

Justification for Changes made to ELIMS Information Collection Instruments, CDC Specimen Submission Form 50.34 and Global File Accessioning Template (GFAT), from October 2020 to April 2021

- 1.) Change Number 17066: “The following changes shall be made to the ELIMS database as well as the 50.34 and GFAT forms: Update existing test order SARS Molecular Detection, CDC-10412, to SARS Molecular Detection (not SARS-2) and Add new test order Respiratory Panel (SARS-2, Influenza A/B), CDC-10542.” **Justification: For the COVID-19 response, CDC testing laboratories requested modification to an existing test order name to better align with the type of testing being performed under that test order as well as the addition of a newly created test order.**
- 2.) Change Number 15880: “Add Race field to Patient information section of the Specimen Submission form. Enable a multi-select field with values of: White, Black or African American, Asian, American Indian and Alaska Native, and Native Hawaiian and Other Pacific Islander.” **Justification: The CDC Sample Management Policy of 2019 was updated to allow for the addition of a patient’s race (if known) when a sample is submitted to CDC for laboratory testing;** “When opening the 50.34 Form, incorporate detection that will notify a user when they are using a PDF reader software other than Adobe Acrobat Reader. Provide a warning message that recommends the use of Adobe Acrobat Reader to ensure proper functioning of the form, ‘Please download and use the latest version of Adobe Acrobat Reader DC to ensure proper operation of this form.’ “; **Justification: This requirement was added to the 50.34 form to ensure that a user was opening the form with Adobe Acrobat Reader in lieu of other third-party pdf readers that have sometimes caused problems with the 50.34 form’s proper functioning;** “Enable read-only functionality on the SPHL submitter fields in the 50.34 Form.” **Justification: This requirement was implemented to prevent users from modifying the reviewed and vetted SPHL-level submitter information that is available via picklist in the 50.34 form. Users were able to select an SPHL submitter from the picklist and then clear out fields related to that submitter record and make their own modification to the submitter record. This caused issues with testing reports being sent out with missing and/or incorrect SPHL submitter information.**
- 3.) Change 15952: “Add Race fields columns to Human Origin GFAT template for White, Black or African American, Asian, American Indian and Alaska Native, and Native Hawaiian and Other Pacific Islander. **Justification: The CDC Sample Management Policy of 2019 was updated to allow for the addition of a patient’s race (if known) when a sample is submitted to CDC for laboratory testing.**
- 4.) Change 14041: “Add new values to Suspected Agent Picklist: Sporothrix schenckii complex, Scedosporium species, Aspergillus flavus or Aspergillus oryzae, Pseudallescheria boydii, and Purpureocillium lilacinum.” **Justification: The Suspected Agents values were requested by CDC testing laboratories involved in testing these types of agents.**
- 5.) Change 14281: “Update SPHL Lab Director---SPHL-000057 VT Dept. of Health Laboratory.” **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 6.) Change 14555: “Update eReport recipient email address---SPHL-000137 US Virgin Islands Department of Health.” **Justification: The requesting SPHL lab had an email address change for the account that is designated to receive encrypted specimen testing reports from CDC.**
- 7.) Change 15771: “Update Point of Contact & Institutional email address--- SPHL-000092 NY-Jacobi Med. Ctr.- Parasitic and Tropical Disease Lab.” **Justification: The requesting SPHL lab had an email address change for the**

account that is designated to receive encrypted specimen testing reports from CDC and a change to the person designated as lab director.

