

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0667372	(X3) Date Survey Completed 11/10/2020
Name of Provider or Supplier Linton Regional Medical Center	Street Address, City, State 111 Elm Ave W, Linton, ND	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to follow the manufacturer's instructions for respiratory syncytial virus (RSV) on 12 of 19 patient testing days in March 2020 (3/04, 3/06, 3/08, 3/09, 3/12, 3/13, 3/14, 3/16, 3/17, 3/21, 3/23, and 3/24). The laboratory performed approximately 17 patient tests not following the manufacturer's instructions during this timeframe. Findings include: 1. Reviewed at 4:05 p.m. on 11/10/20, the March 2020 RSV patient records showed the laboratory performed testing on seventeen patients 19 years of age and older on 3/04, 3/06, 3/08, 3/09, 3/12, 3/13, 3/14, 3/16, 3/17, 3/21, 3/23, and 3/24. 2. Reviewed at 4:30 p.m. on 11/10/20, the manufacturer's instructions for Quidel Sofia RSV FIA (fluorescent immunoassay), dated 09/2014, stated, ". . . Limitations - This test is suitable for the pediatric population (less than 19 years of age) only. Performance characteristics have not been established for use with patients older than 19 years of age and for immunocompromised patients. . . ." 3. Reviewed at 4:45 p.m. on 11/10/20, the undated policy "Sofia RSV FIA" stated, "Limitations - This test is suitable for the pediatric population (less than 19 years of age) only. . . . If swab is submitted for testing on a patient greater than 19 years of age and the result is negative, add the following comment to the report, 'Performance characteristics have not been established for patients >19 years of age. Correlate with clinical findings. When testing in this age group consider the use of PCR [polymerase chain reaction] assays since specimens on patients greater than 19 years of age may have low viral loads in their respiratory tract.' . . ." 4. During interview at 4:35 p.m. on 11/10/20, a technical</p>

consultant (Personnel #1) confirmed the manufacturer limited the use of the RSV test to patients less than nineteen years of age and the laboratory had tested patients nineteen years of age and older in March 2020.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the laboratory failed to verify the accuracy, precision, and reportable range for 1 of 1 new test methods (alanine transaminase) on the Ortho Vitros 350 implemented in 2020 before reporting patient results. The laboratory performed approximately 2000 alanine transaminase (ALT) tests since implementation. Findings include: 1. Reviewed at 3:15 p.m. on 11/10/20, the laboratory's 2020 performance specification verification records for ALT lacked evidence the laboratory verified the performance specifications for accuracy, precision, and reportable range. 2. During interview at 4:30 p.m. on 11/10/20, a technical consultant (Personnel #1) confirmed the laboratory began patient testing for ALT in February 2020, and the laboratory did not have evidence the laboratory director and/or technical consultant had verified the performance specifications for accuracy, precision, and reportable range. 3. Reviewed at 4:55 p.m. on 11/10/20, the undated policy "Linton Hospital Evaluation of New Test Methods," stated, ". . . Clinical Laboratory Improvement Amendments (CLIA) requirements - Accuracy . . . - Precision . . . - Reportable Range . . . Putting Method Into Use . . . - Document Method Evaluation . . ."

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the laboratory failed to verify the analytical sensitivity and specificity for 1 of 1 modified FDA approved test method (Quidel Sofia RSV [respiratory syncytial virus] FIA [fluorescent

immunoassay] for patients nineteen years of age and older) implemented in 2019 before reporting patient results. The laboratory performed approximately 12 RSV tests on patients nineteen years of age and older since implementation. Findings include: 1. Reviewed at 4:15 p.m. on 11/10/20, the laboratory's 2019 performance specification verification records for RSV lacked evidence the laboratory verified the performance specifications for analytical sensitivity and specificity for this modified test method. 2. Reviewed at 4:30 p.m. on 11/10/20, the manufacturer's instructions for Quidel Sofia RSV FIA, dated 09/2014, stated, ". . . Limitations - This test is suitable for the pediatric population (less than 19 years of age) only. Performance characteristics have not been established for use with patients older than 19 years of age and for immunocompromised patients. . . ." 3. During interview at 4:35 p.m. on 11/10/20, a technical consultant (Personnel #1) confirmed the laboratory used the Quidel Sofia RSV FIA test method to perform testing on patients nineteen years of age and older when the manufacturer limited the use of the test on patients less than nineteen years of age. Technical Consultant #1 confirmed the laboratory did not have evidence the laboratory director and/or technical consultant had verified the performance specifications of analytical sensitivity and specificity for this modified test method. 4. Reviewed at 4:55 p.m. on 11/10/20, the undated policy "Linton Hospital Evaluation of New Test Methods," stated, "Evaluation Plan Establish the need - Clinical performance - Clinical sensitivity - Clinical specificity . . ."

