

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1107220	(X3) Date Survey Completed 09/17/2020
Name of Provider or Supplier Ut Health San Antonio Cancer Center	Street Address, City, State 7979 Wurzbach, Mc 7878, San Antonio, TX	
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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the McKesson hCG Urine Test Cassette, review of patient test records from 2019 and staff interview, it was revealed the laboratory failed to ensure test results were interpreted after the correct time. The findings were: 1. A review of manufacture's instructions for the McKesson hCG Urine Test Cassette (1155805503, Rev. Date: 2009-4-3) under the section titled "Directions for Use" revealed: "Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes." 2. A review of patient test records from 2019 revealed the following patients whose results were interpreted after 10 minutes: a)</p>

mrn: 6042513 Date: 04/18 start: 2:00 end: 2:15 elapsed time: 15 minutes b) mrn: 60817318 Date: 04/18 start: 2:00 end: 2:15 elapsed time: 15 minutes c) mrn: 20113292 Date: 05/02 start: 10:15 end: 10:30 elapsed time: 15 minutes d) mrn: 06051367 Date: 05/10 start: 08:49 end: 09:00 elapsed time: 11 minutes 3. An interview with the laboratory director on 09/17/2020 at 10:30 hours in the conference room - after her review of the records- confirmed the findings. Key: mrn: medical record number