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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>40D0873176             | <b>(X3) Date Survey Completed</b><br>12/21/2018 |
| <b>Name of Provider or Supplier</b><br>Jollymar Clinical Laboratory  | <b>Street Address, City, State</b><br>Calle 18 N-24 Toa Alta Heights, Toa Alta, PR |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5002</b>              | <p><b>BACTERIOLOGY</b><br/>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:<br/>Based on bacteriology quality control records review and interview with the laboratory director and general supervisor on December 21, 2018 at 12:00 P.M., 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 check each day of testing ( with the appropriate control organisms) the susceptibility test procedure. Refer to D 5507.</p>  |
| <b>D5014</b>              | <p><b>GENERAL IMMUNOLOGY</b><br/>CFR(s): 493.1208</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on ANA test manufacturer's instructions, laboratory written instructions review and interview with the laboratory director and laboratory general supervisor on December 21, 2018 at 12:00P.M. it was determined that the laboratory failed to meet the requirements in the subspecialty of General immunology for ANA test. The finding include: 1. The laboratory failed to follow manufacturer's instruction when patient's samples ,were tested and reported for ANA test. Refer to D 5405</p> |

**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 antinuclear antibody test ( ANA) manufacturer's instruction review, laboratory written instructions review and laboratory director interview on December 21, 2018 at 10:30 A.M., it was determined that the laboratory failed to follow manufacturer's instruction when began to performed the ANA test on October 25,2018. The findings include: 1. The laboratory began to performed ANA test by Hep-2000 Colorzyme ANA-Ro test system on October 2018. 2. The manufacturer's instruction establishes that a positive, negative and Phosphate buffered saline powder ( PBS ) controls should be run in the wells provided for quality control on each slide. The kit provided a substrate slides with seven wells. 3. The laboratory written instruction establishes that a positive, negative and PBS controls must be run once each day of testing no matter how many patients were run during the day, instead with each slide. 4. The records showed that the following days the laboratory performed ANA test patient samples and did not include controls materials on each slide: November 13, 2018- 10 patient samples November 27, 2017 -14 patient samples December 7, 2018-11 patient samples 5. The laboratory director confirmed on December 21, 2018 at 12:00 P.M, that the laboratory included a positive, negative and PBS controls ) with each day of testing instead with each slide.

**D5507**

**BACTERIOLOGY**

CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on bacteriology susceptibility tests quality control records review since March 2018 and interview with the laboratory supervisor on December 21, 2018 at 11:00 A. M. , it was determined that the laboratory did not check each day of testing the susceptibility test procedure. The findings include: 1. The laboratory began to performed antimicrobial susceptibility test by the Microscan WalkAway 40 system since March 21, 2018. 2. Review of susceptibility tests quality control records showed that the laboratory performed quality control procedures on a weekly basis. 3. The laboratory supervisor stated on December 21, 2018 that the laboratory performed a weekly susceptibility check instead of each day of testing. 4. The laboratory supervisor stated that 406 susceptibility tests were performed since March 2018.

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| <p><b>D6076</b></p> | <p><b>LABORATORY DIRECTOR</b><br/>CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on bacteriology quality control records review( 2018) , ANA test manufacturer's instructions and laboratory director and laboratory general supervisor interview on December 21, 2018 at 12:00P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems requirements. Refer to D 6093 .</p>   |
| <p><b>D6093</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/>CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of bacteriology quality control records , antinuclear antibody test ( ANA) manufacturer's instruction review and interview with the laboratory director and laboratory general supervisor on December 21, 2018 at 12:0P.M., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory did not include a control material every day for susceptibility tests. Refer to D5507. 2. The laboratory failed to follow manufacturer's instruction when began to performed the ANA test on October 25,2018. Refer to D5405.</p> |
| <p><b>D6144</b></p> | <p><b>GENERAL SUPERVISOR RESPONSIBILITIES</b><br/>CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of bacteriology quality control records , antinuclear antibody test ( ANA) manufacturer's instruction review and interview with the laboratory director and laboratory general supervisor on December 21, 2018 at 12:0P.M., it was determined that the laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory did not include a control material every day for susceptibility tests. Refer to D5507. 2. The laboratory failed to follow manufacturer's instruction when began to performed the ANA test on October 25,2018. Refer to D5405.</p>                                     |