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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 05D2068755 | (X3) Date Survey Completed 03/11/2026 |
| Name of Provider or Supplier Orange County Labs Inc | Street Address, City, State 15165 Triton Ln, Huntington Beach, 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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| D2087 | <p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) 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 American Proficiency Institute (API) proficiency testing (PT) records, and interview with the laboratory manager on March 11, 2026, it was determined that the laboratory failed to attain a score of at least of 80 percent of acceptable responses for the routine chemistry analyte Calcium Total for the third PT event of 2024. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for routine chemistry testing using Horiba Yumizen C series analyzer. According to the API evaluation report, the laboratory attained an unsatisfactory score of 60% for Calcium Total in third PT event of 2024. 2. On March 11, 2026, at approximately 12:30 pm, the laboratory manager affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory information system reported that 930 panels were ordered for routine chemistry in 2024.</p> |
| D2089 | <p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of</p> |

patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the laboratory manager on March 11, 2026, it was determined that the laboratory failed to participate in the first and second testing events of 2024 for the specialty of routine chemistry. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for routine chemistry testing using Horiba Yumizen C series analyzer. According to the API evaluation report, the laboratory attained scores of 0 % in routine chemistry in the first and second testing events of 2024. 2. On March 11, 2026, at approximately 12:30 pm, the laboratory manager affirmed that the laboratory did not participate in specified testing event and received the above unsatisfactory proficiency scores. 3. The laboratory information system reported that 930 panels were ordered for routine chemistry in 2024.

D2121

HEMATOLOGY

CFR(s): 493.851(a)

(a) 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.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing (PT) records, and interview with the laboratory manager on March 11, 2026, it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for the Hematology analyte White Blood Cell (WBC) count for the third PT event of 2024. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for Hematology testing using Horiba ABX Pentra analyzer analyzer. According to the API evaluation report, the laboratory attained an unsatisfactory score of 20% for WBC count in third PT event of 2024. 2. On March 11, 2026, at approximately 12:40 pm, the laboratory manager affirmed that the laboratory received the above unsatisfactory proficiency scores. 3. The laboratory information system reported that 975 hematology panels were ordered for Hematology in 2024.

D2123

HEMATOLOGY

CFR(s): 493.851(c)

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing records, and interview with the laboratory manager on March 11, 2026, it was determined that the laboratory failed to participate in the first testing event of 2024 for the specialty of Hematology. The findings included: 1. The laboratory enrolled in the American Proficiency Institute (API) proficiency testing program for Hematology testing using Horiba ABX Pentra analyzer. According to the API evaluation, the laboratory attained scores of 0 % in Hematology in the first testing event of 2024. 2. On March 11, 2026, at approximately 12:40 pm, the laboratory manager affirmed that the laboratory did not participate in specified testing event and received the above unsatisfactory proficiency scores. 3. The laboratory information system reported that 975 hematology panels were ordered for Hematology in 2024.