- 8.) Change 16044: "Update Institutional email address & eReport recipient email address---SPHL-000037 AR Dept. of Health-PHL, Clinical Micro Lab." **Justification: The requesting SPHL lab had an email address change for the primary Institutional email account for the lab and a change to the account that is designated to receive encrypted specimen testing reports from CDC.**
- 9.) Change 16435: "Update Institutional email address & eReport recipient email address---SPHL-000073 CDC Occupational Health Clinic." **Justification: The requesting SPHL lab had an email address change for the primary Institutional email account for the lab and a change to the account that is designated to receive encrypted specimen testing reports from CDC.**
- 10.) Change 16504: "Update eReport recipient email address and the SPHL Lab Director information for all of the Arkansas Dept. of Public Health Labs." **Justification: The requesting SPHL lab had an email address change for the account that is designated to receive encrypted specimen testing reports from CDC and a change to the person designated as lab director.**
- 11.) Change 16678: "Update eReport recipient email address---SPHL-000015 DE Public Health Laboratory." **Justification: The requesting SPHL lab had an email address change for the account that is designated to receive encrypted specimen testing reports from CDC.**
- 12.) Change 16691: "Update Institutional email address & eReport recipient email address---SPHL-000096 Houston Health Department Laboratory." **Justification: The requesting SPHL lab had an email address change for the primary Institutional email account for the lab and a change to the account that is designated to receive encrypted specimen testing reports from CDC.**
- 13.) Change 16837: "Update Institutional email address--- SPHL-000157 PR - Biological and Chemical Emergencies Lab Office of Public Health Preparedness and Response." **Justification: The requesting SPHL lab had an email address change for the primary Institutional email account for the lab.**
- 14.) Change 18452: "Update Lab Director----SPHL-000010 Unified State Labs: Public Health Utah DOH." **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 15.) Change 19292: "Update Lab Director & Institutional email address---SPHL-000047 ALASKA State Public Health Lab, State Health Department." **Justification: The requesting SPHL lab had a new person assigned as lab director and change to the email address change for the primary Institutional email account for the lab.**
- 16.) Change 19299: "Test Order Directory Updates: Remove pre-approval/supplemental information required flag for CDC-10255 Varicella Zoster Virus (VZV) Serology and CDC-10254 Varicella Zoster Virus Detection (Wild-type vs. Vaccine); Add pre-approval/supplemental information required flag (50.34 and CSTOR) for CDC-10547 Yersinia pestis Molecular Detection, CDC-10546 Francisella tularensis Molecular Detection, CDC-10545 Influenza Molecular Surveillance, CDC-10541 HIV-1 Rapid Recency Assay, and CDC-10540 HIV-1 Limiting Antigen Avidity Enzyme Immunoassay (International Only); Revise test order names for CDC-10423 Influenza Antiviral Resistance Detection in Clinical Specimens, CDC-10421 Influenza Molecular Detection in Clinical Specimens, CDC-10241 Mumps Genotyping, and CDC-10240 Measles Genotyping; New Test Order Code and New Test Order for CDC-10549 Polio Direct Detection and Titration, CDC-10548 Polio Cell Culture Isolation, CDC-10547 Yersinia

pestis Molecular Detection, CDC-10546 Francisella tularensis Molecular Detection, CDC-10545 Influenza Molecular Surveillance, CDC-10544 Mumps Detection, CDC-10543 Measles Detection, CDC-10541 HIV-1 Rapid Recency Assay, CDC-10540, and HIV-1 Limiting Antigen Avidity EnzymeImmunoassay (International Only); and Delete Test orders and associated test code for CDC-10536 HIV-1 Laboratory Algorithm for Dried Blood Spots (DBS), CDC-10492 Toxoplasmosis Special Study, and CDC-10271 Blood Disorders Coagulation Study.”

Justification: The different types of changes identified here were requested by various CDC laboratories that perform testing specific to the identified test orders.

- 17.) Change 20069: “COVID Request--Add new picklist value to Additional ID Type fields.” **Justification: The requesting laboratory needed an additional metadata picklist value to be added to support the COVID-19 testing it was performing.**
- 18.) Change 20080: “Update Lab Director----SPHL-000073 - CDC Occupational Health Clinic.” **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 19.) Change 20275: “Update Lab Directors--SPHL-000072 and SPHL-00087.” **Justification: The requesting SPHL labs had a new person assigned as their respective lab director.**
- 20.) Change 20373: “Add Specimen source (type) picklist values Nasal midturbinate swab and Anterior nasal swab.” **Justification: The requesting lab required these two additional source (type) values be added because they received specimen material on swabs from taken from these two sources.**
- 21.) Change 20595: “Update Lab Director----SPHL-000017 WY- Public Health Laboratory.” **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 22.) Change 20859: “Update Lab Director---Georgia Department of Public Health Laboratory.” **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 23.) Change 20992: “Update lab Director---SPHL-000056 LA Office of Public Health Laboratories.” **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 24.) Change 21277: “Update lab Director---SPHL-000084 FL Bureau of Public Health Laboratories-Miami.” **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 25.) Change 21517: “Add values to Immunization Picklist: SARS-CoV-2 AstraZeneca, SARS-CoV-2 BIBP, SARS-CoV-2 Medicago, SARS-CoV-2 Bharat Biotech, SARS-CoV-2 JandJ, SARS-CoV-2 Moderna, SARS-CoV-2 Novavax, SARS-CoV-2 other, SARS-CoV-2 Pfizer, SARS-CoV-2 Sinovac, SARS-CoV-2 WIBP, and SARS-CoV-2 ZFSW.” **Justification: These Immunization picklist values were requested by the CDC COVID-19 Task Force to allow specimen submitter organizations to specify the type of COVID-19 vaccination a patient may have received.**
- 26.) Change 21602: “Test Order Directory Updates: Add pre-approval/supplemental information required flag for CDC-10551 SARS-CoV-2 Whole Genome Sequencing and CDC-10550 Rubella Genotyping; Revise Test Order Names for CDC-10242 Rubella Detection (PCR) and Genotyping; and Add New Test Orders for CDC-10551 SARS-CoV-2 Whole Genome Sequencing and CDC-10550 Rubella Genotyping.” **Justification: The different types of changes identified here were requested by various CDC laboratories that perform testing specific to the identified test orders.**

