# NEBRASKA

# Nebraska Department of Health and Human Services Laboratory Reporting

# **Implementation Guide**

Submission of Laboratory Test Results to DHHS
Using CSV or Excel Data Format

#### Introduction

The Nebraska Department of Health and Human Services (DHHS) is committed to the health and safety of all people in Nebraska. Statute 173 NAC 1 requires that all healthcare providers and laboratories performing clinical testing on Nebraska residents must electronically report laboratory test results for reportable conditions.

DHHS uses the electronically submitted data for the purpose of disease surveillance. The Electronic Laboratory Reporting (ELR) process does not replace or relieve requirements for laboratories and facilities to report results back to the requesting providers.

ALL Long Term Care and Assisted Living reporting Facilities can report lab data electronically via an Excel file to avoid the critical delays experienced with manual reporting.

## Report Using an Excel File or CSV File

If your facility is not capable of generating HL7 messages for ELR this guide is for you.

\*\*NOTE: Long Term Care and Assisted Living Facilities are encouraged to use NHSN to report COVID Testing results. NHSN routes all results to the State for you. Once set up to successfully report via NHSN, it is no longer necessary to report using this method to the State.

Complete the following steps in order to enroll in electronic lab reporting using an Excel file:

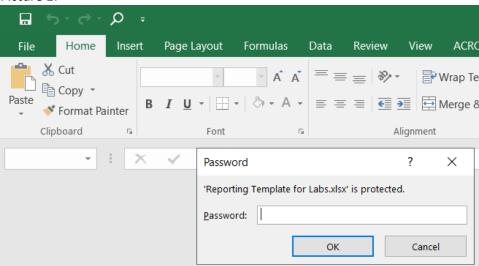
#### Forms To Download and/or Complete

- 1. Download the Excel Template for Reporting Lab Data this is a listing of all required data elements to be reported
  - a. Save it to your computer (must create a new sheet for each new report submitted)
  - b. The Excel Template has been password protected; the password will be sent to you in a separate email
- 2. Those capable of creating a CSV file must report all the data elements included in the Excel sheet.

#### Unlock the Excel Template file using the Password

1. Open the saved file on your computer and enter the password sent to you in the separate email.

Picture 1:



#### Create the CSV or Excel File

- 1. Create your Excel file by filling in/downloading the information on the 'Excel Template for Reporting Lab Data'
  - One row per laboratory test result
  - All data listed on this Excel file is required and must have data entered into those fields
  - Do NOT change any of the headers for each required data element
  - Do NOT add any additional columns or information in headers
  - Do NOT create a cumulative report with results that have already been reported
  - Only use one Excel or CSV file per test-type. Example: Antigen and PCR tests must be on separate sheets/files.
  - Facilities with Residents: if you created a Master Spreadsheet that listed all Staff and all Residents;
     must delete any staff or residents rows that were NOT tested from the sheet before sending it
  - Do not leave blank rows between results being reported
  - Do NOT paste data on dropdown list columns. Choose from the dropdown list.
- 2. CSV Files: Download the required data elements from your health information system (HIS) using the format from the Excel file in that order.

#### **Excel Spreadsheet Values**

#### Please read the following to understand the elements in the Excel Template sheet:

- 1. CLIA Number: Each facility has been issued a CLIA number if they are performing laboratory testing (including point of care, rapid antigen COVID-19).
  - \*\*The CLIA number is used to associate test results with a particular facility, and use of the incorrect CLIA number, may cause delays in processing. Please use the CLIA number of the facility where the testing was performed. If you are 3rd party reporters, please use the CLIA number for the facility where the testing was performed; if you are a laboratory performing testing for another facility, please use your own CLIA number, as the CLIA number used should be the number of the laboratory performing the testing.
- 2. Medical Director First and Last Name as well as their National Provider Identification (NPI) NO middle initial
  - IF the facility does not have a Medical Director this field may be left blank
- 3. DOB: date of birth format as M/D/YYYY or document will error
- 4. Lab Result: Choose from dropdown. (ALL results must be reported)
  - One line per result
- 5. Use the dropdown arrow next to cells in the following columns:
  - Lab Results
  - Gender
  - Race
  - Ethnicity
- 6. If the content in the above (#5) columns needs to be deleted for any reason please select the cell or the range of cells > right click > clear contents.
- 7. Device Name: There are several devices for each test type-MOLECULAR, ANTIGEN, ANTIBODY.
  - For Molecular tests your device must be FDA authorized and it can be found at <a href="https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas">https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas</a> under table named <a href="Individual EUAs for Molecular Diagnostic Tests">Individual EUAs for Molecular Diagnostic Tests</a> for SARS-CoV-2

