| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D1077766 | 10/04/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Beverly Hills Cancer Center | 8900 Wilshire Blvd, Beverly Hills, 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 |
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| **D2000** | ENROLLMENT AND TESTING OF SAMPLES<br>CFR(s): 493.801<br><br>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory test records for twelve (12) randomly selected patients' test requisitions and test results (medical records), quality control review from 09/27/2018 to 10/04/2019, proficiency testing (PT) result reports, and interview with the laboratory technical consultant (TC), it was determined that the laboratory failed to enroll and participate in a proficiency testing (PT) program that meets the criteria in subpart H of 42 CFR part 493 and is approved by HHS. The findings included: a. The laboratory performed routine chemistry and endocrinology testing which is in the list of subpart I of 42 CFR part 493 using the OCD Vitros system analyzer. b. The laboratory failed to show evidence of enroll in a PT program for routine chemistry and endocrinology testing event using a CMS approved PT program American Proficiency Institute (API) for the first event (Q-1), 2018 (which meets the criteria in subpart H of 42 CFR part 493). The laboratory analyzed and reported routine chemistry and endocrinology patient test results during the approximate time of non-enrollment in a proficiency testing (PT) program. c. The laboratory technical consultant (TC), confirmed 10/04/2018 15:30 (survey date) that patient test results were reported during the period of the PT 1st event (Q-1), 2018 for routine chemistry and endocrinology, yet the laboratory was not enrolled in an accredited PT program. |

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| | d. The laboratory annual testing declaration (04/11/2019) estimated the routine chemistry and endocrinology, estimated the total test volume as 111,721. |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of third quarter (Q3-2017), first quarter (Q1-2018), third quarter (Q3-2018) and second quarter (Q2-2019) of the American Proficiency Institute (API) proficiency testing records, laboratory's proficiency testing reports, random patient test records and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that the laboratory successfully performed in a CMS-approved proficiency testing program. See D 2087. |
| **D2087** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of analyte performance for the third quarter (Q3-2017), first quarter (Q1-2018), second quarter (Q3-2018) and second quarter (Q3-2019) of the American Proficiency Institute (API) proficiency testing performance summary records, (12) randomly selected patients' test requisitions and test results (medical records), quality control review from 09/27/2018 to 10/04/2019, proficiency testing (PT) result reports, and interview with the laboratory technical consultant (TC), it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Sodium (NA). The findings included: a. API reported Proficiency Testing Sodium (NA) scores: Event Score % Q3 2017 60 Q1 2018 0 Q3 2018 60 Q2 2019 60 b. Patient test results reviewed covering period from 09/27/2018 to 10/04/2019, the laboratory analyzed and reported Sodium (NA) tests during the approximate time the laboratory received three (3) sequential unsatisfactory failed proficiency scores of Q3, 2017, Q1, 2018, Q3, 2018 and Q2, 2019. c. The technical consultant confirmed (10/04 |

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| | /2019, 15:30) that the laboratory received the above unsatisfactory proficiency testing score. d. The laboratory annual testing declaration (04/11/2019) for routine chemistry (NA included) estimated that a total test volume of 111,721. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on the severity of the deficiencies cited herein, the Condition: Laboratories Performing Moderate Complexity Testing: Laboratory director was not met. The laboratory director, moderate complexity testing, failed to ensure that PT samples were tested as required under Subpart H of this part. (See D6016, D6018) |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) performance summaries reports for the third quarter (Q3), 2017, first quarter (Q1), 2018, third quarter (Q3), 2018 and second quarter (Q2), 2019, and an interview with the laboratory technical consultant (TC), it was determined that the laboratory director failed to be responsible for assuring compliance with the applicable CLIA regulations pertaining to successful performance of PT samples tested as required for the analyte sodium (NA) in 2017, 2018 and 2019. |
| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>Based on reviews of analyte performance for the second quarter (Q3-2018) and second quarter (Q3-2019) of the American Proficiency Institute (API) proficiency |

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| | testing performance summary records, (12) randomly selected patients' test requisitions and test results (medical records), quality control review from 09/27/2018 to 10/04/2019, proficiency testing (PT) result reports, and interview with the laboratory technical consultant (TC), the laboratory failed to ensure that the proficiency testing reports received are reviewed to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: a. No documentation was retrieved on 10/04/2019 (survey date) to show that the laboratory director had reviewed the proficiency testing performance evaluation and corrective action for the unsatisfactory analtye Sodium (NA) performance results for the second quarter (Q3-2018) and second quarter (Q3-2019). The laboratory's policy and procedure manual under "Quarterly Quality Control Meetings" stated: 1. Within 14 days of the receipt of the complete proficiency testing survey reports, a review will be scheduled with the Laboratory Director or his designee, Supervisor(s) and testing personnel. This meeting will discuss: a. proficiency test results just received, b. corrective actions (if any are necessary) to identify and correct problems which may have led to an unsatisfactory testing results. c. reviews with the staff any recurring or unusual calibration, control material performance, or any other material quality control issues. d. Survey Exception Reports on corrective action measures taken in response to unacceptable performance in proficiency testing discussed at the prior quarterly meeting(s) will be reviewed to assess the effectiveness of corrective action measures previously taken. 2. This review will be evidenced by participant's initials on the report. Laboratory Director has responsibility for maintaining these records for a minimum of two years. b. The technical consultant confirmed (10/04 /2019, 15:30) that the laboratory received the above unsatisfactory proficiency testing scores, and no documentation could be retrieved to show that the laboratory Director had reviewed the proficiency testing performance evaluation and corrective action for the unsatisfactory analtye performance results for the second quarter (Q3-2018) and second quarter (Q3-2019). |