SARS-CoV-2 is the virus responsible for COVID-19. It was previously known as 2019 Novel coronavirus (2019-nCoV).

Event Name:	SARS
Event Time Period:	90 days
CSTE Description (2021):	**Clinical Criteria:** In the absence of a more likely diagnosis: • Acute onset or worsening of at least two of the following symptoms or signs: fever (measured or subjective); chills; rigors; myalgia; headache; sore throat; nausea or vomiting; diarrhea; fatigue; congestion or runny nose; **OR** • Acute onset or worsening of any one of the following symptoms or signs: cough; shortness of breath; difficulty breathing; olfactory disorder; taste disorder; confusion or change in mental status; persistent pain or pressure in the chest; pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone; inability to wake or stay awake; **OR** • Severe respiratory illness with at least one of the following: clinical or radiographic evidence of pneumonia or acute respiratory distress syndrome (ARDS) **Laboratory Criteria:** Laboratory evidence using a method approved or authorized by the FDA* or designated authority**: *Confirmatory*** laboratory evidence:* • Detection of SARS-CoV-2 RNA in a post-mortem respiratory swab or clinical specimen using a diagnostic molecular amplification test performed by a CLIA-certified provider, OR • Detection of SARS-CoV-2 by genomic sequencing****. *Presumptive*** laboratory evidence:* • Detection of SARS-CoV-2 specific antigen in a post-mortem obtained respiratory swab or clinical specimen using a diagnostic test performed by a CLIA-certified provider. *Supportive*** laboratory evidence:* • Detection of antibody in serum, plasma, or whole blood specific to natural infection with SARSCoV-2 (antibody to nucleocapsid protein), OR • Detection of SARS-CoV-2 specific antigen by immunocytochemistry in an autopsy specimen, OR • Detection of SARS-CoV-2 RNA or specific antigen using a test performed without CLIA oversight*****. *FDA Emergency Use Authorizations https://www.fda.gov/medical-devices/emergency-situations-medicaldevices/emergency-use-authorizations and https://www.fda.gov/medical-devices/emergency-situationsmedical-devices/faqs-testing-sars-cov-2#nolonger **On March 13, 2020, the President issued a Memorandum on Expanding State-Approved Diagnostic Tests: "Should additional States request flexibility to authorize laboratories within the State to develop and perform tests used to detect COVID-19, the Secretary shall take appropriate action, consistent with law, to facilitate the request." ***The terms confirmatory, presumptive, and supportive are categorical labels used here to standardize case classifications for public health

	surveillance. The terms should not be used to interpret the utility or validity of any laboratory test methodology. ****Some genomic sequencing tests that have been authorized for emergency use by the FDA do not require an initial PCR result to be generated. Genomic sequencing results may be all the public health agency receives. ***** These primarily include private at-home tests and will not be routinely entered into MAVEN. **Epidemiological Linkage Criteria:** • One or more of the following exposures in the prior 14 days: o Close contact[a] with a confirmed or probable case of COVID-19 disease; OR o Member of an exposed risk cohort as defined by public health authorities during an outbreak or during high community transmission. [a] Close contact is generally defined as being within 6 feet for at least 15 minutes (cumulative over a 24-hour period). However, it depends on the exposure level and setting; for example, in the setting of an aerosol-generating procedure in healthcare settings without proper PPE, this may be defined as any duration. **Vital Records Criteria**: • A death certificate that lists COVID-19 disease or SARS-CoV-2 or an equivalent term as an underlying cause of death or a significant condition contributing to death.[b] [b] MA is also accepting cause of death listed as COVID, novel coronavirus, or coronavirus 2019. A cause of death of coronavirus, without an indication of which coronavirus, is not considered to meet vital records criteria. Death certificates with a qualifier on the cause of death such as, but not limited to, "suspected", or "possible" are not considered to meet vital records criteria but would be considered as suspect cases. **COVID Associated Death Criteria:** CSTE has provided a supplemental definition for COVID associated deaths. These criteria should be used in conjunction with the case classification to determine when a death should be counted as associated with COVID-19
CSTE Event Classification (2021):	*Confirmed*	Meets confirmatory laboratory evidence
	Confirmed associated death	Meets confirmatory laboratory evidence AND at least ONE of the following criteria is met: • A case investigation determined that COVID-19 was the cause of death or contributed to the death. • The death certificate indicates COVID-19 or an equivalent term as one of the causes of death, regardless of the time elapsed since specimen collection of the confirmatory laboratory test used to define the case, and was due to natural causes (e.g., the Manner of Death is coded as "natural" on the death certificate).
	Probable	• Meets clinical criteria AND epidemiologic linkage with no confirmatory or presumptive laboratory evidence for SARS-CoV-2. **OR;** • Meets presumptive laboratory evidence.