For Antigen type your device must be FDA authorized and can be found at <a href="https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas">https://www.fda.gov/medical-devices/vitro-diagnostics-euas</a> under the table named Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2

For Antibody tests your device has to be FDA approved and can be found at <a href="https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas">https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas</a> under the table named <a href="Individual EUAs for Serology Tests for SARS-CoV-2">Individual EUAs for Serology Tests for SARS-CoV-2</a>

- 8. Searching for your device on FDA list:
  - Use the link in point # 7.
  - Locate the table that applies, based on device type.
  - On top left corner in search bar, search for the device name (See Picture 2).
  - Click on device/description name. (See Picture 2, circled in red).
  - On FDA's pdf file for device authorization see the official name to use (See Picture 3).



# Picture 3: FDA U.S. FOOD & DRUG March 24, 2021 Mary Ann Fiechtner Senior Regulatory Affairs Specialist Becton, Dickinson and Company (BD) BD Integrated Diagnostic Solutions 7 Loveton Circle Sparks, MD 21152 BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu Device: A+BEUA Number: EUA203152 Company: Becton, Dickinson and Company (BD)

- **9.** Test Performed: There are several names for SARS-CoV-2 and COVID-19 tests. A test can be Molecular, Antigen or Antibody based on the device in use. **Use one sheet for each test type.** 
  - This sheet is only for tests done by your staff using a Point of Care or facility device. Any samples sent to a lab for testing will be reported to DHHS by that lab
  - Do NOT record any pending results and do NOT record results if the test did not work
- 10. Sample Collection Date: format as MM/DD/YYYY avoid text or any other format. Do NOT report the time.

- 11. Sample Source: Choose from the dropdown list.
- 12. Result Sent Date is formatted as MM/DD/YYYY. Do NOT report the time.
- 13. For Race, Ethnicity, Gender refer to point #5
- 14. Patient Address, City, State, Zip and Phone: for Residents living in a LTC or Assisted Living facility this should be same as the Facility address. Staff testing use their home address and phone. List only one phone number per person.
- 15. Facility phone, name, address, city, state and zip
- 16. Comments: For additional information about the test.
- 17. Final Excel Sheet Naming
  - Name of Facility COVID Test Results Date Sent
  - Example: Happy Haven COVID Test Results 01-01-21

#### Submitting a report with results: Using Email

- 1. Email the spreadsheet to the following email dhhs.epi@nebraska.gov
- 2. The file is password protected; no need to send via secure email.
- 3. DHHS will enter upload test results into the State Lab Reporting System.
- Report all Positive and Negative lab test results. visit this link to see if you are required to report both
  positive and negative results <a href="https://dhhs.ne.gov/Documents/Clarification-Regarding-Public-Health-Reporting-Requirements-For-COVID-19-Testing.pdf">https://dhhs.ne.gov/Documents/Clarification-Regarding-Public-Health-Reporting-Requirements-For-COVID-19-Testing.pdf</a>
- 5. Upload files within 24 hours of receipt of the test result.
- 6. You will be notified if data is missing or corrections are needed and requested to resubmit. Corrections must be received within 5 days of notification.

How to Encrypt an Excel File: IF you create your own Excel file you must encrypt it before sending. Use the same password sent to you or we cannot open it.

#### Picture 4:



- Select File > Info
- Select the Protect Workbook box and choose Encrypt with Password

- By using the <u>SAME PASSWORD</u> sent to you by DHHS, Enter the password in the Password box > Select **OK**
- Confirm the password in the **Reenter Password box >** Select **OK**
- Email to DHHS.epi@nebraska.gov

