Explanation for Program Changes or Adjustments

There are 11 total forms being changed as a part of this non substantive change request. This change request includes minor revised language, formatting and re-wording to improve clarity and readability of the data collection forms.

In response to the Notice of Decision published in the Federal Register on March 29, 2024 regarding the update of the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), the EIP programs (ABCs, FoodNet, FluSurv-NET, and HAIC) under OMB 0920-0978 will comply with the updated standards set for Federal data on Race and Ethnicity by and/or before the March 2029 deadline.

FluSurv-NET has incorporated the updated race and ethnicity (R/E) data standards in their data collection forms as part of a recently approved Revision. The remaining 3 EIP programs (ABCs, FoodNET, and HAIC) will update the R/E variable in a subsequent non-substantive by and/or before the March 2029 deadline in efforts to maintain data integrity. Maintaining data integrity and consistency is paramount to quality data analysis therefore, waiting to incorporate the race and ethnicity changes for ABCs, FoodNET and HAIC would ensure that the race ethnicity data variable will possess consistent parameters and easier for analysis. Within this change request a few of the data collection tools have updated the R/E variable. The remaining data collection tools will be ultimately updated before the March 2029 deadline.

Details of each collection instrument are as follows:

ABCs:

This non-substantive change request includes minor proposed changes to 2 approved data collection tools (form/s) detailed below:

Approved Forms:
1) ABCs Case Report Form (ABC.100.1)
2) ABCs Neonatal Infection Expanded Tracking Form (ABC.100.5)

ABCs Case Report Form (ABC.100.1)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Revision	2026 Active Bacterial Core surveillance (ABCs) Case Report **Justification:** Updated header to reflect surveillance year	No change to burden
Revision	T1 – Test Type 1=Nucleic acid amplification test (NAAT) 2=Culture 7=Other (specify) 9=Unknown **Justification:** The label for the T1 test-type category has been updated from **1=PCR** to **1=NAAT** to more accurately reflect the data captured under this category. This change improves data accuracy, reduces misclassification, and aligns the CRF with current diagnostic practices across ABCs laboratories. In addition, the label for **7=Other** has been revised to **7=Other (specify)** to clearly indicate that additional details should be provided when this option is selected.	No change to burden
Revision	T3 – Test Method 1=Biofire Filmarray Meningitis/Encephalitis Panel 2=Other (Specify) 3=Biofire Filmarray Blood Culture (BCID) Panel 4=Verigene Gram + Blood Culture (BCT) Test 5=Bruker MALDI Biotyper CA System 9=Unknown 10=Biofire Joint Infection (JI) Panel 11=Roche cobas eplex BCID Panel 12=Karius 13=16s rRNA sequencing 14=Delve Bio mNGS **Justification:** The test-method value set was expanded to incorporate additional diagnostics increasingly used across ABCs sites but not previously captured in a systematic manner. These additions allow for more complete and accurate reporting of CIDT methods that have emerged. In addition, an option to specify the test when “Other” is selected was added to ensure that novel, uncommon, or evolving diagnostic methods can be consistently documented. This change improves data quality by reducing reliance on freetext comments and better supports ongoing efforts to track new testing technologies and trends across sites.	No change to burden
Deletion	Q27d. Other Substances:	No change to

	Documented Use Disorder (DUD/Abuse) **Justification:** The checkbox for indicating documented use disorder or abuse for other substances such as marijuana, opioids, cocaine, and methamphetamine is being removed as it has contributed little analytic value while adding abstraction burden. Removing this field simplifies data collection and ensures that substance use information focuses on variables that are reliably captured and directly used in analysis.	burden
Deletion	Q27d. Other Substances: Mode of delivery: Skin popping **Justification:** "Skin popping" is being removed as a standalone response option because it represents a specific form of injection drug use (IDU), and distinguishing it separately has not been necessary for ABCs analyses.	No change to burden
ABCs Neonatal Infection Expanded Tracking Form (ABC.100.5)		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Revision	Q9b. IF YES, were any of the following ICD-10 codes reported in the discharge diagnosis of the chart? (Check all that apply) ☐ A40.1: Sepsis due to streptococcus, group B ☐ A40.8: Other Streptococcal sepsis ☐ A40.9: Streptococcus sepsis, unspecified ☐ A49.1: Streptococcal infection, unspecified site ☐ B95.1: Streptococcus, group b as the cause of disease classified elsewhere ☐ B95.5: Unspecified streptococcus as the cause of disease classified elsewhere ☐ G00.2: Streptococcal meningitis ☐ J15.3: Pneumonia due to streptococcus, group B ☐ P00.82: Newborn affected by (positive) maternal group B streptococcus (GBS) colonization ☐ P23.3: Congenital pneumonia due to streptococcus, group B ☐ P36: Bacterial sepsis of newborn ☐ P36.0: Sepsis of newborn to due to streptococcus, group B ☐ P36.1: Sepsis of newborn to other unspecified streptococci ☐ P36.9: Bacterial sepsis of newborn, unspecified **Justification**: To ensure more complete and accurate identification of Group G *Streptococcus* (GBS)–related hospitalizations, we added three additional ICD10 codes (J15.3, P00.82, P23.3) to the existing discharge diagnosis question. These additional codes helps ensure that all GBS-related discharge diagnoses that may appear in the medical record are captured. This change does **not** increase burden for surveillance staff. Sites are already reviewing discharge diagnoses during chart abstraction, and the expanded list simply clarifies which codes should be recorded when present.	No change to burden

FluSurv-NET

This non-substantive change request includes minor proposed changes to 2 approved data collection tools (form/s) detailed below:

Approved Forms:

1) FSN 300.1 2024-25 Influenza Hospitalization Surveillance Network (FluSurv-NET) Case Report Form
2) FSN 300.4 2024-25 Influenza Hospitalization Surveillance Network (FluSurv-NET) Lab Survey

Influenza Hospitalization Surveillance Network (FluSurv-NET) Case Report Form (FSN 300.1)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Non-substantive change (clarification)	**C. Enrollment Information** **1. Case Classification:** • Surveillance Discharge Audit • Observation Only **Justification** • Clarifying the type of case by adding the observation status to the case report form could better characterize the severity of influenza-associated hospitalizations. This field of "Observation Only" was collected in previous seasons.	No change to burden
Non-substantive change (simplification)	**C. Enrollment Information** **11. Pregnant (15-49 years of age)?** • Yes • No • ~~Not applicable (male/pregnant outside of applicable age range)~~ **Justification** • Branching logic could be applied to streamline this question in the database, so that this option "Not applicable (male/pregnant outside of applicable age range" could be removed.	No change to burden
Non-substantive change (clarification)	**D. Influenza Testing Results** **Test Results 1-4:** • Flu A (no subtype) • 2009 H1N1 • ~~H1, Unspecified~~ • ~~H1, Seasonal~~ • H1 • H3 • H5 • Flu A, Unsubtypable • Flu B (no lineage) • Flu B, Victoria	No change to burden

