

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2104154	(X3) Date Survey Completed 01/26/2021
Name of Provider or Supplier Next Bio Research Services, Llc	Street Address, City, State 11601 Iron Bridge Road - Suite 101, Chester, VA	
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
D0000	<p>An unannounced Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (#VA00050543) was conducted for Next Bio Research Services, LLC from January 13-26, 2021 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Based on a review of documents and interviews, the inspector found the complainant's allegation to be substantiated. Specific deficiency cited is as follows:</p>
D5207	<p>COMMUNICATIONS CFR(s): 493.1234</p> <p>The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.</p> <p>This STANDARD is not met as evidenced by: Based on a complaint investigation review of patient accession logs, patient result logs, protocols, incident reports, and interviews, the laboratory failed to have a system of specimen reconciliation/tracking mechanisms in place to identify one (1) missing SARS-CoV-2 (COVID-19) respiratory specimen (Patient #1) collected and sent from an urgent care (Client A) on December 11, 2020. Findings include: 1. Review of COVID-19 Transport Accession Log for Client A (date of service 12/11/20) revealed thirty (30) patients identified for SARS-CoV-2 (COVID-19) referral to Next Bio Research Services (NEXT) laboratory that included Patient #1. 2. Review of NEXT laboratory patient result logs (date of collection 12/11/20) referred for SARS-CoV-2 (COVID-19) testing from Client A revealed no receipt/results for Patient #1. The inspector noted for the date of service, 12/11/20, NEXT reported the 29 test results listed into Urgent Care A's portal within three (3) days of collection. The COVID-19 specimen processing and result reporting protocols did not document that Patient #1's sample was not received/tested during the timeframe of 12/12/20 to 12/20/20. 3.</p>

Review of NEXT laboratory policy ("Registration and Accessioning of Clinical Cases") revealed no protocols for a tracking communication mechanism or specimen manifest reconciliation in place with their ordering providers/clients. The inspector inquired regarding reconciliation of specimens received from Client A on the date outlined above. The Director of Clinical Business Operations (CBO) stated "We do have clients that send us manifests that are used and if there are any issues, we do contact the clients. This particular urgent care client does not provide manifest." 4. On 1/13/21 at approximately 4:00 PM, the inspector requested to review available NEXT quality assurance reports for the timeframe of 12/11/20 to 12/20/21. On 1/25/21, the CBO provided the above requested records. The inspector reviewed NEXT laboratory's operational effectiveness incident report (dated 12/21/20). The report revealed the following statements: "The findings of investigations show that the package containing the sample in question and the package that was sent from department store to a person in Illinois were next to each other for several scan points in the UPS package Richmond, Virginia sorting line. UPS has told us that their audit shows that the two packages were next to each other on the line, both packages opened during sorting, the package from our Urgent Care A client had a sample to fall out, and it was inadvertently placed in the package to the person in Illinois. As a corrective action, we have implemented a personal courier service with Urgent Care A office that will now include a manifest so that samples received can be compared to samples sent." 5. The CBO confirmed the above findings on 1/26/21 at approximately 1:30 PM.