

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0417052	(X3) Date Survey Completed 10/13/2021
Name of Provider or Supplier Quest Diagnostics Llc (II)	Street Address, City, State 1355 Mittel Blvd, Wood Dale, IL	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews; the laboratory failed to ensure optimum integrity of patient specimens from the time of collection through completion of testing for one of four urine toxicology specimens reviewed. Findings Include: 1. Review of the laboratory procedure, "Drug Abuse Screen by Enzyme Immunoassay" (Document No. CHICDTWD805[5.0]), under section "3.2 Specimen Type & Handling" indicated the following: a. "Transport Container & Temperature Requirements" - "Plastic urine transport container, transport at room temperature". b. "Stability & Storage Requirements" - "Room Temperature: 5 Days, Refrigerated: 7 Days (1 week), Frozen: 30 Days (1 month)". 2. The following four specimens and patient test reports were reviewed: Specimen Collected Received (at 1355 Mittel Blvd, Wood Dale, IL 60191) KS442**** 6-10-21 at 10:02 AM 6-22-21 at 4:16 pm. KS293**** 6-08-21 at 12:00 AM 6-12-21 at 5:32 pm KS298**** 6-08-21 at 12:00 AM 6-12-21 at 6:07 pm KS758**** 6-23-21 7-02-21 at 3:10 pm Specimen KS442**** was held for 12 days before testing and beyond the stability and storage requirements for an ambient or refrigerated specimen based on the laboratory's procedure. 3. Interview with the shipping manager on 10-13-21 at 11:00 AM, confirmed specimen KS442**** was collected on 6-10-21 at 10:02 am, then transported to a distribution center for Quest Diagnostics in Lenexa, KS. The specimen arrived at the Lenexa, KS distribution center on 6-17-21 and was held there till 6-22-21. The shipping manager was unable to confirm how the specimen arrived at the Lenexa, KS location (ambient/room temperature/frozen) or how the specimen was</p>

maintained at the distribution center (ambient/room temperature/frozen). The specimen designation was changed from ambient to frozen at 4:49 am on 06-22-21 prior to shipment of the specimen from the distribution center to the 1355 Mittel Blvd, Wood Dale, IL laboratory. 4. The specimen KS442**** was processed and the results were reported by the 1355 Mittel Blvd, Wood Dale, IL laboratory on 6-22-21. 5. Interview with the LD on 10-13-21 at 12:45 pm confirmed the laboratory was unable to determine how the specimen was initially shipped to the distribution center or how the specimen sample was stored at the distribution center prior to the arrival at the 1355 Mittel Blvd, Wood Dale, IL 60191 laboratory location.