

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0403189	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Ogi - Edina	Street Address, City, State 6405 France Ave S #W400, Edina, 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, Testing Personnel failed to attest to the integration of proficiency testing samples into the routine patient workload on 2 of 6 events. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 2/22/18 at 9:05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) as the PT provider. 3. Testing Personnel failed to attest to the integration of API proficiency testing samples into the routine patient workload as follows: - Microbiology, 2016, 1st PT event. - Microbiology, 2016, 2nd PT event. 4. In an interview on 2/22/18 at 10:45 a.m., the GS confirmed the above findings. .</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> <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 records for at least 2 years on 2 of 6 events. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 2/22/18 at 9:</p>

05 a.m. 2. The laboratory performed proficiency testing (PT) using the American Proficiency Institute (API) as the PT provider. 3. The PT records for Microbiology, 1st Event, 2017 were missing the Documentation of Review by Laboratory Director (LD), or designee. 4. The PT records for Microbiology, 2nd Event, 2017 were missing the Result Evaluation Report and Documentation of Review by Laboratory Director (LD), or designee. 5. The laboratory was unable to provide the required records upon request. 6. In an interview on 2/22/18 at 10:45 a.m., the GS confirmed the above findings. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on document review and interview with laboratory personnel, the Technical Consultant (TC) failed to assess the competency of 1 of 7 new Testing Personnel at least twice annually during the first year of testing. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by General Supervisor (GS) during a tour of the laboratory on 2/22/18 at 9:05 a.m.. 2. Testing Personnel 11 (TP-11) was listed on Form CMS-209 Laboratory Personnel Report (CLIA) as a new employee performing moderate complexity testing. Laboratory records indicated TP-11 began working in the lab on 1/30/17 and was initially assessed for competency in December, 2017. 3. A semi-annual competency assessment for TP-11 was not found during review of laboratory records. The laboratory was unable to provide the required documentation upon request. 4. In an interview on 2/22/18 at 10:45 a.m., the GS confirmed the above findings. .