

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 41D2028914	<b>(X3) Date Survey Completed</b> 12/28/2023
<b>Name of Provider or Supplier</b> University Gastroenterology, Llc	<b>Street Address, City, State</b> 110 Clock Tower Square, Portsmouth, RI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, record review and staff interview with the General Supervisor (GS), the laboratory failed to establish a competency assessment procedure for the GS regulatory responsibilities. Findings include: 1. Record review on 12/13 /2023 of the laboratory's employee competency records revealed the laboratory did not document competency assessment of the GS. 2. Record review on 12/13/2023 of the laboratory's procedure manual revealed the laboratory did not have a procedure for assessing the GS based on their regulatory responsibilities. 3. Staff interview on 12/13 /2023 at 12:00 PM with the GS confirmed the above findings. 4. The laboratory performs 58,892 Histopathology tests annually.</p>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:  
 Based on lack of documentation, record review and staff interview, the laboratory failed to document the verification of performance specifications for the Ki67 immunostain. Findings include: 1. Record review on 12/13/2023 of the laboratory's quality assurance data revealed the laboratory did not have documentation that it performed a validation study to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer. 2. Record review on 12/20/2023 of an email received from the laboratory director (LD) on 12/20/2023 at 4:33 PM revealed: a. "Although completed via established laboratory procedures below, no paper records of the March 2022 validation, completed with Leica representatives on known positive control tissue, were found as proof of successful validation." b. "Overall, 80 completed Ki67 immunostain tests were performed during the period from March 2022 through November 2023." 3. Record review on 12/20/2023 of the "ANTIBODY TESTING: QUALITY CONTROL AND VALIDATION" procedure received via email on 12/20/2023 at 4:33 PM revealed: a. "Antibody testing performed in the laboratory must undergo validation and quality control inspection on known positive control tissue prior to test performance on patient tissues. Quality control and validation will be inspected and verified by the medical laboratory director." b. "When a new antibody is brought online in the laboratory, it must be validated before being placed into clinical use. i. Manufacturer's instructions will be used when using and validating a new antibody. ii. For a well-characterized antibody with a limited spectrum of antigenic targets the validation can be limited to a panel of 10 positive and 10 negative samples. iii. Some antibodies may require a more extensive validation. iv. The validation procedure for each new antibody will be documented." 4. During staff interview on 12/13/2023 at 11:30 AM the LD stated, "We will look for the validation data and send it to you." 5. The laboratory performs 58,892 Histopathology tests annually.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
 CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
 Based on lack of documentation, record review and staff interview with the General Supervisor (GS), the laboratory failed to document routine maintenance on the Leica Bond III and Leica Bond Max instruments for 2022 and 2023. Findings include: 1. Record review on 12/13/2023 of the laboratory's "Histology Equipment Quality Control" procedure revealed: Leica Bond Max and Leica Bond III "Daily: Check bulk reagent containers Clean covertiles at end of day Weekly: Clean slide staining assembly Check covertile clamps Wipe aspirating probe Check mixing station, clean or replace Monthly: Clean dip trays Replace mixing station Clean bulk fluid reagent containers Clean bulk waste container Clean slide trays Clean bulk fluid robot probes Check syringes When prompted: Clean main robot aspirating probe Replace main robot aspirating probe Replace syringe" 2. Record review on 12/13/2023 of the laboratory's "Cleaning and Maintenance Schedule Leica Bond" logs revealed: a. Daily

and weekly maintenance was not documented for 2022 and 2023 to date for the Leica Bond III and Leica Bond Max. b. Monthly maintenance was not documented for 23 of 24 months from January 2022 to December 2023 for the Leica Bond III and Leica Bond Max. 3. Staff interview on 12/13/2023 at 11:34 AM with the GS confirmed the above findings. The GS stated, "It is being done but it is not being documented." 4. The laboratory performs 58,892 Histopathology tests annually.