

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0544572	<b>(X3) Date Survey Completed</b>  01/24/2019
<b>Name of Provider or Supplier</b>  Beverly Lab Associates	<b>Street Address, City, State</b>  8750 Wilshire Blvd, Ste 350, Beverly Hills, CA	
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>
<b>D2075</b>	<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 second quarter (Q2-2017) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Complement C3 analyte. The findings included: a. Q2-2017, API reported 0% proficiency testing score for Complement C3 analyte. b. For four (4) out of four (4) random patient sampling test results reviewed covering period from 1/22/2016 to 5/15/2018, the laboratory analyzed and reported Complement C3 analyte during the time the laboratory received an unsatisfactory proficiency testing score. c. The technical consultant confirmed (1/24 /2019, 1300), that the laboratory received the above unsatisfactory proficiency test score.</p>
<b>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(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 first quarter (Q1-2017) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain a</p>

score of at least 80 percent of acceptable responses for Prothrombin Time (PT) analyte. The findings included: a. API reported the following unsatisfactory proficiency testing score. Analyte: Score: Event/Year PT 60% Q1-2017 b. For four (4) out of sixteen (16) random patient sampling test results reviewed covering period from 3/15/2017 to 4/3/2017, the laboratory analyzed and reported PT analyte during the time the laboratory received an unsatisfactory proficiency testing scores. c. The technical consultant confirmed (1/24/2019, 1300) that the laboratory received the above unsatisfactory proficiency test score.

**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 third quarter (Q3-2017), second quarter (Q1-2018), third quarter (Q3-2018) of the American Proficiency Institute (API) proficiency testing records, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to attain at least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I. The findings included: a. API reported the following unsatisfactory proficiency testing scores. Analyte: Score: Event/Year UIBC 20% Q3-2017 Sed Rate 50% Q3-2017 PTH 67% Q2-2018 CRP 50% Q3-2018 b. For fourteen (14) out of fourteen (14) random patient sampling test results reviewed covering period from 1/22/2016 to 12/13/2018, the laboratory analyzed and reported CRP analyte. For two (2) out of two (2) random patient sampling test results reviewed from 5/25/2018 and 5/29/2018, the laboratory analyzed and reported PTH analyte. For two (2) out of two (2) random patient test results reviewed from 8/24/2018 and 9/19/2018, laboratory analyzed and reported UIBC, and For sixteen (16) of out sixteen (16) random patient test results reviewed covering period from 1/22/2016 to 12/1/2018, the laboratory analyzed and reported Sed Rate during the time the laboratory received the above unsatisfactory proficiency testing scores. c. The technical consultant confirmed (1/24/2018, 1300), that the laboratory received the above unsatisfactory proficiency test scores.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on direct observation, request for an International Sensitivity Index (ISI) value, Normal Prothrombin Time (PT) mean values entered into the instrument (Dade Behring BTH12 model), random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory director failed to meet the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. See D 6007

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(1)

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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on direct observation, request for an International Sensitivity Index (ISI) value, Mean Normal Prothrombin Time (PT) value entered into the instrument (Dade Behring BTTII2 model), random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. a. Based on the laboratory's Mean Normal PT documented on the laboratory's data sheet performed and accepted on 2/5/2018, the Geometric PT mean was (10.5), Innovin Lot # 549706, Exp Date 9/20/2020. b. The mean Normal PT value entered on the instrument was 11.5 while mean Normal PT calculated based on normal patient samples performed by the laboratory was 10.5. c. The following are random selected patient sampling test results reviewed. Date Patient: PT: INR: Analyzed: Results: 2/28/18 02111065 8.3 0.70 3/7/18 00211480 71.1 0.84 3/9/18 00211693 9.2 0.79 3/9/18 00211694 31.3 3.91 3/14/18 00211980 28.8 2.88 3/15/18 00212047 9.0 0.85 3/15/18 00212048 59.1 5.77 4/2/18 00212857 17.4 1.64 4/5/18 00213105 24.1 2.37 4/23/18 00214023 31.4 3.21 5/1/18 00214567 47.1 5.08 5/31/18 00216134 24.9 2.46 6/28/18 00217484 49.0 5.33 7/5/18 00217863 22.7 2.21 12/6/18 00226384 19.7 1.88 d. The laboratory analyzed and reported approximately 125 PT tests covering period from 2/28/2018 to 1/4/2019. There were 25 patients with an abnormal PT results, that the INR results cannot be assured. e. The technical consultant confirmed (1/24/2019, 1300) that the laboratory failed to ensure that the correct mean Normal PT value was entered into the instrument.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on direct observation, request for the laboratory's current International Sensitivity Index (ISI) value, Normal Prothrombin Time (PT) mean value entered into the instrument (Dade Behring BTTII2 model), random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory to meet the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. See D 6036.

**D6036****TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on direct observation, request for the laboratory's current International Sensitivity Index (ISI) value, Normal Prothrombin Time (PT) mean value entered into the instrument (Dade Behring BTTII2 model), random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. The findings included: a. Based on the laboratory's Mean Normal PT documented on the laboratory's data sheet performed and accepted on 2/5/2018, the Geometric PT mean was (10.5), Innovin Lot # 549706, Exp Date 9/20/2020. b. The mean Normal PT value entered on the instrument was 11.5 while mean Normal PT calculated based on normal patient samples performed by the laboratory was 10.5. c. The following are random selected patient sampling test results reviewed. Date Patient: PT: INR: Analyzed: Results: 2/28/18 02111065 8.3 0.70 3/7/18 00211480 71.1 0.84 3/9/18 00211693 9.2 0.79 3/9/18 00211694 31.3 3.91 3/14/18 00211980 28.8 2.88 3/15/18 00212047 9.0 0.85 3/15/18 00212048 59.1 5.77 4/2/18 00212857 17.4 1.64 4/5/18 00213105 24.1 2.37 4/23/18 00214023 31.4 3.21 5/1/18 00214567 47.1 5.08 5/31/18 00216134 24.9 2.46 6/28/18 00217484 49.0 5.33 7/5/18 00217863 22.7 2.21 12/6/18 00226384 19.7 1.88 d. The laboratory analyzed and reported approximately 125 PT tests covering period from 2/28/2018 to 1/4/2019. There were 25 patients with an abnormal PT results, that the INR results cannot be assured. e. The technical consultant confirmed (1/24/2019, 1300) that the laboratory failed to ensure that the correct mean Normal PT value was entered into the instrument.