Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2161577	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cosmosid Ngs Laboratory Services, Llc	20030 Century Blvd, Suite 300, Germantown, MD	

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
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 on review of the procedure manual and interview with the Business Operation Manager (BOM) and Director of Scientific Operations & Quality (DSOQ), the laboratory failed to verify the accuracy of the virology testing which currently has no proficiency testing (PT) samples available. Findings: 1. According to the BOM the laboratory started testing and reporting patient test results in the summer of 2019. 2. According to the DSOQ the previous policy for blind sample testing had not been implemented and was replaced with the procedure titled "Alternative, Blind Sample and Performance Testing" with an effective date of 11/12/2020. 3. The documentation available shows that the first time the laboratory "completed proficiency testing for microbiome analysis of genomic sequences of stool samples" was on 03/10/2021. 4. During the exit interview on 03/12/2021 at 3:15 PM, the DSOQ confirmed that the laboratory had not performed split sample PT in 2019 and 2020.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the

	condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: A. Based on review of final reports and interview with the technical supervisor, the final report for virology DNA testing did not include the address of where the test was performed. Findings: 1. Test reports are releaseed to the users electronically; 2. The electronic report did not include the address of the laboratory performing the test; and 3. This was confirmed during interview with the technical supervisor in the afternoon of March 12, 2020. B. Based on review of final reports and interview with the technical supervisor, the final report for virology DNA testing did not include the source of the test specimen. Findings: 1. Test reports are releaseed to the users electronically; 2. The electronic report did not include the source of the specimen used to perform the test; and 3. This was confirmed during interview with the technical supervisor in the afternoon of March 12, 2020.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the Business Operation Manager (BOM) and Director of Scientific Operations & Quality (DSOQ), the laboratory director failed to ensure that the quality assurance (QA) plan was implemented to assure quality laboratory services. Findings: 1. According to the BOM the laboratory started testing and reporting patient test results in the summer of 2019. 2. According to the DSOQ the previous QA policy had not been implemented and was replaced with the procedure titled "Clinical Diagnostic Sample QA Plan" with an effective date of 11/12/2020. 3. The new QA plan requires annual management reviews twice a year and monthly clinical diagnostic QA audits that include preanalytical, analytical and post analytical phases of testing. 4. The only QA documentation available at the time of the survey was a Management Review Meeting form dated 01/14/2021 and 01/19/2021. When questioned about the lack of a signature for the laboratory director, the DSOQ stated that the LD should have received a copy for review and signature but as of 03/12/2021 that had not been done. 5. During the exit interview on 03/12/2021 at 3:15 PM, the DSOQ confirmed that the laboratory had not performed any QA reviews until January 2021.