

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0624280	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Kaiser Interstate Medical Office Lab	Street Address, City, State 3500 N Interstate Ave, Portland, OR	
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
D5655	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic slide preparations are identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations are identified and reported as unsatisfactory for evaluation. 2. During a phone interview on February 8, 2023 at 10:15 AM the Laboratory Director confirmed these findings.</p>
D6115	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: A. Based on the microscopic review of 3 unsatisfactory nongynecologic cytology cases/7 slides from January 2021 through December 2022 and confirmation by Technical Supervisor on February 13, 2023 the Technical Supervisor failed to verify the accuracy of one nongynecologic cytology test. 1. N21-1147-C 03/12/2021 Left</p>

Ureter Wash LABORATORY DIAGNOSIS: Unsatisfactory due to cellularity
SURVEY TEAM DIAGNOSIS: Negative for High Grade Urothelial Carcinoma-
abundant cellular material TECHNICAL SUPERVISOR DIAGNOSIS: Part C:
Negative for High Grade Urothelial Carcinoma B. Based on the microscopic review
of 99 negative and unsatisfactory gynecologic cytology cases/110 slides from January
2021 through December 2022 and confirmation by Technical Supervisor on February
13, 2023 the Technical Supervisor failed to verify the accuracy of two gynecologic
cytology tests. 1. G21-27926 08/19/2021 ThinPrep Pap Test (TPPT) LABORATORY
DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS:
Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR
DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. G21-41358 12/02/2021
ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for
Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for
Interpretation; scant cellularity TECHNICAL SUPERVISOR DIAGNOSIS:
Unsatisfactory

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