Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1086268	11/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Icon Clinical Research	9755 Ridge Drive, Lenexa, KS	

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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for barbiturates performed on the Siemens Atellica Solution chemistry analyzer from 10/1/24 to 10/31/24, lack of evaluation documentation for barbiturates patient results and interview with TC #1, the laboratory failed to evaluate patient test results since the last acceptable QC test run to determine if patient barbiturates results had been adversely affected and may require corrective action. Findings: 1. Review of barbiturates QC records from the Siemens Atellica Solution chemistry analyzer serial number CMO3500 revealed unacceptable QC values on 10/2/24. The barbiturates assay required calibration in order to obtain acceptable QC values post calibration on 10/2/24. 2. Prior to the calibration listed in item #1, the last acceptable barbiturates QC was obtained on 10/1 /24. 3. The surveyor asked how many patient barbiturates results were reported since the last acceptable QC obtained on 10/1/24. The laboratory records showed 29 patient barbiturates results were reported. 4. The surveyor asked if the patient barbiturates results from 10/1/24 were evaluated for possible corrective action. No documentation of result evaluation for 29 patient barbiturates results were provided at the time of survey. 5. Interview with TC #1 on 11/7/24 at 11:30 a.m. confirmed, the laboratory

	failed to evaluate patient test results since the last acceptable QC test run to determine if patient barbiturates results had been adversely affected and may require corrective action.