 2022 at 9:39 am revealed the laboratory utilizes the Sysmex XN-100 for CBC testing. 2. Review of the laboratory's performance verification (validation) studies for the Sysmex XN-100 revealed the instrument had a "Implementation Date of 10/07/21." 3. Review of the laboratory's precision studies and raw data revealed the White Blood Cell (WBC) raw data did not correspond to the values utilized in their studies. 4. Further review of the laboratory's "WBC Precision " form revealed three (3) levels of XN Check controls were run over the course of the following dates and times: Level 1: "08/26/21, 08/27/21. 09/13/21, 9/14/2021 a, 9/14/2021 p" Level 2: "8/23/21 a, 8/23/21 p, 8/26/21 a, 8/26/21 p, 08/27/21" Level 3: "08</p>

/19/21, 8/20/21 a, 8/20/21 p, 8/23/21 a, 8/23/21 p" 5. In interview on February 14, 2022 at 1:03 pm Technical Consultant 1 and Technical Consultant 2 initially stated the white blood count reported for patients are the "WBC-D" values. Technical Consultant 2 later stated the "WBC" values are reported for patients. Technical Consultant 2 stated the WBC values utilized for the precision studies should have been from the "WBC" column not "WBC-D." 6. Review of the corresponding precision raw data revealed the laboratory utilized values from the "WBC-D" column not the "WBC" column for the following dates: Level 1: 9/13/21 Run 1: WBC-D value 3.16 Run 2: WBC-D value 3.10 Run 3: WBC-D value 3.10 Run 4: WBC-D value 3.16 Run 5: WBC-D value 3.11 Level 1: 9/14/21 a Run 1: WBC-D value 3.07 Run 2: WBC-D value 3.07 Run 3: WBC-D value 3.05 Run 4: WBC-D value 3.09 Run 5: WBC-D value 3.08 Level 1: 9/14/21 p Run 1: WBC-D value 3.17 Run 2: WBC-D value 3.16 Run 3: WBC-D value 3.09 Run 4: WBC-D value 3.06 Run 5: WBC-D value 3.13 7. Further review of the corresponding raw data for the precision studies revealed the Level 2 control data for August 27, 2021 utilized on the summary page did not match the WBC raw instrument data. 8. In further interview on February 14, 2022 at 1:03 pm, Technical Consultant 1 stated she was unsure where the WBC values for Level 2 on August 27, 2021 came from. Technical Consultant 1 stated she thinks the wrong date was utilized on the summary page as the values match for August 20, 2021, not August 27, 2021. 9. Review of the laboratory's test menu revealed the laboratory performs 45,648 CBC tests annually. II. Based on observation by surveyor, review of the laboratory's performance verification studies, policies, test menu, and interview with personnel, the laboratory failed to verify reference ranges in use to ensure appropriate for the laboratory's patient population. Findings: 1. Observation by surveyor during the laboratory tour on February 14, 2022 at 9:39 am revealed the laboratory utilizes the Sysmex XN-100 for CBC testing. 2. Review of the laboratory's "RRL Inspection Checklist" under "Section 7-Method Validation /Analytic Performance" revealed "129. Are reference intervals established or verified by the RRL?" 3. Review of the laboratory's "BPT Verification of a Hematology System" forms revealed under the "Reference Interval Studies [sic]" section "The reference intervals for the hematology assays has been determined at the corporate level for all Quest Diagnostics Laboratories." 4. In interview on February 14, 2022 at 1:03 pm, Testing Personnel 1 initially stated the laboratory verified reference ranges with normal patients. Technical Consultant 1 stated the laboratory did not perform reference range studies as they are using the nationwide reference ranges utilized by the company. " 5. Review of the laboratory's test menu revealed the laboratory performs 45,648 CBC tests annually.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of patient laboratory reports and interview with personnel, the

laboratory failed to include the name and address of the reference laboratory where testing was performed for one (1) of five (5) patients reviewed. Findings: 1. In interview on February 14, 2022 at 9:48 am, Testing Personnel 1 stated manual differentials are sent to a reference laboratory for testing. 2. Review of the laboratory's patient final reports revealed the name and addresses of the reference laboratory that performed the testing was not included for the following patient: Collection date: October 18, 2021, Patient DL512640Q 3. Further review of the identified patient final reports revealed a cover sheet that stated "Form for Secondary Review or Manual Diff QLS-Manual Diff/Slide Review Deliver to Hematology ASAP!!! Please place Lav top, slide & copy of CBC results from instrument into a transport bag, Send to your main lab. Reason to Review: Moderate Complexity (X) Manual Differential" 4. In interview on February 14, 2022 at 1:52 pm, Technical Consultant 1 stated the manual differential for the identified patient was performed at a reference laboratory, not their laboratory as listed on the report. Technical Consultant 1 confirmed the name and address of the reference laboratory that performed the manual differential was not included on the patient final report.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421 I and D5421 II.

D6026

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(8)

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)(8) Ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.

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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The Technical Consultant(s) failed to include testing of external proficiency test samples, previously analyzed sample or internal blind sample as part of semi-annual competency assessment for one (1) of two (2) testing personnel reviewed. Refer to D6051. 2. The Technical Consultant(s) failed to perform the semi-annual competency assessment for one (1) of two (2) testing personnel reviewed. Refer to D6053.

D6040

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(2)

The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant(s) failed to ensure performance specification verification studies were complete. Refer to D5421 I and D5421 II.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with personnel, the Technical Consultant(s) failed to include testing of external proficiency test samples, previously analyzed sample or internal blind sample as part of the semi-annual competency assessment for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of personnel records for Testing Personnel 1 revealed a "SNX Sysmex XN Series Operation for CBC Sysmex XN 6 Month Assessment Direct Observation/Record Review" form completed February 7, 2022. 2. Further review of the identified form revealed assessment of previously analyzed sample, internal blind sample, or external proficiency test sample was not included as part of the semi-annual competency. 3. In

interview on February 14, 2022 at 12:33 pm Testing Personnel 1 stated Testing Personnel 2 performed her assessment.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the personnel records and interview with personnel, the Technical Consultant(s) failed to perform the semi-annual competency assessment for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of personnel records for Testing Personnel 1 revealed a "SNX Sysmex XN Series Operation for CBC Sysmex XN 6 Month Assessment Direct Observation/Record Review" form completed February 7, 2022. 2. Further review of the semi-annual competency assessment form for Testing Personnel 1 revealed Testing Personnel 2 performed the assessment not the Technical Consultant(s). 3. In interview on February 14, 2022 at 12:33 pm Testing Personnel 1 stated Testing Personnel 2 performed her assessment.