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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 24D0900330 | (X3) Date Survey Completed 02/03/2021 |
| Name of Provider or Supplier Ogi - Mg | Street Address, City, State 9550 Upland Lane N #230, Maple Grove, MN | |
| 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 |
|---------------------------|--|
| D2009 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director or designee failed to attest to the integration of proficiency testing samples into the routine patient workload on three occasions in 2020. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Testing Personnel 12 (TP12) during a tour of the laboratory on 02/3/20 at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The Laboratory Director (LD) and Testing Personnel (TP) were required to sign the attestation statements as established in the Quality Assurance Plan procedure / Section C. Proficiency Testing, located in the Lab Procedure - Maple Grove Manual. 4. The LD or designee failed to attest to the integration of PT samples into the routine patient workload for 3 of 3 API PT events reviewed in the January 2019 through February 2020 timeframe. See below. Event Missing item Microbiology No LD signature 2020 - 1st Microbiology No LD signature 2020 - 2nd Microbiology No LD signature 2020 - 3rd 5. In an interview on 02/03/20, at 11:15 a.m., TP12 confirmed the above finding. .</p> |
| D3037 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> |

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least 2 years. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Testing Personnel 12 (TP12) during a tour of the laboratory on 02/3/20 at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The API PT Performance Evaluation Reports for Microbiology / 2019 / 3rd Event and Microbiology / 2020 / 1st Event were not present in laboratory records on date of survey. The laboratory was unable to provide these documents upon request. 4. In an interview on 02/03/20, at 11:15 a.m., TP12 confirmed the above finding. .

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Microbiology proficiency testing (PT) result for 1 analyte in 2018. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Testing Personnel 12 (TP12) during a tour of the laboratory on 02/3/20 at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The laboratory received an unacceptable Gardnerella vaginalis PT result in the API Microbiology / 2018 / 3rd Event. 4. Investigation of unacceptable PT results was required as established in the Quality Assurance Plan procedure / Section C. Proficiency Testing, located in the Lab Procedure - Maple Grove Manual. 5. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview on 02/03/20, at 11:15 a.m., TP12 confirmed the above finding. .

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the Laboratory Director or designee failed to review and evaluate proficiency testing (PT) results for 2 of 7 events reviewed. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the Testing Personnel 12 (TP12) during a tour of the laboratory on 02/3/20 at 10:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) PT provider. 3. The

results of the following PT events were not reviewed or evaluated by the Laboratory Director or designee : API Microbiology / 2019 / 2nd Event. API Microbiology / 2019 / 3rd Event. The laboratory was unable to provide these documents upon request. 4. In an interview on 02/03/20, at 11:15 a.m., TP12 confirmed the above finding. .