



COVID TESTING IN MONTROSE COUNTY

A Pandemic Response Update for the Board of Health

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Executive Summary

Montrose County has 5 different ways for the community to obtain COVID-19 testing. These can be obtained by order of public health, a medical professional, the medical director of a long-term care facility, an occupational health department of an employer, or by the consumer. There are 3 common test styles within the county, including serology, molecular point of care, and molecular RT-PCR (real time polymerase chain reaction). There are 3 major labs and several smaller ones available in the area.

Public Health carries out testing for suspected and confirmed outbreak sites. Long-term care facilities carry out surveillance testing of their employees and vendors. The medical community carries out testing for non-outbreak illness and exposures that the clinician determines reasonable. Public Health follows up on all positive cases to determine any case links that might suggest an outbreak and to identify close contacts for purpose of education and support in quarantine or isolation efforts.

Montrose County has secured the Event Center for use by Montrose County Public Health and Montrose Memorial Hospital for specimen collection. This allows for a drive through testing option (order required). Several medical offices in town offer on-site specimen collection including send-out and rapid testing options. After December 30, 2020, the Event Center will no longer be available for specimen collection. Decentralization of specimen collection will be key to ensuring access to specimen collection for those who need testing and Montrose County has been working with stakeholders for months to ensure a smooth transition.

Montrose County does not possess a State sponsored specimen collection site and never has. There is not the financial, human capital, clinical, or public health benefit to open access (no order required) specimen collection due to the nature of the diagnostic tests being used, the current public health orders related to isolation and quarantine, and the distraction from the basic public health preventative measures that do not involve testing. A non-test best prevention strategy is the most effective for reducing the negative impact of this pandemic on Montrose. In select populations, a frequently administered surveillance testing program may be appropriate, such as for employees in long-term care settings.

Montrose County continues to promote the basics of prevention and mitigation, which are social distancing, mask use, hand hygiene, isolation of the sick, and quarantine of the exposed to someone who is sick. A test-based mitigation strategy correlates (not causally linked) with a higher case rate, a higher death rate, fewer community outbreaks, and tighter restrictions on social and economic activity. Higher testing frequency does not correlate with fewer hospitalizations. A review of metropolitan areas in Colorado reveals a high testing rate, a high case rate, and high hospital bed occupancy. Conversely, Montrose has a relatively low testing rate, relatively low case rate, and low hospital census. This all may reflect disease prevalence variations across the State.

Limited public health resources, increasingly constrained as the year comes to an end while the pandemic continues, must transition specimen collection and testing to its eventual place in the medical sphere. Never in modern history has mass testing been conducted by public health on such a scale and for such duration. This is not the primary function of public health, but rather the medical community. Montrose County is a partner to our excellent medical community but it is not in the interest of the public to overtake the medical community's long entrusted role as diagnosticians who use studies when appropriate in the care of their patients. Public Health also does not have the human capital to carry out

the level of demand for specimen collection. We must depend on our medical community to support any pandemic response.

The most effective public health intervention is prevention followed by mitigation and containment. Continuing to message, model, educate, and enforce the basics will lead to the greatest spread reduction. Testing will complement those efforts to prevent spread into high-risk populations such as long-term care facilities. Testing, when conducted using public resources, should be reserved for someone who a public health official believes presents a public health concern and where the test result will further the aim of mitigation and containment, such as in outbreaks.

A test result in someone with or exposed to another with symptoms of COVID is not released from isolation or quarantine early. The misunderstanding that it does is likely a contributing factor to ongoing spread. The more messaging focuses on testing, as testing is currently available, and away from prevention, the more spread we will have. Testing as is currently available often detects the virus far after one's peak infectious period. Therefore, it is not a substitute for distance and mask use.

