|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Objective** | **Specific Questions** | **Data Element** *(category)* | **Variable Name** | **Variable Definition** | **Priority**Please **rank priority** of question from 1-5: 1=lowest; 5=highest | **Can be answered in:**1 = LT 1 month2 = 2-3 months3= 4+ months | **Feasibility**Please **rank feasibility** of question from 1-5: 1=lowest (not possible without linkage to multiple other source data); 5=highest (access to all data elements and appropriate database)  |
| **I. TEST** | A.1. What is the accuracy (sensitivity & specificity) of SARS-CoV-2 rapid antigen, antibody, and SARS-CoV-2 rt-PCR tests?A.2. How does the accuracy of each specific test compare to others in its category and between categories? | **Test** | Test ordered | If possible, please provide harmonized LOINC[codes per CDC](https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html) (See LIVD mapping tool) |  |  |  |
| Test device identifier |  |  |  |  |
| Test result | If possible, please provide harmonized LOINC[codes per CDC](https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html) (See LIVD mapping tool) |  |  |  |
| Test order date |  |  |  |  |
| Test result date |  |  |  |  |
| **Lab** | Performing lab name and/or CLIA number |  |  |  |  |
| Performing lab zip |  |  |  |  |
| **Demographic Info** | Age (categorical) | Age at index* <18 years
* 18-44 years
* 45-64 years
* 65-79 years
* 80+ years
 |  |  |  |
| Sex | * Male
* Female
* Other / Unknown
 |  |  |  |
| Race/ethnicity | * White
* Black
* Hispanic
* Other/unknown
* Missing
 |  |  |  |
| **Medical History** | **Severe Comorbidities** Defined with diagnosis codes (ICD-10-CM), procedure codes (ICD-10-PCS, CPT/HCPCS), laboratory values (where available)Identify top 10 most prevalent comorbidities within datasetSuggested to include top 10 associated diagnostic codes as new evidence emerges.  | * Charlson Comorbidity Index
* Alcohol Use (high/moderate/low)
* Obesity (BMI)
* Diabetes
* Cancer
* Any kidney disease
* Any chronic lung conditions
	+ COPD
	+ Asthma
	+ Chronic bronchitis
* Immunosuppressive condition
* Any cardiovascular disease
	+ Hypertension
	+ Coronary artery disease
	+ Congestive heart failure
* Any liver disease
	+ FIB-4 Index
* Dementia
 |  |  |  |
| Smoking Status | * Current
* Former
* Never
* Unknown
 |  |  |  |
| Pregnant | * Yes
* No
* Previously
* Estimated delivery date (will allow calculation of gestational age at index)
* Date of delivery (catch pre-term deliveries)
* gestational hypertension
* gestational diabetes
* Live birth. Yes/no
 |  |  |  |
| Concomitant medications/Medications at baselineUse of comedications defined with generic name, brand name, and NDC codes | * Statin
* ACE inhibitor or ARB
* Systemic glucocorticoid
* Direct oral anticoagulant or warfarin
* Antibiotic agent (other than Azithromycin)
* Tocilizumab
* Remdesivir
* Famotidine
* Antiretrovirals
 |  |  |  |
| On Oxygen | * Yes
* No
* Unknown
 |  |  |  |
| **Onset History** | Laboratory Tests | * WBC count
* Lymphocytes
* Creatinine or eGFR
* Albumin
* Blood glucose levels
* D-dimer
* Ferritin
* C-reactive protein
* Lactate dehydrogenase
 |  |  |  |
| Oxygen saturation  | * <90
* 90-93
* >93
* Calculated Pao2:Fio2
 |  |  |  |
| Vital signs & Symptoms at disease onsetIdentify top 10 most prevalent symptoms within datasetCo-infections: Positive flu test; Pneumonia-causing bacteria: gram stain/sputum; Presumptive labs associated with secondary bacterial pneumonia: C-reactive protein, total white blood cell and neutrophil counts | * Fever > 100.4 (measured or subjective)
* Abnormal chest imaging finding
* High respiratory rate
* Low blood pressure
* Diarrhea
* Hypoglycemic
* Chest pain
* Delirium/confusion
* Chest pain
* Headache
* Sore throat
* Cough
* Shortness of breath
* Pneumonia
* Acute bronchitis
* Acute respiratory infection
* Acute respiratory distress, arrest, or failure
* Cardiovascular condition
* Renal condition
 |  |  |  |
| **COVID DX** | COVID-19 diagnosis | * COVID-19 diagnosis
	+ Positive/presumptive positive COVID-19 lab result
	+ ICD-10 diagnosis of U07.1 – COVID-19, virus identified
	+ ICD-10 diagnosis of B97.21 – SARS-associated coronavirus as the cause of diseases classified elsewhere
	+ ICD-10 diagnosis of B97.29 – Other coronavirus as the cause of diseases classified elsewhere
