

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D2084528	<b>(X3) Date Survey Completed</b>  02/13/2019
<b>Name of Provider or Supplier</b>  Mygenomics, Llc	<b>Street Address, City, State</b>  11535 Park Woods Circle, Suite E, Alpharetta, GA	
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>	An offsite revisit survey was conducted on March 21, 2019, for all previous deficiencies cited on 2/13/2019. All deficiencies have been corrected. The facility is in compliance with with all regulations surveyed.
<b>D5219</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency test (PT) results and staff interview, the laboratory failed to twice annually verify the accuracy of any test or procedure for which compatible PT samples are not offered by a CMS-approve PT program. Findings include: 1. PT document review revealed the laboratory failed to verify twice annually in 2018 the accuracy of their clinical cytogenetics testing. 2. An interview with the General Supervisor in the front office on 2/13/2019 at approximately 2 p.m. confirmed PT was only performed once in 2018.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory maintenance document review and staff interview, the laboratory</p>

failed to document instrument maintenance as required. Findings include: 1. Laboratory maintenance document review revealed the laboratory was unable to produce Illumina maintenance logs for 2017, 2018, and 2019 thus far. 2. An interview with the General Supervisor in the front office on 2/13/2019 at approximately 2:00 p. m. confirmed there were no Illumina maintenance logs available at the time of survey for 2017, 2018, and 2019 thus far.

**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 proficiency test (PT) document review and staff interview, the laboratory director/technical supervisor (LD/TS) failed to ensure all PT reports are reviewed by appropriate staff as required. Findings include: 1. Qualigene Limited PT document review for 2017 and 2018 revealed the LD/TS did not review the PT reports for 2017 and 2018. 2. Pachyonychia split-sample document review revealed the LD/TS failed to review the PT reports for 2017. 3. An interview in the front office with the General Supervisor on 2/13/2019 at approximately 2:00 p.m. confirmed the aforementioned lack of PT report review.

**D6112**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:

Based on maintenance and temperature log review and staff interview, the technical supervisor /laboratory director (TS/LD) failed to provide technical and scientific oversight of the laboratory as required Findings include: 1. Review of eye wash maintenance and temperature logs revealed the TS/LD failed to perform a review of the aforementioned logs for 2017, 2018, and 2019 thus far. 2. An interview with the general supervisor in a front office on 2/13/19 at approximately 2:00 p.m. confirmed the aforementioned logs were not reviewed by the TS/LD.