Soon, Montrose County will start to distribute vaccinations. Testing options will continue to come on-line and become more affordable. At the same time, public funding will dwindle. More community clinics will take on specimen collection which will broaden access. More offices will acquire rapid point-of-care test equipment and higher compliance with isolation instructions will be seen. These efforts, along with increasing vaccination, will continue to mitigate. Likely in the 2nd quarter of 2021, Public Health and the Emergency Operations Center will support a mass vaccination effort and then, once enough of our neighbors have beat this virus or have been vaccinated, we can gradually return to a socially close and maskless society where business is free to fill to their occupancy limit. Eventually, we will close the book on this pandemic. Until then, we must remain diligent, dedicated, and determined.

Ways To Obtain A COVID-19 Test In Montrose

In Montrose, there are five ways to obtain a COVID-19 test:

1. By order of a healthcare provider licensed to order laboratory diagnostic studies.
2. By order of public health.
3. By order of a long-term care facility medical director following CMS regulations for staff and vendor testing on a frequency determined by CMS dependent on the percent of tests returning positive within that facility's area.
4. Employer-provided testing through their occupational health department or contract.
5. Direct-to-consumer lab ordering and specimen collection (the consumer orders their own test without a healthcare professional's direct involvement).

There are three different tests widely available in Montrose currently:

1. Antibody testing (serology testing)
2. Molecular point-of-care (commonly known as a rapid COVID test; isothermal amplification)
3. Molecular RT-PCR (real-time polymerase chain reaction)

Lab Options In Montrose

There are various lab options in Montrose. The three large labs in Montrose that are operational are:

1. Montrose Memorial Hospital
2. Quest Diagnostics
3. LabCorp

Montrose Memorial Hospital (MMH) is the lab that is most used by healthcare professionals in the service area. If MMH processes the specimen, then this ensures that the hospital teams have access to a person's test result if or when care is needed. They also ensure that test results are transmitted to the regional health information exchange (HIE) so that if a patient presents for care at another hospital or facility on the western slope of Colorado, the healthcare team will have those results. By using the regional HIE, Montrose County providers received their patient test results in a time when the State Reference Lab had no interface built and could not transmit results directly to the ordering provider.

Quest Diagnostics operates a draw station in Montrose and is the preferred lab by some insurance companies. Quest also offers what they call "QuestDirect" which allows one to order their own tests. Quest is offering COVID-19 active infection testing using either a drive-through set-up or an at-home kit. The link to their ordering site is

<https://questdirect.questdiagnostics.com/products?category=Infectious%20Disease>. There is an associated physician services fee to the lab diagnostic fee. The total cost for a drive-through test from Quest is currently at \$128.30 and more for an at-home kit (1).

LabCorp provides in-office testing solutions for some clinics and some long-term care facilities within Montrose County. LabCorp does have a direct-to-consumer option similar to Quest. They do not offer in-person collection out of a doctor's office and encourage the ill to see their healthcare professional (2). They do offer an in-home collection kit. That can be found here: <https://www.pixel.labcorp.com/covid-19>. They advertise that there are no *upfront* costs (emphasis added).

As mentioned, some private offices possess POCT equipment or have contracted with specialty labs to process COVID-19 specimens.

Current Testing Policy of Montrose County Public Health

Public Health Orders

The current policy allows for cohort and outbreak testing to be performed under the Medical Advisor to the Public Health Director's standing order in support of the County's COVID-19 mitigation and containment efforts. This will activate public resources for specimen collection (either through department staff or through contracted services), handling, and publicly funded testing (either through CDPHE's State Reference Lab or a CDPHE contracted lab vendor). There is no cost to the consumer and there is no need for an independent clinical exam because there has been a Public Health Department identified public health threat that activates the mitigation response, which includes testing for surveillance data, contact tracing, and outbreak disinfection and containment effectiveness containment efforts (applicable when serial testing is required of a site).

Our mission from the Emergency Operations Center (EOC) is to *Save Lives. Save Jobs*. First and foremost, we want people to be safe and not suffer morbidity or mortality from COVID-19. We also must balance the strength of public interventions with the important mission of savings jobs. Testing is not a top-five public health intervention and may encourage some to leave isolation or quarantine prematurely.