	+ ICD-10 diagnosis of J12.81 - Pneumonia due to SARS-associated coronavirus
	+ ICD-10 diagnosis of B34.2 - Coronavirus infection, unspecified
* COVID-19 diagnosis date
 |  |  |  |
| B.1. How does the accuracy (sens/spec) of each specific test compare by specimen type and collection site/method? | - *All data elements from I.A above, plus:* |  |  |  |  |  |
| **SPECIMEN** | Accession #/ specimen ID (and type) |  |  |  |  |
| Specimen source | If possible, please provide (harmonized LOINC, SNOMED, SPM4 codes, or alternative [codes](https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html)) |  |  |  |
| Specimen collected date |  |  |  |  |
| Specimen analyzed date |  |  |  |  |
| Specimen collection site (if different from test site) |  |  |  |  |
| Specimen transport mechanism |  |  |  |  |
| C.1. For patients with classic COVID-19 symptoms and initial negative SARS-CoV-2 rt-PCR test, what is their clinical course, subsequent test results and discharge diagnosis?C.2. For patients with an admission diagnosis other than COVID-19, but with positive PCR test, what is their clinical course and discharge diagnosis? | **TEST***- All data elements from I.A TEST above (for all tests performed)***DEMOGRAPHIC***- data elements from I.A DEMOGRAPHIC above***MEDICAL HX**-*data elements from I.A MEDICAL HISTORY above***ONSET HX***data elements from I.A ONSET HISTORY above**plus:*  |  |  |  |  |  |
| **COVID-19 Status & Prgress** | Admission Date |  |  |  |  |
| Admitting DX |  |  |  |  |
| Discharge Date |  |  |  |  |
| Discharge DX |  |  |  |  |
| II. PATIENT | A.1 Is a prior positive SARS-CoV-2 rt-PCR test and/or a serology Ab+ (e.g., IgM, IgG, IgA) test associated with reduced risk of re-infection with SARS-CoV-2? | **TEST***- All data elements from I.A TEST above* **SPECIMEN*** *Data elements from I.B SPECIMEN above*

**DEMOGRAPHIC***- data elements from I.A DEMOGRAPHIC above***MEDICAL HX**-*data elements from I.A MEDICAL HISTORY above***ONSET HX***data elements from I.A ONSET HISTORY above* |  |  |  |  |  |
| B.1. For patients who present with negative PCR result and a positive Ab test, what are their presenting symptoms, demographics, clinical course?B.2. For patients presenting with positive PCR result and who later test negative for Ab, what are presenting symptoms, demographics, clinical course? | **TEST***- All data elements from I.A TEST above* **SPECIMEN*** *Data elements from I.B SPECIMEN above*

**DEMOGRAPHIC***- data elements from I.A DEMOGRAPHIC above***MEDICAL HX**-*data elements from I.A MEDICAL HISTORY above***ONSET HX***data elements from I.A ONSET HISTORY above* |  |  |  |  |  |
| III. POPULATION | A.1. What is the correlation between test result and clinical symptoms, by demographic characteristics? |  **TEST***- All data elements from I.A TEST above*  |  |  |  |  |  |
| **DEMOGRAPHIC***- data elements from I.A DEMOGRAPHIC above***MEDICAL HX**-*data elements from I.A MEDICAL HISTORY above***ONSET HX***data elements from I.A ONSET HISTORY above**plus:* |  |  |  |  |  |
| Geography | Patient residence zip code |  |  |  |  |
| Patient residence county |  |  |  |  |
| Ordering provider zip |  |  |  |  |
| B.1. What is the PPV/NPV for each test, analyzed by geography and demographic characteristics? | **TEST***- All data elements from I.A TEST above***LAB**- *All data elements from I.A LAB above***DEMOGRAPHIC***- data elements from I.A DEMOGRAPHIC above***MEDICAL HX**-*data elements from I.A MEDICAL HISTORY above***ONSET HX***data elements from I.A ONSET HISTORY above***GEOGRAPHY** *-data elements from III.A GEOGRAPHY above* |  |  |  |  |  |
| C.1. What are the trends in SARS-CoV-2 infection and presence of antibody over time, analyzed by geography and demographic characteristics? | **TEST***- All data elements from I.A TEST above (for all tests performed)***LAB**- *All data elements from I.A LAB above***DEMOGRAPHIC***- data elements from I.A DEMOGRAPHIC above***GEOGRAPHY***-data elements from III.A GEOGRAPHY above* |  |  |  |  |  |
| D. What has been the impact of various public health and policy level interventions on infection rates and trends over time? | **TEST***- All data elements from I.A TEST above (for all tests performed)***LAB**- *All data elements from I.A LAB above* |  |  |  |  |  |