

Protocol for notification of COVID-19 test results

One of the main objectives of combating corona virus is to test and monitor the results of COVID-19 tests in the Brazilian population.

To ensure that this happens for the first time in Brazil, it was necessary to proceed with the National Health Data Network (RNDS) to receive directly from the laboratories of public and private clinical analyses the individualized information of the examinations performed and their respective results. This information stored in The RNDS can then be distributed to citizens and health professionals through the CONNECT-SUS applications and portals.

The Ministry of Health published Ordinance No. 1,792, which makes it mandatory to notify the RNDS of all diagnostic test results for the detection of COVID-19. The obligation applies to all laboratories of the public network, private network, university and any other, throughout the national territory. The notification must be made within 24 hours from the test result, upon registration and transmission of information in the RNDS.

The Ministry of Health should be notified to all the results of diagnostic tests performed, whether positive, negative, inconclusive and correlated, in whatever testing methodology used.

The results of laboratory tests performed by private laboratories will be made available to local managers of the Unified Health System (SUS) to update and complete the investigation. The notification will be borne by the managers and managers of the respective laboratories and will be supervised by the local health manager.

Laboratories must request their accreditation from RNDS to DATASUS, which has provided technical documentation and accreditation system for laboratories, available in the Services Portal (<https://servicos-datasus.saude.gov.br/home>), based on best practices and interoperability standards. The accreditation flow can be found at: <https://rnds.saude.gov.br/wp-content/uploads/2020/07/Infogr%C3%A1fico-acesso-RNDS-via-Portal-de-Servi%C3%A7os.pdf>

The information exchange messages about the test results have been implemented with the HL7 FHIR standard, and the corresponding documentation is available at <https://simplifier.net/RedeNacionaldeDadosEmSaude/> and the summary can be found in Appendix 1.

The connection of public and private laboratories to RNDS is a relevant milestone in the fight against COVID-19 and will additionally bring long-term benefits as a fundamental reference for Brazilian Digital Health. By August 2020, RNDS had already received more than 3 million COVID-19 test results.

With the mandatory submission of the results of COVID-19 exams to the RNDS, the updating of suspected cases with test results became automatic in the e-SUS Notifies system, transforming into digital and dynamic a process that was performed manually by health surveillance teams in municipalities and states.

The results of COVID-19 tests from public and private laboratories connected to RNDS are available to citizens and health professionals through the CONECTE-SUS Portal. (<https://conectesus.saude.gov.br/home>).

This portal is the central point of access to procedures performed, allowing citizens to monitor their health situation, as well as health professionals to access the examinations and clinical history of their patients aiming at continuity of care.

Appendix 1

Brazil - Ministry of Health

Department of Informatics of SUS (DATASUS)

National Health Data Network (RNDS)

INTEROPERABILITY STANDARD FOR EXCHANGING EXAM RESULTS INFORMATION (COVID-19)

1. Objective

The purpose of this document is to present the model for exchanging information on COVID-19 test results with RNDS.

2. Chosen standard - HL7 FHIR

The exchange standard chosen was the HL7 FHIR for being fast, flexible, free and widely used worldwide.

HL7 FHIR uses the concept of features, which are the smallest exchange units of the standard. E.g. Encounter, Procedure, Observation.

The features follow the 80/20 philosophy: the standard focuses on 20% of interoperability needs that meet 80% of problems.

Few elements are required, making it possible not to use most of them or create extensions for specific needs.

For the modeling of the Brazilian standard, we sought to follow some premises:

- a. Maintain the "native" standard, ensuring that the modeling rules were fully adherent: features were tested and reviewed using wide-ranging free validators.
 - b. Extend only when inevitable.
 - c. Ensure the semantics of features and elements.
 - d. Canonize resources, ensuring their reuse.
- #### 3. Reference Resources - Exam Results

The reference features used can be found in the following links:

Bundle: is the "header" of the message, packages the other features:

<https://www.hl7.org/fhir/bundle.html>

Composition: represents the document being transmitted and references the other resources that make up the document:

<https://simplifier.net/redenacionaldedadosemsade/brresultadoexamelaboratorial>

Observation: measurements and statements about a patient (and other subjects), including laboratory tests:

<https://simplifier.net/redenacionaldedadosemsade/brdiagnosticolaboratorioclinico>

Specimen: the sample that was examined:

<https://simplifier.net/RedeNacionaldeDadosEmSade/BRAmostraBiologica>

4. Standard Vocabulary and Adoption Definitions

For the use of a standard vocabulary, some strategies were defined, in order of adoption:

- a. Translate and use the required vs. extensible vocabularies.
- b. Use terminologies, tables, classifications and other reference vocabularies already defined in national systems.
- c. Translate and use terminologies, tables, rankings and other reference vocabularies or suggested by FHIR, as long as they are free.
- d. Create new vocabularies.

The reference terminologies used can be found in the following links:

Exam Category (subgroup of group 02 of Table SUS):

<https://simplifier.net/RedeNacionaldeDadosemSade/BRSubgrupoTabelaSUS>

Exam Name (LOINC): <https://simplifier.net/redenacionaldedadosemsade/brnomeexamecovid19loinc>

Qualitative Result and Qualitative Interpretation (GAL):

<https://simplifier.net/RedeNacionaldeDadosemSade/BRResultadoQualitativoExame>

Biological Sample Type (HL7 + GAL)

<https://simplifier.net/RedeNacionaldeDadosemSade/BRTipoAmostra-1.0>

5. Questions and suggestions

Questions and suggestions can be sent to the rnds@saude.gov.br

FHIR information and messaging models: <https://simplifier.net/redenacionaldedadosemsade>

See the <https://saudedigital.saude.gov.br/>