

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0858501	(X3) Date Survey Completed 08/27/2026
Name of Provider or Supplier La County Harbor-Ucla Medical Center	Street Address, City, State 1000 W Carson Street - Box 12, Torrance, 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
D0000	An on-site validation survey was conducted on 08/26/26 and 08/27/26. A standard-level deficiency was cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a direct observation, a review of the laboratory's written procedures, patient requisitions, and interview with the laboratory safety & quality control coordinator, the laboratory failed to document the specimen acceptability for 7 of 7 patient specimens. Findings included: 1. On 08/26/26 at 09:45 am, the laboratory safety & quality control coordinator confirmed the following: a. The laboratory performed Hematology testing on the Sysmex XN-9100 analyzer. b. The laboratory performed Cancer Antigen 125 (CA 125), Carcinoembryonic Antigen (CEA), Ferritin, Hepatitis B Surface Antigen II, Hepatitis C Antibody Assay, and Thyroid Stimulating Hormones (TSH) testing on the Roche Cobas e801 analyzer. c. The laboratory accepted outside specimens from six outside clinics. 2. A review of the laboratory's written procedures revealed the following: a. "HEM51.000 Pre-Analytical Processing of Hematology Specimens" section "F. SPECIMEN STABILITY AND STORAGE" stated, "1. Stored at 2-8C, EDTA peripheral blood samples may be analyzed up to 48 hours" and "Sample stability at room temperature is 24 hours." C= Celsius b. "CHR56.000 CA 125 (Cancer Antigen 125)" section "Specimen Stability" stated, "8 hours at 20-25 C" and "5 days at 2-8 C". c. "CHR57.000 CEA (Carcinoembryonic

Antigen) section "Specimen Stability" stated, "7 days at 20-25C" and "14 days at 2-8C". d. "CHR60.000 Ferritin" section "Specimen Stability" stated, "48 hours at 20-25C" and "7 days at 2-8C". e. "CHR-72.000 ROCHE ELECSYS Hepatitis B Surface Antigen II Assay" section "Stability of Centrifuged (separated from RBCs for blood collection) stated, "4 days at 20-25C". f. "CHR-74.000 ROCHE ELECSYS Hepatitis C Antibody Assay" section "Stability of Centrifuged (separated from RBCs for blood collection) stated, "3 days at 20-25C". g. "CHR 88.000 TSH (Thyroid Stimulating Hormone) section "Specimen Stability" stated, "8 days at 20-25C". 3. Direct observation on 08/27/26 at 01:20 pm of specimens delivered to the laboratory by a courier revealed the laboratory did not have a mechanism to ensure specimen stability (appropriate temperature) during transportation for the following: a. Patient Requisition# 103002177 - Collected on 08/26/26 and received into the laboratory on 08/27/26 for Ferritin, Hepatitis C, Hematology, and TSH testing. b. Patient Requisition# 102704955 - Collected on 08/26/26 and received into the laboratory on 08/27/26 for TSH testing. c. Patient Requisition# 102926879 - Collected on 08/26/26 and received into the laboratory on Hepatitis B Surface Antigen II testing and Hepatitis C testing. d. Patient Requisition# 103415554 - Collected on 08/26/26 and received into the laboratory on 08/27/26 for Ferritin, TSH, and Hematology testing. e. Patient Requisition# 103116984 -Collected on 08/26/26 and received into the laboratory on 08/27/26 for Hematology testing. f. Patient Requisition# 103416978 - Collected on 08/26/26 and received into the laboratory on 08/27/26 for TSH testing. g. Patient Requisition# 103111855 - Collected on 08/26/26 and received into the laboratory on 08/27/26 for CA 125 and CEA testing. 4. In an interview on 08/27/26 at 02:25 pm with the laboratory safety & quality control coordinator, the laboratory safety & quality control coordinator confirmed the laboratory failed to document temperatures of specimens arriving in the laboratory to ensure specimen acceptability.