

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0696875	(X3) Date Survey Completed 05/08/2018
Name of Provider or Supplier North Western Medical Laboratory	Street Address, City, State Ave Severiano Cuevas 24, Apartamento 101, Aguadilla, PR	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on manufacturer's instructions, tests reports records review and general supervisor interview on May 8, 2018 at 12:10 PM, it was determined that the laboratory failed to follow manufacturer's instruction when 98 out of 98 patients specimens were reported for Influenza A&B Quick vue method by Quidel from April 1, 2018 to April 30, 2018. January , 2018 to May 7, 2018. The findings include: 1 The laboratory validated the Influenza A&B Quick vue method by Quidel (waived tests) in December 2017. 2. The Influenza A&B Quick vue method by Quidel manufacturer instructions establish that the negative test is a presumptive results, the negative test results do not rule out possible other non-influenza viral infection and the positive test results do not rule out co-infections with other pathogens. 3. From January , 2018 to May 7, 2018, the laboratory reported 98 out of 98 patients specimens for Influenza A&B Quick vue method by Quidel and reported as negative or positive for Influenza A or Influenza B. The laboratory includes a reference value as Negative and the method identified as Immunoassay. 4. The general supervisor confirmed on May 8, 2018 at 12:10 PM, testing personnel confirmed on May 4, 2018 at 11:05 AM, that the Influenza A/B Quick vue method by Quidel reports did not include the required information.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on lack of Statfax 4700 linearity check records and laboratory general supervisor interview on May 8, 2018 at 11:30 AM, it was determined that the laboratory did not have available the linearity check records of the Statfax 4700 system from January 2017 to to May 8, 2018. The findings include: 1. The laboratory did not have available the linearity check records of the Statfax 4700 system from January 2017 to to May 8, 2018. 2. The general supervisor confirmed on May 8, 2018 at 11:30 AM, that the laboratory did not have available the linearity check records of the Statfax 4700 system from January 2017 to to May 8, 2018. She stated that the laboratory director is who does the linearity check of the Statfax 4700 system and keeps those records and she is out of the country.

D5012

SYPHILIS SEROLOGY

CFR(s): 493.1207

If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on syphilis serology quality control records (years 2017 to 2018) review and general supervisor interview on May 8, 2018 at 10:10 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory failed to follow the manufacturer's instruction when 11 out of 11 patients specimens patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method from May 22, 2017 to April 18, 2018. Refer to D 5405.

D5014

GENERAL IMMUNOLOGY

CFR(s): 493.1208

If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:

Based on C reactive protein (CRP) and Rheumatoid Arthritis (RA) quality control records (years 2017 and 2018) review and general supervisor interview on May 8, 2018 at 10:50 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of General immunology for the CRP and RA quantitative tests. The finding includes: 1. The laboratory failed to include at least once a day, a negative control material and a positive control material when 11 out of 11 patients specimens were tested for CRP quantitative tests from January 27, 2017 to February 20, 2018 and when two out of two patients specimens were tested for RA quantitative tests from November 29, 2017 to February 15, 2018. Refer to D 5449.

D5405

PROCEDURE MANUAL

CFR(s): 493.1251(c)

Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

This STANDARD is not met as evidenced by:

Based on syphilis serology quality control records (years 2017 to 2018) review and general supervisor interview on May 8, 2018 at 10:10 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 11 out of 11 patients specimens patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method from May 22, 2017 to April 18, 2018. The findings include: 1. The manufacturer's instruction establishes that two levels of control material (non reactive reactive) must be included each day of testing. 2. From May 22, 2017 to April 18, 2018, the syphilis serology quality control records showed that the laboratory did not include the two levels of control material when it processed and reported 11 out of 11 patients specimens for syphilis serology by RPR method the followings days: on May 22, 2017 (one patient specimen), November 12, 2017 (one patient specimen), December 13, 2017 (two patients specimens), January 12, 2018 (two patients specimens), February 1, 2018 (one patient specimen), February 20, 2018 (two patients specimens), March 6, 2018(one patient specimen) and April 18, 2018 (one patient specimen). 3. The general supervisor confirmed on May 8, 2018 at 10:15 that the syphilis serology quality control records did not include the quality control procedures those days.

