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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>31D1028817 | <b>(X3) Date Survey Completed</b><br>08/28/2024 |
| <b>Name of Provider or Supplier</b><br>Hmhmg Specialty Care  | <b>Street Address, City, State</b><br>360 Essex Street, Hackensack, NJ |   |
| 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>   |
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| <b>D5291</b>              | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br/>CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish in detail a Biannual Assessment Procedure (BAP) for Histopathology tests which includes how review and evaluation processes will be documented from 4/5/23 to 8/28/24. The finding includes: 1. The laboratory failed to have a detailed BAP which included how review and evaluation processes would be documented. 2. The laboratory failed to have a procedure if a discrepancy occurs with the Biannual Assessment. 3. The TP confirmed on 8/28/24 at 1:00 pm the laboratory failed to have a detailed BAP.</p> |
| <b>D5403</b>              | <p>PROCEDURE MANUAL<br/>CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in</p>   |

493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP) the laboratory failed to have all applicable procedures for Histopathology tests in the PM from 4/5/23 to 8/28/24. The finding includes: 1. The laboratory failed to have a slide retention and storage procedure in the PM. 2. The TP confirmed on 8/28/24 at 1:00 pm that the PM did not have the above mentioned procedures.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(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 surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for verifying manually transcribed results into the Electronic Medical Record (EMR) from 4/5/23 to 8/28/24. The finding includes. 1. The laboratory failed to have a procedure to verify manually entered test results to ensure accuracy in the postanalytic systems. 2. The TP confirmed on 8/28/24 at 1:15 pm that the laboratory failed to have a procedure for verifying manually transcribed results in to the EMR.