	• Flu B, Yamagata • Flu A & B • Flu A/B (not distinguished) • Unknown Type • Negative • H3N2v • Other, please specify **Justification** • Checkboxes “H1, Unspecified” and “H1, Seasonal” were removed because they are rarely applicable and are confusing terms for data collection. Added “H5” reflects what can be identified in current laboratory results.	
Non-substantive change (clarification)	**F. Outcome** **2. If patient discharged alive, please indicate to where:** • Private residence • Private residence with services • Homeless/Shelter/Temporary housing • Nursing home/Skilled nursing facility • Substance abuse treatment center • Rehabilitation facility • Corrections facility • Hospice • Assisted living/Residential care • LTACH • Group/Retirement home • Psychiatric/Behavioral Health Facility • Other long term care facility • Against medical advice (AMA)/Elopement • Discharged to another hospital • Other, specify • Unknown **Justification** • Including “elopement” as a clarification to the existing “against medical advice (AMA)” option reflects common language used for this discharge scenario in medical records.	No change to burden
Non-substantive change (clarification)	**G. Admission and Patient History** **3. Date of onset of fever or acute respiratory symptoms (within 2 weeks before a positive test), whichever is earlier: __/__/____** • Approximate date entered • Unknown • Not applicable **Justification** • Fever was the most common non-respiratory symptom recorded	No change to burden

	among influenza-associated hospitalizations. Additionally, pediatric influenza-associated hospitalizations often present with fever first or may lack other respiratory symptoms. Thus, clarifying the date of onset of acute respiratory symptoms to include fever is anticipated to more accurately capture symptom onset date related to an acute influenza illness, particularly for children. • Clarified whether the date of fever or acute respiratory symptom onset reflects an exact or approximate date to increase capture of symptom onset dates and also allow refinement to those with an exact symptom onset date for relevant data analyses, including the impact of timely antiviral treatment.	
Non-substantive change (clarification)	**H. Underlying Medical Conditions** **1n. Gastrointestinal/Liver Disease (Do Not Record GERD):** ☐ Yes ☐ No/Unknown ☐ Alcoholic hepatitis ☐ Autoimmune hepatitis ☐ Barrett's esophagitis ☐ Chronic liver disease ☐ Chronic pancreatitis ☐ Cirrhosis/End stage liver disease (ESLD) ☐ Crohn's disease ☐ Esophageal strictures ☐ Esophageal varices ☐ Hepatitis B, chronic (HBV) ☐ Hepatitis C, chronic (HCV) ☐ Non-alcoholic fatty liver disease (NAFLD)/NASH/Metabolic dysfunction-associated steatotic liver disease (MASLD) ☐ Ulcerative colitis (UC) **Justification** • Clarifying underlying medical condition terminology of NAFLD/NASH to include metabolic dysfunction-associated steatotic liver disease (MASLD) updates the current medical terminology for the condition.	No change to burden
Non-substantive change (clarification)	**H. Underlying Medical Conditions**	No change to burden

	1r. PEDIATRIC CASES ONLY ☐ Abnormality of airway *(see instructions)* ☐ Chronic lung disease of prematurity/Bronchopulmonary dysplasia (BPD) ☐ History of febrile seizures ☐ Long term aspirin therapy **For pediatric patients <2 years old: Premature?** *(gestational age < 37 weeks at birth)* ☐ Yes If yes, specify gestational age at birth in weeks:_____ ☐ Unknown gestational age at birth ☐ No ☐ Unknown **Justification** • Clarifies question language to minimize confusion. Adding "No" and "Unknown" allows for complete capture of all possible answers.	
Non-substantive change (clarification)	**I. Viral Pathogens** **1. Was the patient tested for any of the following viral respiratory pathogens within 14 days prior to admission or ≤ 3 days after admission?** 1a. RSV 1b. Coronavirus SARS-CoV-2 1c. Adenovirus 1d. Parainfluenza 1 1e. Parainfluenza 2 1f. Parainfluenza 3 1g. Parainfluenza 4 1h. Parainfluenza (not further specified) 1i. Human metapneumovirus 1j. Rhinovirus/Enterovirus 1k. Coronavirus 229E 1l. Coronavirus HKU1 1m. Coronavirus NL63 1n. Coronavirus OC43 1o. Coronavirus (not further specified) **Justification** • Clarifies available options for hospital lab diagnostic test results.	No change to burden
Non-substantive change (clarification)	**L. Discharge Summary** 1. Did the patient have any of the following new diagnoses at discharge? (select all that apply) ☐ No discharge summary available	No change to burden

Acute complication of sickle cell	☐ Yes	☐ No/Unknown	
Acute encephalopathy/encephalitis	☐ Yes	☐ No/Unknown	
Acute necrotizing encephalopathy/encephalitis (ANE)	☐ Yes	☐ No/Unknown	
Influenza-associated encephalopathy/encephalitis (IAE)	☐ Yes	☐ No/Unknown	
Acute liver failure	☐ Yes	☐ No/Unknown	
Acute myocardial infarction	☐ Yes	☐ No/Unknown	
Acute myocarditis	☐ Yes	☐ No/Unknown	
Acute renal failure/acute kidney injury	☐ Yes	☐ No/Unknown	
Acute respiratory distress syndrome (ARDS)	☐ Yes	☐ No/Unknown	
Acute respiratory failure	☐ Yes	☐ No/Unknown	
Asthma exacerbation	☐ Yes	☐ No/Unknown	
Atrial fibrilation (Afib) new-onset or paroxysmal/chronic	☐ Yes	☐ No/Unknown	
Bacteremia	☐ Yes	☐ No/Unknown	
Bronchiolitis	☐ Yes	☐ No/Unknown	
Bronchitis	☐ Yes	☐ No/Unknown	
Cardiac arrest	☐ Yes	☐ No/Unknown	
Chronic lung disease of prematurity/BPD	☐ Yes	☐ No/Unknown	
Congestive heart failure exacerbation	☐ Yes	☐ No/Unknown	
COPD exacerbation	☐ Yes	☐ No/Unknown	
Deep vein thrombosis (DVT)	☐ Yes	☐ No/Unknown	
Diabetic ketoacidosis	☐ Yes	☐ No/Unknown	
Disseminated intravascular coagulation (DIC)	☐ Yes	☐ No/Unknown	
Guillain-Barre syndrome	☐ Yes	☐ No/Unknown	
Hemophagocytic syndrome	☐ Yes	☐ No/Unknown	
Invasive pulmonary aspergillosis	☐ Yes	☐ No/Unknown	
Kawasaki disease	☐ Yes	☐ No/Unknown	
Mucormycosis	☐ Yes	☐ No/Unknown	
Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)	☐ Yes	☐ No/Unknown	
Other thrombosis/embolism/coagulopathy	☐ Yes	☐ No/Unknown	
Pneumonia	☐ Yes	☐ No/Unknown	
Pulmonary embolism (PE)	☐ Yes	☐ No/Unknown	
Reye's Syndrome	☐ Yes	☐ No/Unknown	
Rhabdomyolysis	☐ Yes	☐ No/Unknown	
Sepsis	☐ Yes	☐ No/Unknown	
Seizures	☐ Yes	☐ No/Unknown	
Stroke (CVA)	☐ Yes	☐ No/Unknown	
Supraventricular tachycardia (SVT)	☐ Yes	☐ No/Unknown	
Toxic shock syndrome (TSS)	☐ Yes	☐ No/Unknown	
Ventricular fibrillation (Vfib)	☐ Yes	☐ No/Unknown	
Ventricular tachycardia (V-tach)	☐ Yes	☐ No/Unknown	
Justification			

	• Adding acute necrotizing encephalopathy/encephalitis (ANE) and acute influenza-associated encephalopathy/encephalitis (IAE) clarifies more specific types of acute encephalopathy/encephalitis could be identified, though these types of encephalopathy/encephalitis have been rare. Due to recent increased attention and awareness of these rare influenza-associated complications in children hospitalized with influenza, monitoring the occurrences of these complications is a priority for our program.	
Non-substantive change (clarification)	**P. Additional Comments (For site use only)** **Justification** • "Additional Comments" field has been established as site-use only for multiple seasons. Updating field to state "for site use only" would clarify the purpose of the field.	No change to burden

Influenza Hospitalization Surveillance Network (FluSurv-NET) Lab Survey (FSN 300.4)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Non-substantive change (simplification)	Testing facility name:_____ Testing facility ID: _____ Name of person responding to questions from laboratory: _____ ~~Title:_____~~ Date: _____ **Justification** • The "Title" field is redundant with later form question asking the role of the person completing the survey. Removing the field removes redundancy.	Reduction in burden
Non-substantive change (correction)	3. Does the laboratory perform diagnostic testing for influenza on-site? • Yes -> *Answer question 4* • No -> *Skip to question 8* **Justification:** • Correction of the skip logic due to the renumbering of later questions in the survey. This is needed to ensure accuracy of the question numbering of the survey.	No change to burden
Non-substantive change (clarification)	4a. Select the kit name(s) (manufacturer) for the rapid influenza antigen diagnostic test(s) performed or planned to be used at the laboratory:	No change to burden

