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Governor

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Commissioner

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Executive Deputy Commissioner

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**Re: The release of unfinalized HIV results to patients, as it pertains to the 21st Century Cures Act**

Dear Colleague,

I am writing to communicate the establishment of a New York State best practice to address the unintended harm caused to patients by the premature release of non-finalized HIV positive test results:

*Sequester non-finalized HIV results for up to 72 hours prior to releasing the results to patients.*

Background

The importance of universal HIV testing as a key component to ending the HIV epidemic cannot be understated. Accessible and routine HIV testing for all individuals ≥13 years old expands the number of people who know their HIV status and facilitates entry into the continuum of care or prevention. Once screened, ensuring that patients are expediently made aware of the results of their HIV test is the next key component in linking people to care.

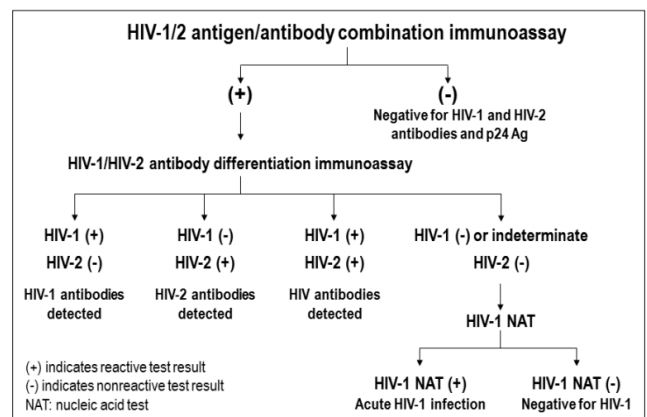
Impacting the manner in which patients can receive their HIV test results is the [21st Century Cures Act \(Cures Act\)](#), which revolutionized the exchange of electronic health information (EHI); and the [Information Blocking](#) final rule, which aims to eliminate intentional barriers to EHI exchange, give patients greater control over their personal health data, and make it easier to share patient records between organizations and with patients. While an important and positive development in health information technology, it can present the challenge of unfinalized results being released to patients.

Recognizing that not all practices which may interfere with EHI sharing constitute information blocking, the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS) has provided clarification to the Cures Act, including the [outlining of reasonable and necessary activities that do not constitute information blocking](#).

The Problem: Causing Patient Harm with Non-Finalized Results

An unintended consequence of the Cures Act has been the release, to patients, of non-finalized HIV screening results, specifically positive non-finalized HIV results. These non-finalized positive HIV results are a direct product of the multi-step laboratory process for HIV screening. In 2018, the CDC issued a 3-step HIV testing algorithm (see illustration) for HIV diagnostic testing performed on serum and plasma specimens. When performing an HIV screening test of anyone ≥2 years old, testing is ordered from a laboratory that offers an FDA-approved HIV Ag/Ab immunoassay as an initial HIV test. If the initial Ag/Ab immunoassay is reactive, most laboratories will follow the recommended algorithm steps to confirm or exclude laboratory evidence of HIV.

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



Given the potential for release of multiple non-finalized HIV results within this process, and the fact that health entities are attempting to comply with the Cures Act, many patients are receiving non-finalized HIV positive results as EHI. Receiving an HIV positive test result may have significant distressing emotional and psychological consequences to the patient, including acts of domestic violence and other negative social consequences towards the person with the HIV positive result. Though clinicians and support staff aid to reduce these negative consequences for patients receiving an HIV positive test, **receiving a non-finalized/intermediate HIV positive test, that then finalizes as a negative result, leads to unnecessary harm to the patient.** As universal HIV screening expands, making the prevalence of HIV among those being screened lower, the likelihood for obtaining false positives increases for these intermediate screening steps.

#### Rationale for the NYS Best Practice to Prevent Patient Harm

As discussed in the ONC 21st Century Cures Act Final Rule, laboratory results pending confirmation are examples of data points that may not be appropriate to disclose or exchange until they are finalized. Thus, the practice of delaying fulfillment of a request for an initial HIV test until the laboratory conducts confirmatory testing does not constitute information blocking. 85 Fed. Reg. 25830 (May 1, 2020).

Furthermore, the Health and Human Services has defined [eight specific exceptions](#) to the Cures Act, including the Preventing Harm Exception. 45 CFR §171.201. This exception recognizes that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of EHI. As such, it will not be information blocking to engage in practices that are reasonable and necessary to prevent harm to a patient or another person, provided the certain conditions outlined by ONC are met.

To prevent unintended harm from releasing non-finalized HIV positive test results, the NYS AIDS Institute supports all actors and health entities, to sequester non-finalized HIV results for up to 72 hours prior to releasing the results to patients. The sequestering of these results and delaying fulfillment of the request for the results until the results are finalized will substantially reduce a risk of harm to patients and is permitted by the Cures Act.

Sincerely,

Charles John Gonzalez, M.D.  
Medical Director  
AIDS Institute