

# RALS™ AND THE CARES ACT

## Pandemic Response, Laboratory Data Reporting (CARES Act Section 18115)

In the COVID-19 Pandemic Response, Laboratory Data Reporting (CARES Act Section 18115) all laboratories—including laboratories, testing locations operating as temporary overflow or remote locations for a laboratory, and other facilities or locations performing testing at point of care or with at-home specimen collection related to SARS-CoV-2—shall report data for all testing completed, for each

individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department based on the individual's residence.

For more on CARES Act Section 18115, go to <https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf>

## HOW CAN RALS HELP WITH CARES ACT DATA COLLECTION REQUIREMENTS?

In hospitals where RALS is used, the following data fields are specific to SARS-CoV-2 and considered “Ask on Order Entry” (AOE) questions for traditional Electronic Health Records or Laboratory Information Management Systems.

1. First test (Y/N/U)
2. Employed in healthcare? (Y/N/U)
3. Symptomatic as defined by CDC? (Y/N/U);
  - a. If yes, then Date of Symptom Onset mm/dd/yy
4. Hospitalized? (Y/N/U)
5. ICU? (Y/N/U)
6. Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelter, foster care or other setting): (Y/N/U)
7. Pregnant? (Y/N/U)



These elements should be collected and be conformant with the HL7 Version 2.5.1 Lab Order Interface Implementation Guide and associated standards, and comprehensive of the above data fields.

At this time, RALS can help using either an Orders Workflow solution or a Manual Test Entry (MTE) solution, both described on the next page.

For more information, contact your RALS representative.

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## 1. ORDERS WORKFLOW

In a typical POC workflow data is collected ‘unsolicited’ (see section below). But hospitals, physician offices, offsite clinics, and labs are also common places for an ‘orders’ or ‘solicited’ workflow method for patient data collection.

Our Orders Interface allows RALS to send the ‘ordering physician’ in the outbound solicited message instead of the ‘physician of record’ as is used in a point-of-care (POC) outbound message. In this workflow scenario (Figure 1).

1. A physician places an order for a patient test
2. Mandatory responses to the AOE questions are answered
3. The order is sent to a nurse/operator and to RALS
4. In response to the order, the test is performed on the patient
5. The result is downloaded to RALS.
6. The result is matched and validated in RALS against the open orders
7. A solicited result is transmitted to the LIS/HIS/EMR system that is connected to RALS

When test results are reported to your LIS/HIS the data is immediately “married” with the preexisting order record that contains the questions and responses.

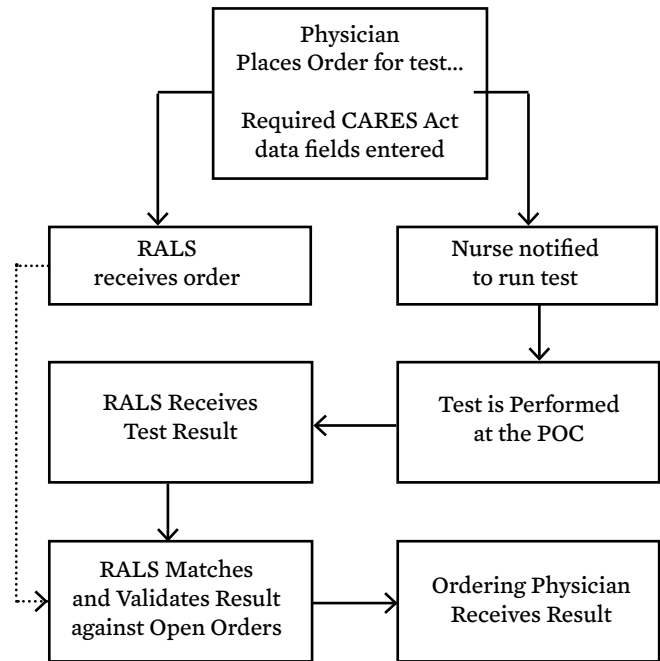


Figure 1: Orders/Solicited Workflow

### UNSOLICITED WORKFLOW

1. Doctor requests a test or series of tests
  - a. There is no order with order # in HIS/EMR
2. Operator performs test entering patient ID into meter.
  - a. Using the ADT received by RALS, PPID may or may not be turned on for device
  - b. If turned on this is used to fulfill the regulatory requirement for a second point of patient validation prior to testing
3. Meter downloads to RALS
4. Patient test result sent to the unsolicited LIS Interface for processing
  - a. LIS Interface uses ADT information to validate based on the meter’s time stamp
5. LIS receives message from RALS and takes the following action:
  - a. Creates an accession number for the result
  - b. Using patient info and the order info supplied by RALS, places the order in the HIS/EMR
  - c. On receiving the order number from the HIS/EMR, sends the result information
  - d. If the LIS is bi-directional, the accession number is returned to RALS

## 2. RALS MANUAL TEST ENTRY (MTE)

In our MTE module, we are adding the additional questions required by the CARES Act, and listed on the previous page, as configuration options for your MTE COVID testing.

**For more information, contact your RALS representative or visit [www.rals.com](http://www.rals.com)**