- 27.) Change 21904: "Allow Printing of 50.34 form with population of Original Submitter Institutional email address or selection of SPHL submitter record." **Justification: This is a functional change to the CDC Specimen Submission 50.34 Form to provide the user with increased flexibility to print the form by selecting either a SPHL submitter record from the form's read-only picklist or by providing an email in the Original Submitter Institutional email field. Previously, the form would only print on selection of SPHL submitter record which caused issues with some specimen submissions that only had an Original submitter and no associated SPHL submitter organization.**
- 28.) Change 22795: "Update laboratory address---SPHL-000057 - VT Dept. of Health Laboratory." **Justification: The requesting SPHL lab had a change to its mailing address.**
- 29.) Change 21281: "Update Lab Director---SPHL-000052 DC Public Health Lab/ Dept. of Forensic Sciences." **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 30.) Change 21646: "Update Lab address---SPHL-000130 CDPH - Vector-Borne Disease Section." **Justification: The requesting SPHL lab had a change to its mailing address.**
- 31.) Change 21662: "Update Lab Director and Institution Street Address for All Lab Sections--- NYSDOH - Wadsworth Center, Bacteriology Lab, Biodefense Lab, Bloodborne Viruses Lab, Diag. Immunology Lab, Mycology Lab, Parasitology Lab, Tuberculosis Lab, and Virology Lab (SPHL-000023, SPHL-000024, SPHL-000025, SPHL-000026, SPHL-000027, SPHL-000028, SPHL-000029, SPHL-000030, and SPHL-000031)." **Justification: The requesting collective group of NYSDOH labs had a new person assigned as lab director as well as a change to their mailing address.**
- 32.) Change 21671: "Update lab Director---SPHL-000034 - MN PHL Division, Minnesota Department of Health." **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 33.) Change 21683: "Update Lab Director, Institutional Email Address & eReports email recipient ---SPHL-000022 - IN State Department of Health Laboratory Services." **Justification: The requesting SPHL lab had a new person assigned as lab director, an email address change for the primary Institutional email account, and an email address change for the account that is designated to receive encrypted specimen testing reports from CDC.**
- 34.) Change 21687: "Update Institution address & Fax Number---SPHL-000051 - AL Dept. of Public Health Bureau of Clinical Laboratories." **Justification: The requesting SPHL lab had a change to its mailing address and primary Fax number.**
- 35.) Change 21695: "Update Laboratory Zip Code---SPHL-000050 RI State Health Laboratories." **Justification: The requesting SPHL lab had a change to its mail zip code.**
- 36.) Change 21702: "Update laboratory fax number---SPHL-000063 OR State PHL-Virology/Immunology Section." **Justification: The requesting SPHL lab had a change to its primary Fax number.**
- 37.) Change 23446: "Update Lab Director---SPHL-000067 NV State Public Health Laboratory." **Justification: The requesting SPHL lab had a new person assigned as lab director.**
- 38.) Change 23710: "Add new Global Submitters ---SPHL-000159 GU - Guam Public Health Laboratory and SPHL-000160 MP - Commonwealth Health Center." **Justification: The two SPHL organizations requested to be added**

to the vetted, read-only ELIMS Global Submitters list which makes them eligible to receive encrypted specimen testing reports from CDC.