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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0658189 | (X3) Date Survey Completed 02/22/2019 |
| Name of Provider or Supplier Ponce Clinical Laboratory Inc | Street Address, City, State 609 Ave Tito Castro Ste 101, Ponce, 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 |
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| D5002 | <p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature chart records (year 2018) records review and laboratory technical supervisor interview on February 22, 2019 at 10:30 AM , it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology. The finding includes: 1. The laboratory did not follow the Microscan manufacturer's instruction when 289 out of 289 patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan system from January 2, 2018 to December 29, 2018. Refer to D 5405.</p> |
| D5405 | <p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Microscan manufacturer's instructions, incubator temperature chart records (year 2018) records review and laboratory technical supervisor interview on February 22, 2019 at 10:30 AM , it was determined that the laboratory failed to follow the</p> |

Microscan manufacturer's instruction when 289 out of 289 patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan system from January 2, 2018 to December 29, 2018. The findings include: 1. The Microscan's manufacturer instructed the laboratory to incubate the microorganisms identification and susceptibility panels at temperature of 35 C +/- 1 C. 2. On February 22, 2019 at 10:30 AM, the incubator temperature chart records (year 2018) showed that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at temperatures out of the manufacturer's range in 308 out of 365 days from January 2, 2018 to December 29, 2018. 3. The laboratory technical supervisor confirmed on February 22, 2019 at 10:30 AM, that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at temperature range of 37 C +/- 1 C from from January 2, 2018 to December 29, 2018. 4. The laboratory processed and reported 289 out of 289 patients culture specimens for microorganisms identification and susceptibility tests by the Microscan system from January 2, 2018 to December 29, 2018.

D5429

MAINTENANCE AND FUNCTION CHECKS
 CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on Sysmex CA-500 manufacturer's instructions for maintenance and supplies replacement, Sysmex CA-500 preventive maintenance records (years 2017 and 2018) review and interview with the testing personnel on February 22, 2019 at 11:25 AM, it was determined that the laboratory failed to follow written instructions for the monthly and yearly preventive maintenance of the Sysmex CA-500 system when 643 of of 643 Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) patients specimens were processed and reported from January 2, 2018 to December 29, 2018. The findings include: 1. The laboratory processed the PT and PTT by the Sysmex CA-500 system. 2. The Sysmex CA-500 manufacturer instructed the laboratory to perform the monthly preventive maintenance (verification of the LED calibration) and the yearly preventive maintenance (replenish rinse filter). 3. On February 22, 2019 at 11:25 AM, the Sysmex CA-500 preventive maintenance records showed that the laboratory did not perform the required preventive maintenance (monthly and yearly) from January 2, 2018 to December 29, 2018. 4. The testing personnel stated on February 22, 2019 at 11:25 AM, that the LED calibration was verified but not recorded in the preventive maintenance record. Also she confirmed that the laboratory did not perform the yearly preventive maintenance since January 2, 2018. 5. The laboratory processed and reported PT and PTT patients specimens tests by the Sysmex CA-500 system from January 2, 2018 to December 29, 2018.

D5451

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256

(g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on syphilis serology testing records (years 2017, 2018 and 2019) review and testing personnel interview on February 22, 2019 at 10:45 AM, it was determined that the laboratory failed to include at least once a day, a negative control material besides a control material with tittered reactivity when 4 out of 4 patients specimens were tested for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method from June 6, 2018 to December 14, 2018. The findings include: 1. The laboratory processed and reported the RPR quantitative tests by ASI method. 2. On February 22, 2019 at 10:45 AM, the syphilis serology testing records showed that the laboratory did not include at least once a day, the negative control material besides the control material with tittered reactivity when 4 out of 4 patients specimens were tested for RPR quantitative tests by ASI method from June 6, 2018 to December 14, 2018: on June 6, 2018, July 3, 2018, September 13, 2018 and December 14, 2018. 3. The testing personnel confirmed on February 22, 2019 at 10:45 AM, that the laboratory did not include the negative control material when it performed the quantitative RPR test. She stated that the laboratory includes this control material when it processing the qualitative RPR test.

