Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2149368	10/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Neogenomics Laboratories Inc	10560 Nw Glenmore Way, Portland, OR	

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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of the procedure (SOP) for interpretation of Clinical Cytogenetics patient results, the laboratory failed to ensure access of patient results in the laboratory. Findings include: 1. The Laboratory Director (LD) has access to the LIS system (Forticlient) for the remote lab performing the wet lab prep of patient samples in Tennessee but not a back up storage of his results in his laboratory in Oregon.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) 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. This STANDARD is not met as evidenced by: Based upon review of the laboratory's procedure (SOP) for evaluating studies in Clinical Cytogenetics, the laboratory failed to establish written protocol for the bi-annual verification of the provider's performance as dictated by CFR 493.1236 (c) 2. Findings include: 1. Upon review of the SOP for Clinical Cytogenetic review and interpretation, there is no reference or direction as to how bi-annual verification will be acheived and recorded. 2. During an interview with the Laboratory Director (LD)

	during the survey conducted 10/22/2018, the LD confirmed that bi-annual verification for Clinical Cytogenetics had not yet been written or implemented.