Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0705599	04/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Euclid Hospital Laboratory	18901 Lake Shore Blvd, Cleveland, OH	

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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interviews with the Community Hospital Laboratories Administrator (CHLA), the Regional Accreditation Manager (RAM), the Director of Safety, Quality & Patient Experience (DSQPE), the Laboratory Quality Specialist (LQS) and the Laboratory Manager (LM), the laboratory failed to have a procedure in the quality assessment (QA) postanalytic system to monitor and assess the accuracy of patient test results, including abnormal results to be repeated, and immediate notification of abnormal test results to the ordering provider. This deficient practice affected five of 20 sampled patient creatinine tests out of a total of 215 creatinine tests performed within a comprehensive metabolic panel on 02/13/2025. Findings Include: 1. Review of the laboratory's "Quality Management System" policy and procedure, approved via signature and date by the Laboratory Director on 05/16/2024, found quality assessment activities occurred monthly and revealed the following instructions: "3. Data entered into computer system (whether manually or by automated methods) is reviewed to verify the correctness of the input data before final acceptance and reporting by the computer. Reviews may be performed by a second person or by software as appropriate." 2. Review of the laboratory's "Creatinine" policy and procedure, approved via signature and date by the Laboratory Director on 12/14/2023, found the following: "D. Procedures for handling abnormal or critical results There are no critical or urgent values associated with this analyte." 3. Further review of the laboratory's "Creatinine" policy and procedure revealed the laboratory's established normal range is: Plasma/Serum: Female: 0.58-0.96 mg/dL males: 0.73-1.22 mg/dL mg/dL; milligrams per deciliter 4. Review of the laboratory's policies and

	procedures provided on the date of the complaint investigation did not find any instructions to repeat abnormal creatinine results, including when the delta result from the prior year was significantly different (lower). 5. Review of a sample of 20 patient creatinine test results performed and reported on 02/13/2025 found the following five patient creatinine test results reported without rerunning the sample: Patient Creatinine Result Delta Result A 4.01 mg/dL no delta result B 3.80 mg/dL no delta result C 7.61 mg/dL 4.69 from 09/20/24 D 6.07 mg/dL 0.81 from 03/18/24 E 3.96 mg /dL no delta result 6. Review of the final test reports and Information Technology's audit trails of the above listed five patients did not find any indication that the ordering provider was notified about the abnormal results. 7. The Inspector requested the laboratory's 2025 monthly quality assessment documentation from the CHLA, RAM, DSQPE, LQS and LM. The January, February and March 2025 monthly quality assessment documentation revealed the following assessments were found to be indicated with a "Y" (yes) when no patient specimens were collected and no patient or proficiency testing were performed: "Proficiency tests were handled in the same manner as patient specimens." "Proficiency test results were evaluated, failures were investigated, and remedial action was taken." "Patient specimens were collected and handled according to our protocol." "All lab reports contain correct information." "The system is operating optimally." 8. The Inspector requested the laboratory's creatinine test result recheck criteria and the creatinine test result verifications for the above listed five patient samples performed on 02/13/2025 from the CHLA, RAM, DSQPE, LQS and LM. The CHLA, RAM, DSQPE, LQS and LM stated the laboratory did not establish recheck criteria for abnormal creatinine results, including when the delta result was significantly different (lower) within the past year, did not identify and include a critical result range for creatinine in their policies and procedures and were unable to provide the requested documentation on the date of the complaint investigation. The interviews occurred on 04/08/2025 at 2:08 PM.