	Probable associated death	• The case meets the probable COVID-19 case definition AND a case investigation determined that COVID-19 was the cause of death or contributed to the death. **OR** • The case meets the probable COVID-19 surveillance case definition based on presumptive laboratory evidence AND the death certificate indicates COVID-19 or an equivalent term as one of the causes of death, regardless of the time elapsed since specimen collection of the presumptive laboratory test used to define the case, and was due to natural causes (e.g., the Manner of Death is coded as "natural" on the death certificate).
	Suspect	Meets supportive laboratory evidence with no prior history of being a confirmed or probable case within past 90 days.
	Suspect associated death	• The case meets the suspect COVID-19 case definition AND a case investigation determined that COVID-19 was the cause of death or contributed to the death. **OR** • The case meets the suspect COVID-19 case definition AND the death certificate indicates COVID-19 or an equivalent term as one of the causes of death, and was due to natural causes (e.g., the Manner of Death is coded as "natural" on the death certificate), **OR** • Meets vital records criteria with no confirmatory or presumptive laboratory evidence for SARS-CoV-2.
MA Event Classification (2021):	*Confirmed*	Follows CSTE event classification.
	Confirmed associated Death	Follows CSTE event classification.
	Probable	Follows CSTE event classification with the following exceptions: • Someone with a negative SARS-CoV-2 RNA test collected within 2 days before or after the positive antigen test would be considered revoked.
	Probable associated death	Follows CSTE event classification.
	Suspect	Follows CSTE event classification.
	Suspect associated death	Follows CSTE event classification.
	Revoked	Meets presumptive laboratory evidence with a negative SARS-CoV-2 RNA test collected within 2 days before or after the positive antigen test, except if case meets vitals record critetia.

	Unclassified	Events created when negative, invalid, equivocal, inconclusive, or unsatisfactory laboratory results are received on an individual who had no existing COVID19 event in MAVEN.
	Contact	Events created for individuals exposed to someone with COVID19. Status would remain as "contact" even if negative supportive, presumptive, or confirmatory test results were received.

Data entry notes:
All COVID19 laboratory results should be captured in MAVEN (Positive, Negative, Unsatisfactory, Inconclusive, Equivocal, Invalid), except for laboratory tests resulted outside of a CLIA-certified or CLIA-waived laboratory. These primarily include private at-home tests and will not be routinely entered into MAVEN.

If you are entering any new positive COVID results into an unclassified event:

- Update the disease status as appropriate.
- Modify the event date to be based off the lab specimen collection date of the positive lab. Go to the administrative question package and add the lab specimen collection date of the positive lab into the "Manual override for event date:" field.
- Verify the official address in the demographic question package reflects the address noted on the positive lab result. If it does not, update the address in the Participant Tab and then go to the demographic question package and select that address as the official address.