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 C reactive protein (CRP) and Rheumatoid Arthritis (RA) quality control records (years 2017 and 2018) review and general supervisor interview on May 8, 2018 at 10:50 AM, it was determined that the laboratory failed to include at least once a day, a negative control material and a positive control material when 11 out of 11 patients specimens were tested for CRP quantitative tests from January 27, 2017 to February 20, 2018 when two out of two patients specimens were tested for RA quantitative tests from November 29, 2017 to February 15, 2018. The findings include: 1. From January 27, 2017 to February 20, 2018, the CRP quality control showed that the laboratory did not include at least once a day, a negative control material and a positive control material when 11 out of 11 patients specimens were tested for CRP quantitative tests the following days: January 27, 2017 (one patient), November 7, 2017 (one patient specimen), November 10, 2017 (one patient specimen), November 29, 2017 (one patient specimen), January 4, 2018 (three patients specimens), January 30, 2018 (two patients specimen) and February 20, 2018

(two patients specimens). 2. From November 29, 2017 to February 15, 2018, the RA quality control showed that the laboratory did not include at least once a day, a negative control material and a positive control material when 2 out of 2 patients specimens were tested for RA quantitative on November 29, 2017 and February 15, 2018. 3. The general supervisor confirmed on May 8, 2018 at 10:50 AM, that the CRP and RA quality control records did not include the quality control procedures those days.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on syphilis serology quality control records (years 2017 to 2018), C reactive protein (CRP) and Rheumatoid Arthritis (RA) quality control records (years 2017 and 2018) review and general supervisor interview on May 8, 2018 at 10:50 AM, it was determined that technical consultant failed to ensure compliance with the requirements for analytic systems of following tests: RPR, CRP and RA. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when 11 out of 11 patients specimens patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method from May 22, 2017 to April 18, 2018. Refer to D 5405. 2. The laboratory failed to include at least once a day, a negative control material and a positive control material when 11 out of 11 patients specimens were tested for CRP quantitative tests from January 27, 2017 to February 20, 2018 and when two out of two patients specimens were tested for RA quantitative tests from November 29, 2017 to February 15, 2018. Refer to D 5449.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on syphilis serology quality control records review in 2016-2017 and laboratory testing personnel interview on February 14, 2017 at 10:00 AM, it was determined that testing personnel failed to follow quality control procedures for the analytic systems of following tests: RPR, CRP and RA. The findings include: 1. The laboratory failed to follow the manufacturer's instruction when 11 out of 11 patients specimens patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method from May 22, 2017 to April 18, 2018. Refer to D 5405. 2. The laboratory failed to include at least once a day, a negative control material and a positive control material when 11 out of 11 patients specimens were tested for CRP

quantitative tests from January 27, 2017 to February 20, 2018 and when two out of two patients specimens were tested for RA quantitative tests from November 29, 2017 to February 15, 2018. Refer to D 5449.

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 syphilis serology quality control records (years 2017 to 2018), C reactive protein (CRP) and Rheumatoid Arthritis (RA) quality control records (years 2017 and 2018) review and general supervisor interview on May 8, 2018 at 10:50 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for the Syphilis Serology and General Immunology specialties. The findings include: 1. The laboratory director did not comply with the requirements in the the Syphilis Serology and General Immunology specialties. Refer to D 6093. 2. The laboratory director did not comply with the laboratory records retention requirements. Refer to D 6079.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on lack of Statfax 4700 linearity check records and laboratory general supervisor interview on May 8, 2018 at 11:30 AM, it was determined that the laboratory director failed to ensure compliance with the laboratory records retention requirements. Refer D 3031 (The laboratory did not have available the linearity check records of the Statfax 4700 system from January 2017 to to May 8, 2018).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on syphilis serology quality control records (years 2017 to 2018), C reactive protein (CRP) and Rheumatoid Arthritis (RA) quality control records (years 2017 and 2018) review and general supervisor interview on May 8, 2018 at 10:50 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements for the Syphilis Serology and General Immunology specialties. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements of Syphilis Serology specialty. Refer to D 5012. 2. The laboratory director failed to ensure compliance with the analytic system requirements of General Immunology specialty. Refer to D 5014.