

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0962629	(X3) Date Survey Completed 11/02/2023
Name of Provider or Supplier Kansas City Orthopaedic Institute	Street Address, City, State 3651 College Blvd, Leawood, 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
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of "REPORTING OF RESULTS POLICY", lack of post analytical review documentation, and interview with technical consultant (TC) #3, the laboratory failed to have and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems. Findings: 1. The surveyor requested the policy/procedure for postanalytical quality assessment. The laboratory provided their "REPORTING OF RESULTS POLICY". Review of this policy revealed no ongoing processes to monitor, assess and when needed, correct problems in the post analytic system. 2. Interview with TC #3 on 11/2/23 at 1:55 p.m. confirmed, the laboratory failed to have and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems.</p>
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p> <p>(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on the lack of postanalytical quality assessment documentation and interview with TC #3, the laboratory failed to document postanalytical quality assessment.

Findings: 1. The surveyor requested documentation of postanalytical quality assessment activities. No documentation was made available at the time of survey. 2.

Interview with TC #3 on 11/2/23 at 1:55 p.m. confirmed, the laboratory failed to document postanalytical quality assessment.