

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0866459	(X3) Date Survey Completed 04/02/2019
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 10200 Pioneer Blvd, Ste 500, Santa Fe Springs, CA	
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
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's evaluation of proficiency test performance documents, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attained a score of at least 80 % of acceptable response for each analyte in each testing event was unsatisfactory analyte performance for the test event. The findings included: a. The laboratory performed immunoglobulins (Ig) using Roche-Cobas 8000 Line instrument. b. To evaluate the proficiency test performance for the IgA, IgG, and IgM testing systems, the laboratory enrolled its proficiency testing with CAP (College of American pathologists) PT programs. c. The laboratory attained scores of 0% for IgA, IgG, and IgM, respectively in the 1st 2018 PT event, which was unsatisfactory performance. d. The laboratory performed IgA, IgG, and IgM in approximately 3,333 patient samples monthly. e. the laboratory personnel affirmed (4/2/2019) that the laboratory attained scores of 0% for IgA, IgG, and IgM, respectively in the 1st 2018 PT event, which was unsatisfactory performance.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's evaluation of proficiency test performance documents, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attained a score of at least 80 % of acceptable response for each analyze in each testing event was unsatisfactory analyte performance for the test event. The findings included: a. The laboratory performed immunoglobulins (Ig) using Roche-Cobas 8000 Line instrument. b. To evaluate the proficiency test performance for the testing system, the laboratory enrolled its NA proficiency testing with CAP (College of American pathologists) PT program. c. The laboratory attained a score of 60% for serum Sodium (NA) in the 1st 2018 PT event, which was unsatisfactory performance. d. The laboratory performed NA in approximately 19,011 patient samples monthly. e. The laboratory personnel affirmed (4/2/2019) that the laboratory attained a scores of 60% for NA in the 1st 2018 PT event, which was unsatisfactory performance.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's evaluation of proficiency test performance documents, and interview with the laboratory testing personnel, it was determined that the laboratory failed to verify, at least twice annually, the accuracy of the test or any procedure which is not listed in the subpart I of 42 CFR part 493. The findings included: a. The laboratory performed Prothrombin Time (PrT) by Stago Compact Max analyzer and reported PrT in second with INR. b. To evaluate the proficiency test performance and ensure the accuracy for INR results, the laboratory elected to enroll with CAP to ensure the accuracy of the testing system. c. The laboratory attained a score of 0 % for INR in the 1st 2018 PT event, which was unsatisfactory performance for that event. d. The laboratory performed PrT with INR in approximately 145 patient samples monthly. e. The laboratory personnel affirmed (4/2/2019) that the laboratory attained a scores of 0% for INR in the 1st 2018 PT event, which was unsatisfactory performance.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records including but not limited to the followings: the test requisition forms, patient test reports, laboratory worksheets, and interview with the laboratory personnel, it was determined that the current new laboratory director failed to ensure and approve the changes of the laboratory's documents, forms, worksheets, or policies and procedures accordingly due to the changes of the ownership and the name of the laboratory before use. The findings included: a. The laboratory has been acquired by the new owners in January 2018 and a new laboratory director was hired to lead the laboratory operations. b. The current laboratory director failed to ensure and approve accordingly due to the changes of the laboratory

operation team and the name of the laboratory. c. Review of the cytology report of ID #19176353 CYT19-02768), collected date of 02/28/2019 with reported date of 03/03 /2019, an e-REQ with name of Physician's Automated Laboratory, Inc. d. Review of a Cytology report with ID #19192231 , collected date of 03/07/2019 with reported date of 03/08/2019 on a paper requisition form name West Pacific Medical Laboratory. e. "West Pacific Medical Laboratory" name was noted in the procedure manual of "Title: Stago Compact Max D-Dimer Liatest" "page 9 of 11". f. Review of the laboratory's records including various testing procedures, requisition form (eREQ) and worksheet documents were noted unchanged or incorrect laboratory name. g. The laboratory must use consistent laboratory names appeared in its various internal and external documents or records.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records and documents, and interview with the testing personnel, it was determined that the laboratory failed to follow the manufacture's instructions and in a manner that provides test result within the laboratory stated performance specifications for each test system. The findings included: a. The laboratory used Hologic Panther System to perform CT/GC with APTIMA Combo 2 Assay, and Trich with APTIMA Trichomonas vaginalis Assay. b. The laboratory failed to follow the manufacturer's instructions for "Lab Contamination Monitoring Protocol for the PANTHER System" c. No evidences for decontamination procedure documents were available at the time of the survey (4/2 /2019 @ 11 AM).

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records, and interview with the laboratory personnel, it was determined that the laboratory failed to have accurate electronic systems in place to ensure the test results and other patient-specific data were accurate and reliably sent from the point of data entry to final report destinations. The findings included: a. A bacteriology patient results were pulled, wound culture ID #19251242 sample received date was 3/29/2019, a reported date of 3/30/2017@ 17:40 with a

"Final" (indicated a final report) appeared after "Isolate 1: Staphylococcus aureus. b. A computerized worksheet (printed on 4/2/2019 11:1) indicated that the 1 Day, 2 Days, and 3 Days, a clinical laboratory scientist (CLS) had worked on the culture and processed records to conclude a final isolation of the organism, Staphylococcus aureus on 4/2/2019. c. That report was retrieved and printed with a "Final" appeared in the report for Isolate 1: Staphylococcus aureus. d. The patient test result report showed a reported date on 03/30/2019 17:40, which was inconsistent with the culturing dates the CLS proceeded. The timing of dates was inconsistent with the worksheet and the final report. e. In addition, one urine culture final report with ID #19250454 had Collected: 03/26/2019 12:35, and Received: 03/28/2019 12:36. f. The receiving date should be the time received by the laboratory location rather than from the Patient Service Center (PSC). g. The laboratory has its IT (Information System) in house and affirmed (03/22/2019) that inconsistencies of these two reports.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of the laboratory patient test result reports records including but not limited to the followings: the test requisition forms, patient test reports, laboratory worksheets, and interview with the laboratory personnel, it was determined that the laboratory failed to follow its written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified. The findings included: See D-5407, and D-5801

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on review of the laboratory proficiency testing (PT) records and documents, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the evaluation of proficiency test performance were performed. The findings included: See- D-2075, D-2087, D-5217

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and documents, and interview with the testing personnel, it was determined that the laboratory director failed to ensure that the quality control and quality assessment programs were established and maintained to assess the quality of the laboratory services provided. The findings included: See D- 5407, D-5411, and D-5801