

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D2289242	<b>(X3) Date Survey Completed</b>  03/13/2024
<b>Name of Provider or Supplier</b>  Sarika Gupta Mbbs	<b>Street Address, City, State</b>  2346 Brandwood Rd Sw, Rochester, MN	
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>D0000</b>	The Sarika Gupta MBBS laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the initial survey performed on March 13, 2024. The following standard-level deficiency was cited: 493.1283 Test Records .
<b>D5787</b>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to maintain a record system for Histopathology microscopic examinations performed from December 2023 through March 2024 which included the four elements required by this regulation. Findings are as follows: 1. The laboratory performed high complexity, microscopic examinations of stained tissue slides under the sub-specialty of Histopathology as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 10:05 a.m. on March 13, 2024. 2. The Specimen Pathway with Bhatti Gastroenterology Consultants procedure (#1.3) found in the Laboratory Procedure manual Section 1, General Information procedures, indicated a manifest would be created by Bhatti Gastroenterology including the identification and number of slides to be sent to Sarika Gupta laboratory. This manifest along with the slides would be sent and delivered to the Sarika Gupta laboratory. The slides would then be accepted into the Sarika Gupta laboratory during normal hours of operation, upon receipt the slides would be checked against the manifest and initialed and dated.</p>

3. The manifest for the slides sent to the Sarika Gupta laboratory was found only for the first day slide were delivered. A record system for December 2023 through March 2024 which included the four elements required by this regulation could not be found on the day of survey, March 13, 2024. The laboratory was unable to provide these records upon request. 4. In an interview at 12:15 p.m. on March 13, 2024, the LD confirmed the above finding, indicating that the laboratory stopped using the manifest after the first attempt because it was not true to the slides that were sent and delivered to the laboratory. .