If the result(s) you are entering are from a Panel Test that includes **any** COVID information:

- Create the Confirmed/Unclassified COVID event, or update their existing COVID event, as you normally would – based on SARS COVID-19 or SARS COVID-19 Negative result from the panel.
- Append any Influenza A/B and Bordetella Pertussis results to the COVID event, including Negative results – no other results from the panel need to be included.
- If Positive results for Influenza A/B or Bordetella Pertussis, then refer to the relevant CCM.

If the result(s) you are entering indicate "rapid SARS", or do not otherwise specify if the "rapid" test was Ag/PCR, you will need to confirm the test type with the lab before entering the result.

Deaths associated with COVID-19 are determined through a daily match with vital records and may be removed if reported by an investigator and no evidence of the death, including obituaries and death certificates, can be found. Different criteria have been used to count deaths over the course of the pandemic. If a death certificate is received, please follow up with the COVID liaison.

Report Type	Test Type	Source	Result	New event or beyond report period?	Data Entry
Laboratory Report	PCR	Clinical specimen	Positive	Yes	New event Confirmed
				No	Same event
Select:	2019-nCoV Real-time RT-PCR				
Select:	2019-NCOV RNA PNL XXX NAA+PROBE				
Laboratory Report	PCR	Clinical specimen	Negative	Yes	New event Unclassified
				No	Same event
Select:	2019-nCoV Real-time RT-PCR				
Select:	2019-NCOV RNA PNL XXX NAA+PROBE				
Laboratory Report	PCR	Clinical specimen	Unsatisfactory, Inconclusive, Invalid	Yes	New event Unclassified
				No	Same event
Select:	2019-nCoV Real-time RT-PCR				
Select:	2019-NCOV RNA PNL XXX NAA+PROBE				
Laboratory Report	PCR Panel	Clinical specimen	SARS COVID-19	Yes	New event Confirmed
				No	Same event
Select:	Flu A/Flu B/SARS COVID-2/SARS-related coronavirus RNA panel				
Laboratory Report	PCR Panel	Clinical specimen	SARS COVID-19 Negative	Yes	New event Unclassified
				No	Same event
Select:	Flu A/Flu B/SARS COVID-2/SARS-related coronavirus RNA panel				
Laboratory Report	PCR Panel	Clinical specimen	Unsatisfactory, Inconclusive, Invalid	Yes	New event Unclassified
				No	Same event
Select:	Flu A/Flu B/SARS COVID-2/SARS-related coronavirus RNA panel				
Laboratory Report	PCR Panel	Clinical specimen	Influenza A Virus	Yes	New event Confirmed
				No	Same event
Select:	Flu A/Flu B/SARS COVID-2/SARS-related coronavirus RNA panel				
Laboratory Report	PCR Panel	Clinical specimen	Negative Influenza A Virus	Yes	New event Unclassified
				No	Same event
Select:	Flu A/Flu B/SARS COVID-2/SARS-related coronavirus RNA panel				

Laboratory Report	PCR Panel	Clinical specimen	Influenza B Virus	Yes	New event Confirmed
				No	Same event
Select:	Flu A/Flu B/SARS COVID-2/SARS-related coronavirus RNA panel				
Laboratory Report	PCR Panel	Clinical specimen	Negative Influenza B Virus	Yes	New event Unclassified
				No	Same event
Select:	Flu A/Flu B/SARS COVID-2/SARS-related coronavirus RNA panel				
Laboratory Report	PCR Panel	Clinical specimen	SARS COVID-19	Yes	New event Confirmed
				No	Same event
Select:	Resp virus Pnl XXX PCR				
Laboratory Report	PCR Panel	Clinical specimen	SARS COVID-19 Negative	Yes	New event Unclassified
				No	Same event
Select:	Resp virus Pnl XXX PCR				
Laboratory Report	PCR Panel	Clinical specimen	Bordetella pertussis	Yes	New event Confirmed
				No	Same event
Select:	Resp virus Pnl XXX PCR				
Laboratory Report	PCR Panel	Clinical specimen	Influenza A Virus	Yes	New event Confirmed
				No	Same event
Select:	Resp virus Pnl XXX PCR				
Laboratory Report	PCR Panel	Clinical specimen	Influenza B Virus	Yes	New event Confirmed
				No	Same event
Select:	Resp virus Pnl XXX PCR				
Laboratory Report	Rapid molecular or molecular point-of-care tests	Clinical specimen	Positive	Yes	New event Confirmed
				No	Same event
Select:	SARS coronavirus 2 RdRp gene				
Laboratory Report	Rapid molecular or molecular point-of-care tests	Clinical specimen	Negative	Yes	New event Unclassified
				No	Same event
Select:	SARS coronavirus 2 RdRp gene				
Laboratory Report	Rapid molecular or molecular	Clinical specimen	Inconclusive, Invalid	Yes	New event Unclassified

