



Laboratory Notice

TO: VALUED CLIENTS

SUBJECT: UPDATED NLCP GUIDELINES FOR DOWNGRADING A FEDERALLY REGULATED TEST

DATE: JANUARY 29, 2024

Effective February 1, 2024, in compliance with updated National Laboratory Certification Program (NLCP) guidance, CRL will follow the procedures described below in order to process requests to change a federally regulated test to non-regulated (downgrade) for specimens collected on Federal CCFs. Please note the differing requirements for DOT versus HHS specimens.

For DOT specimens:

Each DOT agency has unique procedures and requirements for processing downgrade requests. In order to downgrade a DOT specimen, you must first contact the Program Manager for the specific DOT agency and obtain their approval to downgrade to a non-regulated specimen. Once the Program Manager has approved, please provide the DOT agency approval to CRL concurrently with the downgrade request. CRL cannot process a downgrade request without DOT agency approval, and only the client or MRO can obtain approval from the DOT agency. CRL cannot process these requests unless both the request and the approval are received simultaneously at CRL. Contact information for Program Managers may be found on the DOT website (<https://www.transportation.gov/odapc/agencies>).

For HHS specimens:

CRL is able to downgrade HHS specimens for which a Memorandum for the Record (MFR) completed by the collector explaining the use of the Federal CCF for a non-Federal collection is received concurrently at the laboratory with the specimen. MFRs received prior to receipt of the specimen will not be accepted. For a specimen reported Negative, Invalid or Rejected for Testing: once a specimen has been tested, an MRO request is required to downgrade the specimen. For a specimen reported Positive, Substituted, and/or Adulterated, CRL will consult with HHS when a request to downgrade is received from the MRO. If approval to downgrade is granted by HHS, CRL will downgrade per the MRO request.

For both HHS and DOT specimens:

CRL will no longer accept any handwritten attempts to downgrade by making alterations to a Federal CCF.

These changes are scheduled to go into effect on Thursday, February 1, 2024. If you have any questions, please contact your Account Executive at 800-445-6917.