	☐ Acucy Influenza A&B Test (Sekisui Diagnostics, LLC) ☐ BD Veritor™ System for Rapid Detection of Flu A+B (CLIA-waived), (Becton Dickinson & Co.) ☐ BD Veritor™ System for Rapid Detection of Flu A+B (Moderately Complex), (Becton Dickinson & Co.) ☐ BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B (Becton Dickinson & Co.) ☐ Binax NOW® Influenza A&B Card 2 (Abbott) ☐ BioSign® Flu A+B or LifeSign LLC Status Flu A & B (Princeton BioMeditech Corp.) ☐ CareStart Flu A&B Plus, (Access Bio, Inc.) ☐ McKesson Consult Influenza A & B Test (McKesson Medical-Surgical Inc.) ☐ Meridian Bioscience™ ImmunoCard STAT!™ FLU A&B (Fisher Scientific™) ☐ OSOM Flu SARS-CoV-2 Combo Test (Sekisui Diagnostics, LLC) ☐ OSOM Ultra Plus Flu A&B Test (Sekisui Diagnostics, LLC) ☐ QuickVue® Influenza A+B Test (Quidel Corp.) ☐ SARS-CoV-2 & Flu A/B Rapid Antigen Test (Roche) ☐ SEKISUI Diagnostics™ OSOM™ Ultra Plus Flu A and B Test Kit (Fisher Scientific™) ☐ Sofia® Analyzer and Influenza A+B FIA (CLIA-waived) (Quidel Corp.) ☐ Sofia® Analyzer and Influenza A+B FIA (Quidel Corp.) ☐ Sofia® 2 Flu + SARS Antigen FIA, (Quidel) ☐ Sure-Vue™ Signature Influenza A and B Test Kit ☐ XPECT™ Influenza A/B (Remel Inc./Thermo Fisher Scientific™) ☐ Other, specify: _____ **Justification** • Updating checkboxes to reflect new kit names eliminates the need to complete write-in field and lessens burden on surveillance officers and lab staff completing the survey.	
Non-substantive change (correction)	5. Does the laboratory perform molecular assays (including rapid molecular, RT-PCR, RVPs) for influenza? • Yes -> Answer questions 5a-5b • No -> Skip to question 6 **Justification** • Correction of the skip logic due to the removal of question 5b (listed later in the explanation of changes). This is needed to ensure accuracy of which questions to complete.	No change to burden
Non-substantive change (clarification)	5a. Select the kit name(s) (manufacturer) for all molecular assays performed or planned to be used at the laboratory:	No change to burden

	☐ Alinity M Resp-4 Plex Assay (Abbott)‡ ☐ Allplex Respiratory Panel A1 (Seegene)* ☐ Allplex RV Master Assay (Seegene)‡ ☐ Allplex SARS-CoV-2/Flu A/Flu B/RSV Assay (Seegene)‡ ☐ Aptima SARS-CoV-2/Flu/A/B (Hologic)‡ ☐ ARIES® Flu A/B & RSV+SARS-CoV-2 Assay (Diasorin)‡ ☐ BD Respiratory Viral Panel for BD MAX System (BD)‡ ☐ BioCode® CoV-2 Flu Plus Assay (Applied BioCode Inc)‡ ☐ BioCode® Respiratory Pathogen Panel, (Applied BioCode Inc)* ☐ BioFire® FilmArray Pneumonia (PN) Panel ☐ BioFire® FilmArray Pneumonia plus (PNplus) Panel (Biomerieux) ☐ BioFire® Respiratory Panel 2.1 (RP2.1) (Biomerieux)*‡ ☐ BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) (Biomerieux)*‡ ☐ BioFire® Respiratory 2.1plus (RP2.1plus) Panel (Biomerieux)*‡ ☐ BioFire® SpotFire® Respiratory Panel†*‡ ☐ BioFire® SpotFire® Respiratory Panel Mini†‡ ☐ BioFire® SpotFire® Respiratory/Sore Throat (R/ST) Panel†*‡ ☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A Subtyping Kit), (CDC Influenza Division) ☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A/B Typing Kit), (CDC Influenza Division) ☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza B Lineage Genotyping Kit), (CDC Influenza Division) ☐ CDC Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set, (CDC Influenza Division) ☐ CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (CDC Influenza Division)‡ ☐ Cobas Liat Influenza A/B & RSV, (Roche Diagnostics)† ☐ Cobas Liat SARS-CoV-2, Influenza A/B, and RSV (Roche)†‡ ☐ Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics)†‡ ☐ Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test, (Roche Diagnostics)	

	☐ ePlex Respiratory Pathogen Panel 2, (Roche Diagnostics)*‡ ☐ ID Now™ Influenza A&B (CLIA Waived), (Abbott)† ☐ ID Now™ Influenza A&B 2 (CLIA Waived) (Abbott)† ☐ Liaison NES Flu A/B, RSV, & COVID-19 Assay (Diasorin)†‡ ☐ Liaison Plex Respiratory Flex Assay (Diasorin)*‡ ☐ Lyra Influenza A+B Assay, (Quidel) ☐ NeuMoDX Influenza A/b, RSV, and SARS-Cov-2 Vantage Assay (Qiagen)‡ ☐ Nx-TAG® Respiratory Pathogen Panel, (Diasorin)* ☐ Nx-TAG® Respiratory Pathogen Panel v2 (Diasorin)*‡ ☐ Nx-TAG® Respiratory Pathogen Panel + SARS-CoV-2 (Diasorin)*‡ ☐ Panther Fusion® Flu A/B RSV, Assay (Hologic) ☐ Panther Fusion® SARS-CoV-2/Flu A/B/RSV (Hologic)‡ ☐ QIAstat-Dx Respiratory Panel Mini (QIAGEN)‡ ☐ QIAstat-Dx Respiratory Panel Plus (QIAGEN)*‡ ☐ QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)*‡ ☐ Quest Diagnostics RC COVID-19 +Flu RT-PCR, (Quest Diagnostics)‡ ☐ RealStar Influenza Screen & Type RT-PCR (Altona Diagnostics) ☐ RealStar Influenza Screen & Type RT-PCR 4.0 (Altona Diagnostics)* ☐ Simplexa™ COVID-19/Flu A/B/RSV Direct (Diasorin)‡ ☐ Simplexa™ COVID-19 & Flu A/B Direct (Diasorin)‡ ☐ Simplexa™ Flu A/B & RSV Direct Gen II (Diasorin)‡ ☐ Solana Influenza A+B Assay, (Quidel) ☐ Solana Respiratory Viral Panel, (Quidel) ☐ The Metrix COVID/Flu Test (Sekisui Diagnostics)†‡ ☐ Verigene® Respiratory Pathogen Nucleic Acid Test (RP *Flex*), (Diasorin)* ☐ Xpert Xpress COV-2/Flu/RSV plus (Cepheid)†‡ ☐ Xpert Xpress Flu (Cepheid)† ☐ Xpert Xpress Flu/RSV Assay, (Cepheid)† ☐ In-house developed PCR assay ☐ Other, specify: _____ **Justification** • Updating checkboxes to reflect new kit names eliminates the need to complete write-in field and lessens burden on surveillance officers and lab staff completing the survey.	
Non-substantive change (simplification)	~~5b. If more than one kit is selected above, please select the one kit that is (or will be) used most frequently for molecular assay at the laboratory during the current influenza season~~ **Justification** • The relevant information is more appropriately collected through existing questions, so this question can be removed from the form.	Reduction in burden
Non-substantive change (correction)	5b. Does the laboratory perform influenza A subtyping? **Justification:** • Correction of the question number due to the removal of the original 5b question. This is needed to ensure accuracy of the question	No change to burden