## **Frequently Asked Questions:**

- 1. Are there any requirements on frequency of reporting this information to DHHS?
  - All tests must be reported within 24 hours of receipt of the result
  - Submit test results once a day with a summary of all results obtained since the last time the report was submitted (the previous day).
  - Report every time testing is done on the day it was performed when possible but at a minimum within 24 hours of running/receiving the result.
  - IF testing was done AFTER the daily report was submitted; include those results on the next day's report.
- 2. If the facility uses a private lab to perform the tests, do these results need to be reported on these Excel sheets?
  - NO, All tests sent to a private Laboratory are reported to DHHS by that Lab and do NOT need to be reported by your facility.
  - Facilities are only required to report COVID-19 testing that their staff performs using a Point of Care or facility testing device.
  - Report these tests using the Excel spreadsheet or a CSV file.
  - ALL tests done by facility staff using a Point of Care or facility testing device must be reported.
    - i. Report tests on both Staff AND Residents/Patients
    - ii. Report both Negative AND Positive tests visit this link to see if you are required to report both positive and negative results <a href="https://dhhs.ne.gov/Documents/Clarification-Regarding-Public-Health-Reporting-Requirements-For-COVID-19-Testing.pdf">https://dhhs.ne.gov/Documents/Clarification-Regarding-Public-Health-Reporting-Requirements-For-COVID-19-Testing.pdf</a>

#### Reporting Lab Test Results to DHHS via Upload to Website

DHHS has also implemented a method to upload files to a website to create electronic reporting of these test results. This will replace the email process above with an upload of the Excel or CSV file to a secure DHHS website. Priority for reporting using the secure DHHS website is given to facilities and laboratories based on the volume of testing being done. DHHS will reach out to each facility individually to assist you in electronically reporting when your facility is next on this priority list.

When this occurs below is a brief overview:

#### **Setting up Access**

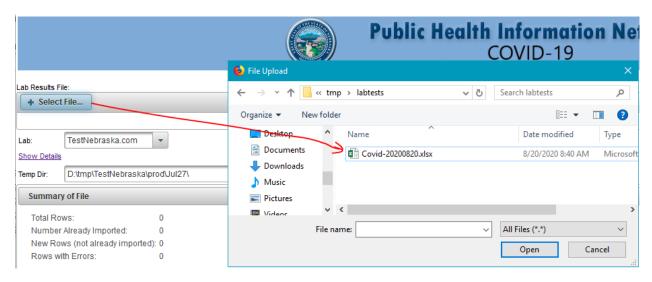
- 1. You will be contacted by a member of the DHHS team
  - DHHS will create Guardian account(s) for each reporting facility provide all individuals that will need an account to upload these files: INCLUDE their email address as well
  - Those individuals with an account will have access to upload their lab files into the system
  - The account information will be sent to you for each individual

## Accessing the DHHS Website to Submit Files

- 1. Log into Guardian
- 2. Go to 'COVID Lab Upload'

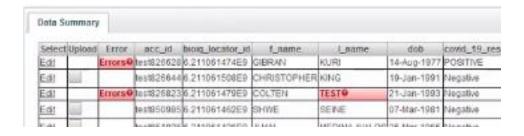
- 3. Lab: IF the correct lab sending this report is not appearing scroll down to the name of your lab and click on it
- 4. Choose the file to upload using a browser:

#### Picture 5:



- 5. The system will validate the file to ensure it passes our requirements
- Errors will appear in RED and MUST be corrected before clicking on 'Stage Files'.
  - a. All messages with errors will not import into NEDSS. Errors can be corrected within the system by clicking on the RED box in the table and typing in the correct data. SEE Picture 6.

#### Picture 6:



- 7. Click on 'Stages Files'
  - a. The file is de duplicated and the elements pulled into the DHHS format this is your final step

#### **DHHS Lab Test Message Validation and Approval**

- 1. DHHS staff log into Guardian and view the list of gueued files.
  - a. Data analysis is performed to ensure all required fields are present and formatted correctly
  - b. Files with all required fields and correct formatting are marked as 'approved'.
  - c. Marking them as 'Approve and Send' queues the messages to be sent via sFTP to the DHHS ELR system

- 2. Files that are missing data or have other issues that prevent them from being sent successfully into the DHHS ELR system;
  - a. The sending facility/lab designated staff members will receive an email with a summary of files that must be corrected and resubmitted.
  - b. Once the corrections are made; follow the steps to report the files to DHHS as above starting with 'Create the CSV or Excel File' to resubmit the corrected files

Thank you!

Last Updated: 5/2022

#### Additional resources:

 $\underline{https://www.cms.gov/Regulations-and Guidance/Legislation/CLIA/Downloads/HowObtainCertificate of Waiver.pdf}$ 

https://dhhs.ne.gov/licensure/Pages/CLIA-Clinical-Labs.aspx

https://dhhs.ne.gov/Pages/Electronic-Lab-Reporting.aspx

For additional questions please reach out to <a href="mailto:dhhs.epi@nebraska.gov">dhhs.epi@nebraska.gov</a>