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 Individualized Quality Control Plan (IQCP) record for the Microscan microorganisms identification and susceptibility tests system, Microscan manufacturer's instructions, incubator temperature chart records (year 2018) records, Sysmex CA-500 manufacturer's instructions for maintenance and supplies replacement, syphilis serology testing records (years 2017, 2018 and 2019) review, interview with the testing personnel and the laboratory technical supervisor on February 22, 2019 at 11:25 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system. The findings include: 1. Refer to D 6079 (The laboratory director failed to ensure to evaluate effectively the Risk Assessment of the IQCP of the Microscan tests system). 2. Refer to D 6093 (The laboratory director failed to ensure compliance with the requirements for analytic systems).

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 reapportions 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 Individualized Quality Control Plan (IQCP) record for the Microscan microorganisms identification and susceptibility tests system, Microscan system manufacturer's instructions, incubator temperature chart records (year 2016) and technical supervisor interview on February 22, 2019 at 10:30 AM, it was determined that the laboratory director failed to ensure to evaluate effectively the Risk Assessment of the IQCP of the Microscan tests system from January 1, 2016 to December 30, 2016. The findings include: 1. On February 22, 2019 at 10:30 AM, the IQCP for the Microscan tests system records showed that it was implemented on May 22, 2017. The laboratory evaluated the Risk Assessment components with the quality control data of the year 2016. The Risk Assessment evaluation showed a potential failure for the environmental component due to the laboratory did not follow the Microscan manufacturer's instructions for the incubation's temperature from January 1, 2016 to December 30, 2016. 2. The Microscan manufacturer instructed the laboratory to incubate the Mycroscant identification and susceptibility system at 35 C +/- 1 C. The incubator temperature records(year 2016) showed 280 out of 365 days with temperature out of the manufacturer's temperature range. 3. The laboratory technical supervisor confirmed on February 22, 2019 at 10:30 AM, that the laboratory incubated the Microscan's microorganisms identification and susceptibility panels at temperature range of 37 C +/- 1 C from from January 1, 2016 to December 30, 2016. 4. The laboratory did not follow the Microscan Manufacturer's instruction when it processed 289 patients specimens for microorganisms identification and susceptibility tests by the Microscan system from January 2, 2018 to December 29, 2018. Refer to D 5405.

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 Microscan manufacturer's instructions, incubator temperature chart records (year 2018) records, Sysmex CA-500 manufacturer's instructions for maintenance and supplies replacement, syphilis serology testing records(years 2017, 2018 and 2019) review, interview with the testing personnel and the laboratory technical supervisor on February 22, 2019 at 11:25 AM , it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to: D 5002 (The laboratory failed to ensure compliance with the analytic system requirements of bacteriology). D 5429 (The laboratory failed to follow written instructions for the monthly and yearly preventive maintenance of the Sysmex CA-500 system). D 5451 (The laboratory failed to include at least once a day, a negative control material besides a control material with tittered reactivity for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method).

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for 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 Microscan manufacturer's instructions, incubator temperature chart records (year 2018) records, Sysmex CA-500 manufacturer's instructions for maintenance and supplies replacement, syphilis serology testing records (years 2017, 2018 and 2019) review, interview with the testing personnel and the laboratory technical supervisor on February 22, 2019 at 11:25 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic system. Refer to: D 5405 (The laboratory failed to follow the Microscan manufacturer's instruction when patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan system). D 5429 (The laboratory failed to follow written instructions for the monthly and yearly preventive maintenance of the Sysmex CA-500 system). D 5451 (The laboratory failed to include at least once a day, a negative control material besides a control material with tittered reactivity for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method).

D6177

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(3)

Each individual performing high 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 Microscan manufacturer's instructions, incubator temperature chart records (year 2018) records, Sysmex CA-500 manufacturer's instructions for maintenance and supplies replacement, syphilis serology testing records (years 2017, 2018 and 2019) review, interview with the testing personnel and the laboratory technical supervisor on February 22, 2019 at 11:25 AM, it was determined that the testing personnel failed to follow quality control procedures. Refer to: D 5405 (The laboratory failed to follow the Microscan manufacturer's instruction when patients culture specimens were processed and reported for the microorganisms identification and susceptibility panels by the Microscan system). D 5429 (The laboratory failed to follow written instructions for the monthly and yearly preventive maintenance of the Sysmex CA-500 system). D 5451 (The laboratory failed to include at least once a day, a negative control material besides a control material with tittered reactivity for syphilis serology by rapid plasma reagin (RPR) quantitative tests by ASI method).