	numbering of the survey.	
Non-substantive change (clarification)	6. Of the kits selected in 4a and 5a, which influenza test kit does the laboratory perform most frequently for hospitalized and ED pediatric patients (aged 0-17 years)? (*Select one*) ○ Two kits are equally used most frequently ○ Acucy Influenza A&B Test (Sekisui Diagnostics, LLC) ○ Alinity M Resp-4 Plex Assay (Abbott)‡ ○ Allplex Respiratory Panel A1 (Seegene)* ○ Allplex RV Master Assay (Seegene)‡ ○ Allplex SARS-CoV-2/Flu A/Flu B/RSV Assay (Seegene)‡ ○ Aptima SARS-CoV-2/Flu/A/B (Hologic)‡ ○ ARIES® Flu A/B & RSV+SARS-CoV-2 Assay (Diasorin)‡ ○ BD Respiratory Viral Panel for BD MAX System (BD)‡ ○ BD Veritor™ System for Rapid Detection of Flu A+B (CLIA-waived) (Becton Dickinson & Co.) ○ BD Veritor™ System for Rapid Detection of Flu A+B (Moderately Complex) (Becton Dickinson & Co.) ○ BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B (Becton Dickinson & Co.) ○ Binax NOW® Influenza A&B Card 2 (Abbott) ○ BioCode® CoV-2 Flu Plus Assay (Applied BioCode Inc)‡ ○ BioCode® Respiratory Pathogen Panel (Applied BioCode Inc)* --- ○ BioFire® FilmArray Pneumonia (PN) Panel ○ BioFire® FilmArray Pneumonia plus (PNplus) Panel (Biomerieux) ○ BioFire® Respiratory Panel 2.1 (RP2.1) (Biomerieux)*‡ ○ BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) (Biomerieux)*‡ ○ BioFire® Respiratory 2.1plus (RP2.1plus) Panel (Biomerieux)*‡ ○ BioFire® SpotFire® Respiratory Panel†*‡ ○ BioFire® SpotFire® Respiratory Panel Mini†‡ ○ BioFire® SpotFire® Respiratory/Sore Throat (R/ST) Panel†*‡ ○ BioSign® Flu A+B or LifeSign LLC Status Flu A & B (Princeton BioMeditech Corp.) ○ CareStart Flu A&B Plus (Access Bio, Inc.) ○ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A Subtyping Kit), (CDC Influenza Division) ○ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A/B Typing Kit), (CDC Influenza Division) ○ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza B Lineage Genotyping Kit), (CDC Influenza Division) ○ CDC Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set (CDC Influenza Division)	Reduction in burden

	○ CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (CDC Influenza Division)‡ ○ Cobas Liat Influenza A/B & RSV (Roche Diagnostics)† ○ Cobas Liat SARS-CoV-2, Influenza A/B, and RSV (Roche)†‡ ○ Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics)†‡ ○ Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test (Roche Diagnostics) ○ ePlex Respiratory Pathogen Panel 2 (Roche Diagnostics)*‡ ○ ID Now™ Influenza A&B (CLIA-Waived) (Abbott)† ○ ID Now™ Influenza A&B 2 (CLIA-Waived) (Abbott)† ○ In-house developed PCR assay ○ Liaison NES Flu A/B, RSV, & COVID-19 Assay (Diasorin)†‡ ○ Liaison Plex Respiratory Flex Assay (Diasorin)*‡ ○ Lyra Influenza A+B Assay (Quidel) ○ McKesson Consult Influenza A & B Test (McKesson Medical-Surgical Inc.) ○ Meridian Bioscience™ ImmunoCard STAT!™ FLU A&B (Fisher Scientific™) ○ NeuMoDX Influenza A/b, RSV, and SARS-CoV-2 Vantage Assay (Qiagen)‡ ○ Nx-TAG® Respiratory Pathogen Panel (Diasorin)* ○ Nx-TAG® Respiratory Pathogen Panel v2 (Diasorin)*‡ ○ Nx-TAG® Respiratory Pathogen Panel + SARS-CoV-2 (Diasorin)*‡ ○ OSOM Flu SARS-CoV-2 Combo Test (Sekisui Diagnostics, LLC) ○ OSOM Ultra Plus Flu A&B Test (Sekisui Diagnostics, LLC) ○ Panther Fusion® Flu A/B RSV Assay (Hologic) ○ Panther Fusion® SARS-CoV-2/Flu A/B/RSV (Hologic)‡ ○ QIAstat-Dx Respiratory Panel Mini (QIAGEN)‡ ○ QIAstat-Dx Respiratory Panel Plus (QIAGEN)*‡ ○ QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)*‡	

	○ Quest Diagnostics RC COVID-19 + Flu RT-PCR (Quest Diagnostics)‡ ○ QuickVue® Influenza A+B Test (Quidel Corp.) ○ RealStar Influenza Screen & Type RT-PCR (Altona Diagnostics) ○ RealStar Influenza Screen & Type RT-PCR 4.0 (Altona Diagnostics)* ○ SARS-CoV-2 & Flu A/B Rapid Antigen Test (Roche) ○ SEKISUI Diagnostics™ OSOM™ Ultra Plus Flu A and B Test Kit (Fisher Scientific™) ○ Simplexa™ COVID-19/Flu A/B/RSV Direct (Diasorin)‡ ○ Simplexa™ COVID-19 & Flu A/B Direct (Diasorin)‡ ○ Simplexa™ Flu A/B & RSV Direct Gen II (Diasorin)‡ ○ Sofia® Analyzer and Influenza A+B FIA (CLIA-waived) (Quidel Corp.) ○ Sofia® Analyzer and Influenza A+B FIA (Quidel Corp.) ○ Sofia® 2 Flu + SARS Antigen FIA (Quidel) ○ Solana Influenza A+B Assay (Quidel) ○ Solana Respiratory Viral Panel (Quidel) ○ Sure-Vue™ Signature Influenza A and B Test Kit ○ The Metrix COVID/Flu Test (Sekisui Diagnostics)†‡ ○ Verigene® Respiratory Pathogen Nucleic Acid Test (RP Flex) (Diasorin)* ○ XPECT™ Influenza A/B (Remel Inc./Thermo Fisher Scientific™) ○ Xpert Xpress COV-2/Flu/RSV plus (Cepheid)†‡ ○ Xpert Xpress Flu (Cepheid)† ○ Xpert Xpress Flu/RSV Assay (Cepheid)† ○ Not applicable (no pediatric testing) ○ Other, specify: _____ †= Rapid Molecular *= can detect subtype ‡=Multiplex for influenza/SARS-CoV-2 **Justification** • Clarifies which kits and patient group should be referred to for answering the question. Updating the answer choices to the list of kits eliminates burden of survey respondents classifying the kit by type and number of targets.	
Non-substantive change (clarification)	6a. If you responded to 6 that two kits are used with equal frequency for pediatric testing, please select the two kits. *If not applicable, skip to question 7.*	No change to burden

	☐ Acucy Influenza A&B Test (Sekisui Diagnostics, LLC) ☐ Alinity M Resp-4 Plex Assay (Abbott)‡ ☐ Allplex Respiratory Panel A1 (Seegene)* ☐ Allplex RV Master Assay (Seegene)‡ ☐ Allplex SARS-CoV-2/Flu A/Flu B/RSV Assay (Seegene)‡ ☐ Aptima SARS-CoV-2/Flu/A/B (Hologic)‡ ☐ ARIES® Flu A/B & RSV+SARS-CoV-2 Assay (Diasorin)‡ ☐ BD Respiratory Viral Panel for BD MAX System (BD)‡ ☐ BD Veritor™ System for Rapid Detection of Flu A+B (CLIA-waived) (Becton Dickinson & Co.) ☐ BD Veritor™ System for Rapid Detection of Flu A+B (Moderately Complex) (Becton Dickinson & Co.) ☐ BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B (Becton Dickinson & Co.) ☐ Binax NOW® Influenza A&B Card 2 (Abbott) ☐ BioCode® CoV-2 Flu Plus Assay (Applied BioCode Inc)‡ ☐ BioCode® Respiratory Pathogen Panel (Applied BioCode Inc)* ☐ BioFire® FilmArray Pneumonia (PN) Panel ☐ BioFire® FilmArray Pneumonia plus (PNplus) Panel (Biomerieux) ☐ BioFire® Respiratory Panel 2.1 (RP2.1) (Biomerieux)*‡ ☐ BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) (Biomerieux)*‡ ☐ BioFire® Respiratory 2.1plus (RP2.1plus) Panel (Biomerieux)*‡ ☐ BioFire® SpotFire® Respiratory Panel†*‡ ☐ BioFire® SpotFire® Respiratory Panel Mini†‡ ☐ BioFire® SpotFire® Respiratory/Sore Throat (R/ST) Panel†*‡ ☐ BioSign® Flu A+B or LifeSign LLC Status Flu A & B (Princeton BioMeditech Corp.) ☐ CareStart Flu A&B Plus (Access Bio, Inc.) ☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A Subtyping Kit), (CDC Influenza Division) ☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A/B Typing Kit), (CDC Influenza Division)	

	☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza B Lineage Genotyping Kit), (CDC Influenza Division) ☐ CDC Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set (CDC Influenza Division) ☐ CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (CDC Influenza Division)‡ ☐ Cobas Liat Influenza A/B & RSV (Roche Diagnostics)† ☐ Cobas Liat SARS-CoV-2, Influenza A/B, and RSV (Roche)†‡ ☐ Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics)†‡ ☐ Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test (Roche Diagnostics) ☐ ePlex Respiratory Pathogen Panel 2 (Roche Diagnostics)*‡ ☐ ID Now™ Influenza A&B (CLIA-Waived) (Abbott)† ☐ ID Now™ Influenza A&B 2 (CLIA-Waived) (Abbott)† ☐ In-house developed PCR assay ☐ Liaison NES Flu A/B, RSV, & COVID-19 Assay (Diasorin)†‡ ☐ Liaison Plex Respiratory Flex Assay (Diasorin)*‡ ☐ Lyra Influenza A+B Assay (Quidel) ☐ McKesson Consult Influenza A & B Test (McKesson Medical-Surgical Inc.) ☐ Meridian Bioscience™ ImmunoCard STAT!™ FLU A&B (Fisher Scientific™) ☐ NeuMoDX Influenza A/b, RSV, and SARS-CoV-2 Vantage Assay (Qiagen)‡ ☐ Nx-TAG® Respiratory Pathogen Panel (Diasorin)* ☐ Nx-TAG® Respiratory Pathogen Panel v2 (Diasorin)*‡ ☐ Nx-TAG® Respiratory Pathogen Panel + SARS-CoV-2 (Diasorin)*‡ ☐ OSOM Flu SARS-CoV-2 Combo Test (Sekisui Diagnostics, LLC) ☐ OSOM Ultra Plus Flu A&B Test (Sekisui Diagnostics, LLC) ☐ Panther Fusion® Flu A/B RSV Assay (Hologic) ☐ Panther Fusion® SARS-CoV-2/Flu A/B/RSV (Hologic)‡ ☐ QIAstat-Dx Respiratory Panel Mini (QIAGEN)‡ ☐ QIAstat-Dx Respiratory Panel Plus (QIAGEN)*‡ ☐ QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)*‡ ☐ Quest Diagnostics RC COVID-19 + Flu RT-PCR (Quest Diagnostics)‡ ☐ QuickVue® Influenza A+B Test (Quidel Corp.) ☐ RealStar Influenza Screen & Type RT-PCR (Altona Diagnostics) ☐ RealStar Influenza Screen & Type RT-PCR 4.0 (Altona Diagnostics)* ☐ SARS-CoV-2 & Flu A/B Rapid Antigen Test (Roche) ☐ SEKISUI Diagnostics™ OSOM™ Ultra Plus Flu A and B Test Kit (Fisher Scientific™) ☐ Simplexa™ COVID-19/Flu A/B/RSV Direct (Diasorin)‡ ☐ Simplexa™ COVID-19 & Flu A/B Direct (Diasorin)‡ ☐ Simplexa™ Flu A/B & RSV Direct Gen II (Diasorin)‡ ☐ Sofia® Analyzer and Influenza A+B FIA (CLIA-waived) (Quidel Corp.) ☐ Sofia® Analyzer and Influenza A+B FIA (Quidel Corp.)	

	☐ Sofia® 2 Flu + SARS Antigen FIA (Quidel) ☐ Solana Influenza A+B Assay (Quidel) ☐ Solana Respiratory Viral Panel (Quidel) ☐ Sure-Vue™ Signature Influenza A and B Test Kit ☐ The Metrix COVID/Flu Test (Sekisui Diagnostics)†‡ ☐ Verigene® Respiratory Pathogen Nucleic Acid Test (RP Flex) (Diasorin)* ☐ XPECT™ Influenza A/B (Remel Inc./Thermo Fisher Scientific™) ☐ Xpert Xpress COV-2/Flu/RSV plus (Cepheid)†‡ ☐ Xpert Xpress Flu (Cepheid)† ☐ Xpert Xpress Flu/RSV Assay (Cepheid)† ☐ Other, specify: _____ †= Rapid Molecular *= can detect subtype ‡=Multiplex for influenza/SARS-CoV-2 **Justification** • Clarifies which two kits are used most frequently only for labs that use two kits equally for pediatric testing.	
Non-substantive change (clarification)	7. Of the kits selected in 4a and 5a, which influenza test kit does the laboratory perform most frequently for hospitalized and ED adult patients (aged ≥18 years)? (*Select one*) ○ Two kits are equally used most frequently ○ Acucy Influenza A&B Test (Sekisui Diagnostics, LLC) ○ Alinity M Resp-4 Plex Assay (Abbott)‡ ○ Allplex Respiratory Panel A1 (Seegene)* ○ Allplex RV Master Assay (Seegene)‡ ○ Allplex SARS-CoV-2/Flu A/Flu B/RSV Assay (Seegene)‡ ○ Aptima SARS-CoV-2/Flu/A/B (Hologic)‡ ○ ARIES® Flu A/B & RSV+SARS-CoV-2 Assay (Diasorin‡ ○ BD Respiratory Viral Panel for BD MAX System (BD)‡ ○ BD Veritor™ System for Rapid Detection of Flu A+B (CLIA-waived) (Becton Dickinson & Co.) ○ BD Veritor™ System for Rapid Detection of Flu A+B (Moderately Complex) (Becton Dickinson & Co.) ○ BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B (Becton Dickinson & Co.) ○ Binax NOW® Influenza A&B Card 2 (Abbott) ○ BioCode® CoV-2 Flu Plus Assay (Applied BioCode Inc)‡ ○ BioCode® Respiratory Pathogen Panel (Applied BioCode Inc)*	Reduction in burden

	○ BioFire® FilmArray Pneumonia (PN) Panel ○ BioFire® FilmArray Pneumonia plus (PNplus) Panel (Biomerieux) ○ BioFire® Respiratory Panel 2.1 (RP2.1) (Biomerieux)*‡ ○ BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) (Biomerieux)*‡ ○ BioFire® Respiratory 2.1plus (RP2.1plus) Panel (Biomerieux)*‡ ○ BioFire® SpotFire® Respiratory Panel†*‡ ○ BioFire® SpotFire® Respiratory Panel Mini†‡ ○ BioFire® SpotFire® Respiratory/Sore Throat (R/ST) Panel†*‡ ○ BioSign® Flu A+B or LifeSign LLC Status Flu A & B (Princeton BioMeditech Corp.) ○ CareStart Flu A&B Plus (Access Bio, Inc.) ○ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A Subtyping Kit), (CDC Influenza Division) ○ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A/B Typing Kit), (CDC Influenza Division) ○ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza B Lineage Genotyping Kit), (CDC Influenza Division) ○ CDC Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set (CDC Influenza Division) ○ CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (CDC Influenza Division)‡ ○ Cobas Liat Influenza A/B & RSV (Roche Diagnostics)† ○ Cobas Liat SARS-CoV-2, Influenza A/B, and RSV (Roche)†‡ ○ Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics)†‡ ○ Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test (Roche Diagnostics) ○ ePlex Respiratory Pathogen Panel 2 (Roche Diagnostics)*‡ ○ ID Now™ Influenza A&B (CLIA-Waived) (Abbott)† ○ ID Now™ Influenza A&B 2 (CLIA-Waived) (Abbott)† ○ In-house developed PCR assay ○ Liaison NES Flu A/B, RSV, & COVID-19 Assay (Diasorin)†‡ ○ Liaison Plex Respiratory Flex Assay (Diasorin)*‡ ○ Lyra Influenza A+B Assay (Quidel) ○ McKesson Consult Influenza A & B Test (McKesson Medical-Surgical Inc.) ○ Meridian Bioscience™ ImmunoCard STAT!™ FLU A&B (Fisher Scientific™) ○ NeuMoDX Influenza A/b, RSV, and SARS-CoV-2 Vantage Assay (Qiagen)‡ ○ Nx-TAG® Respiratory Pathogen Panel (Diasorin)* ○ Nx-TAG® Respiratory Pathogen Panel v2 (Diasorin)*‡ ○ Nx-TAG® Respiratory Pathogen Panel + SARS-CoV-2 (Diasorin)*‡ ○ OSOM Flu SARS-CoV-2 Combo Test (Sekisui Diagnostics, LLC) ○ OSOM Ultra Plus Flu A&B Test (Sekisui Diagnostics, LLC) ○ Panther Fusion® Flu A/B RSV Assay (Hologic) ○ Panther Fusion® SARS-CoV-2/Flu A/B/RSV (Hologic)‡ ○ QIAstat-Dx Respiratory Panel Mini (QIAGEN)‡ ○ QIAstat-Dx Respiratory Panel Plus (QIAGEN)*‡ ○ QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)*‡	

