

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0029591	(X3) Date Survey Completed 05/19/2023
Name of Provider or Supplier Trace Regional Hospital	Street Address, City, State 1002 E Madison St, Houston, MS	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter DxH 690 T quality control (QC) records from 10/16/2021 through 4/30/2023 and confirmation with TP #3 at 2:30 p.m. on 5/19/2023, the laboratory failed to retain the QC assay sheets for each lot used to perform daily QC on the Beckman Coulter DxH 690 T. Assay sheets which include acceptable ranges/standard deviations, storage requirements, and lot numbers/expiration dates were not retained for ten of eleven lot numbers of QC. Findings include: 1. Review of the Beckman Coulter DxH 690 T QC records from 10/16/2021 until 5/18/2023, revealed eleven lot numbers of hematology QC lots had been used. No assay sheets were retained for the following lots: a. DxH 690 T QC lot # 123173780 low, 133173780 normal, 143173780 high b. DxH 690 T QC lot # 123173730 low, 133173730 normal, 143173730 high c. DxH 690 T QC lot # 123173790 low, 133173790 normal, 143173790 high d. DxH 690 T QC lot # 123184060 low, 133184060 normal, 143184060 high e. DxH 690 T QC lot # 123174120 low, 133184120 normal, 143194120 high f. DxH 690 T QC lot # 123174160 low, 133184160 normal, 143194160 high g. DxH 690 T QC lot # 123174230 low, 133184230 normal, 143194230 high h. DxH 690 T QC lot # 123174660 low, 133184660 normal, 143194660 high i. DxH 690 T QC lot # 123174710 low, 133184710 normal, 143194710 high j. DxH 690 T QC lot # 123174800 low, 133184800 normal, 143194800 high 2. TP #3 confirmed in an interview at 2:30 p.m. on 5/19/2023 the lab did not retain QC assay sheets with each change of lot number for the QC material for the DxH 690 T hematology analyzer. Ten of eleven QC assay sheets were not retained during the period surveyed.</p>