D5449

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on record review, policy review, and staff interview, the laboratory failed to perform a positive and negative control each day of patient testing for respiratory syncytial virus (RSV) on 9 of 13 patient testing days in March 2020 (3/12, 3/13, 3/14, 3/16, 3/17, 3/21, 3/23, 3/24, and 3/26). The laboratory performed approximately 13 patient tests during this timeframe. Findings include: 1. Reviewed at 4:05 p.m. on 11/10/20, the March 2020 RSV patient and quality control (QC) records lacked evidence the laboratory performed a negative and positive control on nine testing days (3/12, 3/13, 3/14, 3/16, 3/17, 3/21, 3/23, 3/24, and 3/26) for patients seven years of age and older. 2. Reviewed at 4:30 p.m. on 11/10/20, the manufacturer's instructions for Quidel Sofia RSV FIA (fluorescent immunoassay), dated 09/2014, stated, "For use with Sofia only CLIA Complexity: moderate for pediatric patients 7 to less than 19 years of age CLIA Complexity: WAIVED for children less than 7 years of age . . ." 3. Reviewed at 4:45 p.m. on 11/10/20, the undated policy "Sofia RSV FIA" stated, "External Quality Control . . . Quidel recommends that Positive and Negative Controls be run: . . . - Perform QC each day of patient testing when patient is >7 years of age . . ." 4. During interview at 4:35 p.m. on 11/10/20, a technical consultant (Personnel #1) stated the laboratory should perform positive and negative external QC each day of patient testing for patients seven years of age and older since the test was considered moderate complexity for that age group. Technical Consultant #1 confirmed the laboratory had not performed positive and negative external QC each day of testing for patients seven years of age and older in March 2020.

D6039

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(1)

The technical consultant is responsible for-- (b)(1) Selection of test methodology appropriate for the clinical use of the test results;

This STANDARD is not met as evidenced by:

Based on record review, policy review, and staff interview, the technical consultant failed to ensure the test methodology was appropriate for the clinical use for 1 of 1 virology tests (respiratory syncytial virus) used on patients nineteen years of age and older in March 2020. The laboratory performed approximately 17 patient tests on patients nineteen years of age and older in March 2020 using a respiratory syncytial virus (RSV) test method not suitable for this patient population. Findings include: 1. Reviewed at 4:05 p.m. on 11/10/20, the March 2020 RSV patient records showed the laboratory performed testing on seventeen patients nineteen years of age and older on 3/04, 3/06, 3/08, 3/09, 3/12, 3/13, 3/14, 3/16, 3/17, 3/21, 3/23, and 3/24. 2. Reviewed at 4:30 p.m. on 11/10/20, the manufacturer's instructions for Quidel Sofia RSV FIA (fluorescent immunoassay), dated 09/2014, stated, ". . . Limitations - This test is suitable for the pediatric population (less than 19 years of age) only. . . ." 3. Reviewed at 4:45 p.m. on 11/10/20, the undated policy "Sofia RSV FIA" stated, "Limitations - This test is suitable for the pediatric population (less than 19 years of age) only. . . . If swab is submitted for testing on a patient greater than 19 years of age and the result is negative, add the following comment to the report, 'Performance characteristics have not been established for patients >19 years of age. Correlate with clinical findings. When testing in this age group consider the use of PCR [polymerase chain reaction] assays since specimens on patients greater than 19 years of age may have low viral loads in their respiratory tract.' . . ." 4. During interview at 4:35 p.m. on 11/10/20, a technical consultant (Personnel #1) confirmed the manufacturer limited the use of the RSV test to patients less than nineteen years of age and the laboratory had tested patients nineteen years of age and older in March 2020 per requests from the ordering providers. Personnel #1 stated the laboratory added a comment to the RSV test results of patients nineteen years of age and older stating the limitations of the test in that patient population.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure the laboratory director (Personnel #1) possessed the qualifications necessary to be a high complexity laboratory director. (Refer to D6078)

D6078

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an

operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematopathology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure 1 of 1 laboratory director (Personnel #1) possessed the qualifications necessary to be a high complexity laboratory director. Findings include: 1. Reviewed at 12:45 p.m. on 11/10/20, the "Laboratory Personnel Report (CLIA) [Clinical Laboratory Improvement Amendments]" listed Personnel #1 as the laboratory director. 2. Reviewed at 4:05 p.m. on 11/10/20, the March 2020 respiratory syncytial virus (RSV) patient records showed the laboratory performed testing on seventeen patients 19 years of age and older on 3/04, 3/06, 3/08, 3/09, 3/12, 3/13, 3/14, 3/16, 3/17, 3/21, 3/23, and 3/24 using the Quidel Sofia RSV FIA (fluorescent immunoassay) test kit. The manufacturer limited the performance of this test to patients less than nineteen years of age. The laboratory modified the manufacturer's instructions by using this test method on patients nineteen years of age and older causing the test to be considered high complexity. 3. Reviewed at 4:30 p.m. on 11/10/20, the manufacturer's instructions for Quidel Sofia RSV FIA, dated 09/2014, stated, ". . . Limitations - This test is suitable for the pediatric population (less than 19 years of age) only. Performance characteristics have not been established for use with patients older than 19 years of age and for immunocompromised patients. . . ." 4. During interview at 4:35 p.m. on 11/10/20, the laboratory director (Personnel #1) confirmed the laboratory used the Quidel Sofia RSV FIA test on patients nineteen years of age and older, and Personnel #1 did not have the qualifications to be a high complexity laboratory director.