	◯ Quest Diagnostics RC COVID-19 + Flu RT-PCR (Quest Diagnostics)‡ ◯ QuickVue® Influenza A+B Test (Quidel Corp.) ◯ RealStar Influenza Screen & Type RT-PCR (Altona Diagnostics) ◯ RealStar Influenza Screen & Type RT-PCR 4.0 (Altona Diagnostics)* ◯ SARS-CoV-2 & Flu A/B Rapid Antigen Test (Roche) ◯ SEKISUI Diagnostics™ OSOM™ Ultra Plus Flu A and B Test Kit (Fisher Scientific™) ◯ Simplexa™ COVID-19/Flu A/B/RSV Direct (Diasorin)‡ ◯ Simplexa™ COVID-19 & Flu A/B Direct (Diasorin)‡ ◯ Simplexa™ Flu A/B & RSV Direct Gen II (Diasorin)‡ ◯ Sofia® Analyzer and Influenza A+B FIA (CLIA-waived) (Quidel Corp.) ◯ Sofia® Analyzer and Influenza A+B FIA (Quidel Corp.) ◯ Sofia® 2 Flu + SARS Antigen FIA (Quidel) ◯ Solana Influenza A+B Assay (Quidel) ◯ Solana Respiratory Viral Panel (Quidel) ◯ Sure-Vue™ Signature Influenza A and B Test Kit ◯ The Metrix COVID/Flu Test (Sekisui Diagnostics)†‡ ◯ Verigene® Respiratory Pathogen Nucleic Acid Test (RP Flex) (Diasorin)* ◯ XPECT™ Influenza A/B (Remel Inc./Thermo Fisher Scientific™) ◯ Xpert Xpress COV-2/Flu/RSV plus (Cepheid)†‡ ◯ Xpert Xpress Flu (Cepheid)† ◯ Xpert Xpress Flu/RSV Assay (Cepheid)† ◯ Not applicable (no adult testing) ◯ Other, specify: _____ †= Rapid Molecular *= can detect subtype ‡=Multiplex for influenza/SARS-CoV-2 **Justification** • Clarifies which kits and patient group should be referred to for answering the question. Updating the answer choices to the list of kits eliminates burden of survey respondents classifying the kit by type and number of targets.	
Non-substantive change (clarification)	7a. If you responded to 7 that two kits are used with equal frequency for adult testing, please select the two kits. *If not applicable, skip to question 8.*	No change to burden

	☐ Acucy Influenza A&B Test (Sekisui Diagnostics, LLC) ☐ Alinity M Resp-4 Plex Assay (Abbott)‡ ☐ Allplex Respiratory Panel A1 (Seegene)* ☐ Allplex RV Master Assay (Seegene)‡ ☐ Allplex SARS-CoV-2/Flu A/Flu B/RSV Assay (Seegene)‡ ☐ Aptima SARS-CoV-2/Flu/A/B (Hologic)‡ ☐ ARIES® Flu A/B & RSV+SARS-CoV-2 Assay (Diasorin)‡ ☐ BD Respiratory Viral Panel for BD MAX System (BD)‡ ☐ BD Veritor™ System for Rapid Detection of Flu A+B (CLIA-waived) (Becton Dickinson & Co.) ☐ BD Veritor™ System for Rapid Detection of Flu A+B (Moderately Complex) (Becton Dickinson & Co.) ☐ BD Veritor™ System for Rapid Detection of SARS-CoV-2 & Flu A+B (Becton Dickinson & Co.) ☐ Binax NOW® Influenza A&B Card 2 (Abbott) ☐ BioCode® CoV-2 Flu Plus Assay (Applied BioCode Inc)‡ ☐ BioCode® Respiratory Pathogen Panel (Applied BioCode Inc)* ☐ BioFire® FilmArray Pneumonia (PN) Panel ☐ BioFire® FilmArray Pneumonia plus (PNplus) Panel (Biomerieux) ☐ BioFire® Respiratory Panel 2.1 (RP2.1) (Biomerieux)*‡ ☐ BioFire® Respiratory Panel 2.1-EZ (RP2.1-EZ) (Biomerieux)*‡ ☐ BioFire® Respiratory 2.1plus (RP2.1plus) Panel (Biomerieux)*‡ ☐ BioFire® SpotFire® Respiratory Panel†*‡ ☐ BioFire® SpotFire® Respiratory Panel Mini†‡ ☐ BioFire® SpotFire® Respiratory/Sore Throat (R/ST) Panel†*‡ ☐ BioSign® Flu A+B or LifeSign LLC Status Flu A & B (Princeton BioMeditech Corp.) ☐ CareStart Flu A&B Plus (Access Bio, Inc.) ☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A Subtyping Kit), (CDC Influenza Division) ☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza A/B Typing Kit), (CDC Influenza Division)	

	☐ CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (Influenza B Lineage Genotyping Kit), (CDC Influenza Division) ☐ CDC Influenza A/H5 (Asian Lineage) Virus Real-Time RT-PCR Primer and Probe Set (CDC Influenza Division) ☐ CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (CDC Influenza Division)‡ ☐ Cobas Liat Influenza A/B & RSV (Roche Diagnostics)† ☐ Cobas Liat SARS-CoV-2, Influenza A/B, and RSV (Roche)†‡ ☐ Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics)†‡ ☐ Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test (Roche Diagnostics) ☐ ePlex Respiratory Pathogen Panel 2 (Roche Diagnostics)*‡ ☐ ID Now™ Influenza A&B (CLIA-Waived) (Abbott)† ☐ ID Now™ Influenza A&B 2 (CLIA-Waived) (Abbott)† ☐ In-house developed PCR assay ☐ Liaison NES Flu A/B, RSV, & COVID-19 Assay (Diasorin)†‡ ☐ Liaison Plex Respiratory Flex Assay (Diasorin)*‡ ☐ Lyra Influenza A+B Assay (Quidel) ☐ McKesson Consult Influenza A & B Test (McKesson Medical-Surgical Inc.) ☐ Meridian Bioscience™ ImmunoCard STAT!™ FLU A&B (Fisher Scientific™) ☐ NeuMoDX Influenza A/b, RSV, and SARS-CoV-2 Vantage Assay (Qiagen)‡ ☐ Nx-TAG® Respiratory Pathogen Panel (Diasorin)* ☐ Nx-TAG® Respiratory Pathogen Panel v2 (Diasorin)*‡ ☐ Nx-TAG® Respiratory Pathogen Panel + SARS-CoV-2 (Diasorin)*‡ ☐ OSOM Flu SARS-CoV-2 Combo Test (Sekisui Diagnostics, LLC) ☐ OSOM Ultra Plus Flu A&B Test (Sekisui Diagnostics, LLC) ☐ Panther Fusion® Flu A/B RSV Assay (Hologic) ☐ Panther Fusion® SARS-CoV-2/Flu A/B/RSV (Hologic)‡ ☐ QIAstat-Dx Respiratory Panel Mini (QIAGEN)‡ ☐ QIAstat-Dx Respiratory Panel Plus (QIAGEN)*‡ ☐ QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN)*‡ ☐ Quest Diagnostics RC COVID-19 + Flu RT-PCR (Quest Diagnostics)‡ ☐ QuickVue® Influenza A+B Test (Quidel Corp.) ☐ RealStar Influenza Screen & Type RT-PCR (Altona Diagnostics) ☐ RealStar Influenza Screen & Type RT-PCR 4.0 (Altona Diagnostics)* ☐ SARS-CoV-2 & Flu A/B Rapid Antigen Test (Roche) ☐ SEKISUI Diagnostics™ OSOM™ Ultra Plus Flu A and B Test Kit (Fisher Scientific™) ☐ Simplexa™ COVID-19/Flu A/B/RSV Direct (Diasorin)‡ ☐ Simplexa™ COVID-19 & Flu A/B Direct (Diasorin)‡ ☐ Simplexa™ Flu A/B & RSV Direct Gen II (Diasorin)‡ ☐ Sofia® Analyzer and Influenza A+B FIA (CLIA-waived) (Quidel Corp.) ☐ Sofia® Analyzer and Influenza A+B FIA (Quidel Corp.)	