	point-of-care tests			No	Same event
Select:	SARS coronavirus 2 RdRp gene				
Laboratory Report	Antibody tests	Clinical specimen	Positive	Yes	New event Suspect
				No	Same event
IgM specific:	SARS-CoV-2 IgM				
IgG specific:	SARS-CoV-2 IgG				
IgG (spike protein):	SARS-CoV-2 IgG (spike protein)				
IgG (nucleocapsid):	SARS-CoV-2 IgG (nucleocapsid)				
IgA specific:	SARS-CoV-2 IgA				
Antibody Type Unspecified:	SARS-CoV-2 IgG + IgM				
Antibody Type Unspecified:	SARS-CoV-2 IgG + IgM + IgA				
Select:	SARS coronavirus 2 spike protein RBD Ab.neut : PrThr : Pt : Ser/Plas:Ord:IA				
Laboratory Report	Antibody tests	Clinical specimen	Negative, Equivocal, Unsatisfactory	Yes	New event Unclassified
				No	Same event
IgM specific:	SARS-CoV-2 IgM				
IgG specific:	SARS-CoV-2 IgG				
IgG (spike protein):	SARS-CoV-2 IgG (spike protein)				
IgG (nucleocapsid):	SARS-CoV-2 IgG (nucleocapsid)				
IgA specific:	SARS-CoV-2 IgA				
Antibody Type Unspecified:	SARS-CoV-2 IgG + IgM				
Antibody Type Unspecified:	SARS-CoV-2 IgG + IgM + IgA				
Select:	SARS coronavirus 2 spike protein RBD Ab.neut : PrThr : Pt : Ser/Plas:Ord:IA				
Laboratory Report	Antigen test	Clinical specimen	Positive	Yes	New event Probable
				No	Same event
Select:	SARS-CoV-2 Ag				
Laboratory Report	Antigen test	Clinical specimen	Negative	Yes	New event Unclassified
				No	Same event
Select:	SARS-CoV-2 Ag				
Laboratory Report	Antigen test	Clinical specimen	Equivocal	Yes	New event Unclassified
				No	Same event
Select:	SARS-CoV-2 Ag				
Laboratory Report	T Detect	Clinical specimen	Positive	Yes	New event Suspect

				No	Same event
Select:	SARS-CoV-2 TCRB Bld Ql Seq				
Laboratory Report	T Detect	Clinical specimen	Negative, Invalid, Unsatisfactory	Yes	New event Unclassified
				No	Same event
Select:	SARS-CoV-2 TCRB Bld Ql Seq				
Laboratory Report	Sequencing test	Clinical specimen	Because these lineages are routinely being updated, please select from the appropriately named option	Yes	New event Confirmed
				No	Same event
Select:	SARS coronavirus 2 variant : Type : Pt : XXX : Nom : Sequencing				
Laboratory Report	Sequencing test	Clinical specimen	Unsatisfactory, Invalid	Yes	New event Unclassified
				No	Same event
Select:	SARS coronavirus 2 variant : Type : Pt : XXX : Nom : Sequencing				