	☐ Sofia® 2 Flu + SARS Antigen FIA (Quidel) ☐ Solana Influenza A+B Assay (Quidel) ☐ Solana Respiratory Viral Panel (Quidel) ☐ Sure-Vue™ Signature Influenza A and B Test Kit ☐ The Metrix COVID/Flu Test (Sekisui Diagnostics)†‡ ☐ Verigene® Respiratory Pathogen Nucleic Acid Test (RP Flex) (Diasorin)* ☐ XPECT™ Influenza A/B (Remel Inc./Thermo Fisher Scientific™) ☐ Xpert Xpress COV-2/Flu/RSV plus (Cepheid)†‡ ☐ Xpert Xpress Flu (Cepheid)† ☐ Xpert Xpress Flu/RSV Assay (Cepheid)† ☐ Other, specify: _____ †= Rapid Molecular *= can detect subtype ‡=Multiplex for influenza/SARS-CoV-2 **Justification** • Clarifies which two kits are used most frequently only for labs who use two kits equally for adult testing.	
Non-substantive change (correction)	8. Does the lab send specimens to other labs for clinical testing of influenza? (*optional*) • Yes -> Answer question 8a • No -> Skip to question 9 Justification • Correction of the question number and skip logic due to the renumbering of previous questions and addition of a question above. This is needed to ensure accuracy of the question numbering of the survey.	No change to burden
Non-substantive change (correction)	8a. Select all that apply (*optional*) ☐ Commercial lab(s): List names of all labs: _____ ☐ Public Health lab(s): List names of all labs: _____ ☐ Other lab(s): List names of all labs: _____ **Justification:** • Correction of the question number due to the renumbering of previous questions. This is needed to ensure accuracy of the question numbering of the survey.	No change to burden
Non-substantive change (correction)	9. Laboratory Comments: **Justification:** • Correction of the question number due to the renumbering of previous questions. This is needed to ensure accuracy of the question numbering of the survey.	No change to burden
Non-substantive change (correction)	10. List all in-catchment FluSurv-NET hospital IDs (hosp_TX) associated with this testing facility. *(Do not include names – CDC receives this info)* **Justification:** • Correction of the question number due to the renumbering of previous questions. This is needed to ensure accuracy of the question numbering of the survey.	No change to burden

HAIC

This non-substantive change request includes minor proposed changes to 7 approved data collection tools (form/s) detailed below:

Approved Forms:

1) HAIC.400.1 Multi-Site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form

2) HAIC.400.3 HAIC MuGSI Supplemental Surveillance Officer Survey

3) HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report - 2027

4) HAIC.400.5 Healthcare-Associated Infections Community Interface (HAIC) *Staphylococcus aureus* Laboratory Survey

5) HAIC 400.7 CDI Case Report Form - 2027

6) HAIC.400.8 Annual Survey of Laboratory Testing Practices for *C. difficile* Infections

7) HAIC.400.9 CDI Annual Surveillance Officers Survey

HAIC.400.1 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Administrative	2027 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Healthcare-Associated Infections Community Interface (HAIC) Case Report From **Changes:** - Updated year to 2027 **Justification**: Updated to reflect the surveillance year.	**None**
Administrative/Language Modification & Addition of Response Option	Question 19. Substance Use: **Changes:** - Relocated the “Smoking” response option “Marijuana” to the “Other Substances” category - Added “Yes” as a response option under “Other Substances” to clearly delineate when there is documented use of an	**None**

	"Other Substance" **Justification**: The previous iteration of this question was ambiguous and caused confusion for respondents. This change adds no burden, and instead, clarifies the intended data capture.	
HAIC.400.3 MuGSI Supplemental Surveillance Officer Survey		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Administrative	2026 HAIC Multi-site Gram-negative Surveillance Initiative (MuGSI) Supplemental Surveillance Officer Survey **Changes:** - Updated year to 2026 **Justification:** Updated to reflect the correct years in question	**None**
Administrative	Please answer the following questions for the year 2026, unless otherwise specified. The purpose of the survey is to verify and document current surveillance procedures, including isolate collection and testing methods at clinical laboratories. Please enter your responses into the corresponding REDCap database. If you have questions, please contact Joshua Brandenburg (ode4@cdc.gov) and the MuGSI Inbox (mugsi@cdc.gov). **Changes:** - Update year to 2026 - Removed staff whom left; replaced with a functional email inbox **Justification:** Previous contact no longer supports the program	**None**
Administrative	**Laboratory Participation and Isolate Testing – Part 1** Question 2: Did any laboratories drop out of	**None**

	participation in 2025? **Changes:** - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	
Administrative	**Laboratory Participation and Isolate Testing – Part 1** Question 3: In 2025, did you identify additional laboratories, regardless of location, which identify MuGSI isolates from persons who are residents of the MuGSI surveillance area at your site? **Changes:** - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	**None**
Administrative	**Laboratory Participation and Isolate Testing – Part 1** Question 4: Did your site send any MuGSI isolates to CDC for characterization in calendar year 2025? **Changes:** - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	**None**
Administrative	**Laboratory Participation and Isolate Testing – Part 1** Question 5: How many isolates with a specimen collection date in 2025 did you expect to be able to collect from the clinical laboratories? **Changes:** - Updated the year from 2024 to 2025	**None**

	Justification: Specifying the timeframe relative to the question	
Administrative	**Laboratory Participation and Isolate Testing – Part 1** Question 6: What was the total number of isolates with a specimen collection date in 2025 that were collected from the clinical laboratories? **Changes:** - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	**None**
Administrative	**Laboratory Participation and Isolate Testing – Part 2** *Please complete the following information for each clinical laboratory participating in MuGSI surveillance at your site in 2025* **Changes:** - Updated the year from 2024 to 2025 for the section's instructions **Justification:** Specifying the timeframe relative to the instructions for the section.	**None**
Administrative	**Additional information on MuGSI surveillance activities** Question 2: In 2025, did your site update its inventory of facilities within the MuGSI surveillance area? **Changes:** - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	**None**
Administrative	Question 4: Did your site geocode MuGSI cases in 2025?	**None**

	Changes: - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	
Administrative	Question 5. Did your site match MuGSI cases to the state vital statistics death registry in 2025? **Changes:** - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	**None**
Administrative	Question 6: Did your site complete CRF re-abstractions in 2025? **Changes:** - Updated the year from 2024 to 2025 **Justification:** Specifying the timeframe relative to the question	**None**
HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report - 2027		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Wording Change	Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2027 **Change:** Updated year to 2027 **Justification:** Updated to reflect surveillance year	**None**
Removed Question	**Change:** • Removed Q 34a Q34a Did the patient have a positive test(s) for SARS-CoV-2 (molecular assay, antigen or other viral test; excluding serology) in the 90 days before or after the DISC? ☐ Yes ☐ No ☐ Unknown Specimen collection dates for positive tests in the 90 days before or day of DISC: First positive test: __-__-____ ☐ Unknown Most recent positive test: __-__-____ ☐ Unknown	**45 second decrease**

	COVID-NET CASE ID in the year before or day of the DISC: _____ ☐ Unknown **Justification:** Data are no longer being utilized	
Removed Question	**Change:** • Removed Q36 36. Does this case have recurrent MRSA/MSSA disease? ☐ Yes ☐ No ☐ Unknown If yes, previous (1st) STATE ID: _____ **Justification:** Data field no longer being analyzed; can be determined using the dataset	**15 second decrease**
HAIC.400.5 CDC's Healthcare-Associated Infections Community Interface (HAIC) *Staphylococcus aureus* Laboratory Survey		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Wording Change	Thank you for completing this survey. We are asking you to complete this survey because your laboratory serves the catchment area for the Emerging Infections Program's (EIP) culture-based *S. aureus*/MRSA bacteremia surveillance program. Our aim for this survey is to understand how *S. aureus*/MRSA are identified from blood specimens in your lab. We also aim to understand circumstances in which identification of *S. aureus*/MRSA in a blood specimen may not be reported to EIP staff, potentially resulting in a missed surveillance case (e.g., if only positive cultures/isolates are reported in the line list, and a culture-independent diagnostic test is used). ***PLEASE NOTE THAT ALL OF THE QUESTIONS APPLY TO TESTING OF BLOOD SPECIMENS.*** **Changes:** • Removed references to normally sterile sites/invasive *S. aureus* and updated to blood/bacteremia **Justification:** Reflects changes to surveillance (moving from normally sterile sites/invasive *S. aureus* to blood isolates only/bacteremia)	**None**
Wording Change	2. During the past year (i.e., in the past 12 months or since the completion of the last lab survey), has your lab changed testing	**None**

	methods used to detect MRSA or *S. aureus* from blood specimens? **Changes:** • Removed references to normally sterile sites **Justification:** Reflects changes to surveillance (moving to blood isolates only)	
Wording Change	3. Do you routinely set up blood cultures on site (in-house) at your laboratory? **Changes:** • Removed references to normally sterile sites **Justification:** Reflects changes to surveillance (moving to blood isolates only)	**None**
Wording Change and Removed Explanatory Language	4. If a blood culture is positive for *S. aureus,* is an isolate always obtained? **Changes:** • Removed instructional text: Question 4 asks about methods for identifying *S. aureus* or MRSA from a positive sterile site (blood, CSF, bone, etc.) cultures. • Clarified Q4 by specifying blood culture for *S. aureus* **Justification:** Reflects changes to surveillance (moving to blood isolates only)	**None**
Wording Change	4b. Are any tests used to identify *S. aureus* from a positive blood culture performed offsite? **Changes:** • Added “from a positive blood culture” **Justification:** Reflects changes to surveillance (moving to blood isolates only)	**None**
Wording Change	4c. If a blood culture is positive, how do you identify it as *S. aureus*? **Changes:** • Added “blood” **Justification:** Reflects changes to surveillance (moving to blood isolates only)	**None**
Wording Change	4d. Which molecular tests are used to identify *S. aureus* from a positive blood culture? **Changes:** • Added “to identify *S. aureus* from a positive blood culture” **Justification:** Reflects changes to surveillance (moving to blood isolates only)	**None**
Wording Change	4e. Do you anticipate any changes to	**None**

	testing/identification processes for *S. aureus* or MRSA from a positive blood culture within the next year? **Changes:** • Added "blood" **Justification:** Reflects changes to surveillance (moving to blood isolates only)	
Wording Change	Question 5 asks about testing performed directly on blood specimens (a positive culture is not required to perform these tests). **Changes:** • Removed "sterile site" and replaced with "blood" **Justification:** Reflects changes to surveillance (moving to blood isolates only)	**None**
Wording Change and Number Change	5. Do you routinely run any tests on site (in-house) or at another lab that detect *S. aureus* directly from a blood specimen without a culture (i.e., a culture independent diagnostic test)? □ Yes – GO TO Q5a □ No - GO TO Q5g **Changes:** • Removed "normally sterile site" and replaced with "blood" • Removed (e.g., blood, CSF) • Changed No – GO TO Q5e to No – GO TO Q5h **Justification:** Reflects changes to surveillance (moving to blood isolates only) and updated skip pattern due to question reformatting	**None**
Added Explanatory Language	For the table below, please indicate all tests listed in column 5a that are routinely used by your laboratory. For each test that is routinely run, complete the remainder of the row (questions 5b-5f). **Changes:** • Added instructions for completing questions • Reformatted questions 5a-5f from a list of questions to a table **Justification:** Formatting of questions 5a-5f has been updated from previous years. The added text provides background on the question; the question format was changed so that 5b-5f are can easily be associated with a test type in analysis.	**None**
Wording Change	5a. [If yes], which tests are used to detect *S.*	**None**

	aureus directly from a blood specimen without a culture? **Changes:** • Removed "a normally sterile specimen" and "(sterile site sources only, i.e. blood, CSF, pleural fluid, bone, etc)" and replaced with "blood" **Justification:** Reflects changes to surveillance (moving to blood isolates only)	
Number Change	5b. Method **Changes:** • Added question number (5b) **Justification:** Formatting of questions 5a-5f has been updated from previous years.	**None**
Number Change	5c: Date Started **Changes:** • Added question number (5c) **Justification:** Formatting of questions 5a-5f has been updated from previous years.	**None**
Number Change	5d: Where is this testing completed? **Changes:** • Updated question number from 5b to 5d **Justification:** Formatting of questions 5a-5f has been updated from previous years.	**None**
Number Change	5e: Do you still obtain an isolate for *S. aureus* or MRSA if these tests are used? **Changes:** • Updated question number from 5c to 5e **Justification:** Formatting of questions 5a-5f has been updated from previous years.	**None**
Wording Change and Number Change	5f: Do positive culture-independent diagnostic tests *directly* from blood specimens appear in the *S. aureus* surveillance laboratory line lists (even if not positive associated culture)? **Changes:** • Updated question number from 5d to 5f • Replaced "normally sterile specimens" with "blood" **Justification:** Formatting of questions 5a-5f has been updated from previous years; Reflects changes to surveillance (moving to blood isolates only)	**None**
Wording Change and Number Change	5g. Do you plan to start offering any new tests that you are not currently using for detection of *S. aureus* or MRSA directly from blood within the next year? □ Yes – GO TO Q5h □ No – END SURVEY **Changes:** • Updated question number from 5e to 5g • Replaced "a sterile source" with "blood" • Changed Yes – GO TO Q5f to Yes – GO	**None**

	TO Q5h **Justification:** Formatting of questions 5a-5f has been updated from previous years; Reflects changes to surveillance (moving to blood isolates only)	
HAIC 400.7 CDI Case Report Form - 2027		
Type of Change	**Itemized Changes / Justification**	**Impact to Burden**
Response options	23a. Smoking **Change:** Removed marijuana from smoking section **Justification:** Challenging to capture marijuana under smoking when mode of delivery is often unavailable in the medical record	None
Response options	23c. Other substances **Change:** Added marijuana as an option under the other substances section **Justification:** This change will allow us to collect data on marijuana use regardless of the mode of delivery	None
HAIC.400.8 Annual Survey of Laboratory Testing Practices for *C. difficile* Infections		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Administrative	Section 1: Was this a new laboratory in 2026? Did this lab participate in surveillance in 2026? How often did you receive line lists from this lab in 2026? How did you receive line lists from this lab in 2026? Did you receive specimens from this lab in 2026? Was this lab audited in 2026? Types of facilities in your catchment area served	None

	by this lab in 2026 Section 2: Questions 1, 2a, 3a, 3b, 4a, 4b, 5a, 5b, 6, 7, 7a, 8 **Change:** Updated year to 2026 **Justification:** Updated to reflect the appropriate year of data collection	
HAIC.400.9 CDI Annual Surveillance Officers Survey		
Type of Change	**Itemized Change / Justification**	**Impact to Burden**
Administrative	Questions 2, 3, 10, 13 **Change:** Updated year to 2026 **Justification:** Updated to reflect the appropriate year of data collection	None