Long-term care facility employees, vendors, and in some cases, residents

The current CMS policy requires that facilities test staff, vendors, and in some cases, residents. They also outline the frequency at which testing is required (3):

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency
Low	<5%	Once a month
Medium	5% -10%	Once a week*
High	>10%	Twice a week*

***This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.**

The skilled nursing facilities must use CMS's data on the positivity rate for determining the frequency of testing. The current dataset can be found at <https://data.cms.gov/download/hsg2-yqzz/application%2Fzipa> and the archived data can be found at <https://data.cms.gov/stories/s/q5r5-giyu> (4).

Public Health has worked with the three skilled nursing facilities in Montrose County and other long-term care facilities to support surveillance testing. Positive test rate figures can be false representatives of community prevalence depending on whether the community is doing a lot of cohort or pre-op testing compared with very limited testing protocols or testing a high frequency of outbreaks. Therefore, hospital census might be another measure. In any case, we have found that testing infrequently is not very helpful. Testing 3 times a week is likely a better frequency given current testing methods available and current prevalence levels (even if just using modeled actively infected figures which are dependent on hospital census and not tests performed data).

Non-Outbreak Exposure, Symptomatic Individuals, and Pre-Operative Testing

For non-outbreak exposure, symptomatic individuals, and pre-operative testing, the current policy requires that the individual coordinate with their healthcare professional, use a direct-to-consumer test option, or seek testing at a State sponsored specimen collection site, which can be found in Delta or Mesa County. For the sick or exposed non-critical worker (5), the test result is not a factor in the decision tree on when to discontinue isolation or quarantine.

Symptomatic Individuals

If one has symptoms of COVID-19 (6), then they are to self-isolate regardless of the test result (7). This is per public health order 20-36 §I.D. This states (8):

“If an individual has tested positive for COVID-19 and/or has developed symptoms of COVID-19, including early or mild symptoms (such as cough and shortness of breath), they should be in isolation (staying away from others) until they are released by public health. In most cases, individuals are released from isolation when they are fever-free, without medication, for twenty-four (24) hours, other symptoms have improved, and at least ten (10) days have passed since symptoms first appeared.”

An ill individual should be in isolation regardless of a COVID-19 test result. There are no specific therapeutics for COVID-19 for the non-hospitalized individual that are currently available (recognizing that emergency use authorization has been put forth for outpatient use of Bamlanivimab, an infusion for mild to moderately ill individuals with risk factors, but this drug is not widely available at the time of this writing). This limits the usefulness of having that test result for the individual.

If that ill individual is following the current public health order and is isolating, then they are doing their part in decreasing the spread of the virus. Distancing is the most effective intervention to stop the spread. If it turns out that the person is ill for a reason other than COVID-19, then the community still benefits from the reduced spread of whatever the infectious illness is, be that influenza, rhinovirus, Streptococcus pneumoniae, or something else.

There is a reason for the ill person to see their healthcare provider, too. They must be checked for other illnesses and early complications. We are now in the influenza season where there are specific therapeutics (treatments) that if started soon can shorten the duration of illness and the severity. The person needs appropriate counsel and instructions around what the duration of isolation needs to be for their condition. The immunocompromised person will require a longer isolation period and this should be considered between the patient and the healthcare professional (9).

Most important, the clinician should evaluate the patient for vital sign and other clinical abnormalities that require intervention. This can be accomplished only by a history, examination, vital sign check, and potentially other diagnostic studies (labs and imaging) to decide on what treatment is needed. These treatments might require supplemental oxygen, steroids, antibiotics, or other specific treatments depending on what is found. This is not accomplished simply by having access to a test. The data without the context and the support of a healthcare professional limits the usefulness of that data for that individual and may lead to higher emergency department visits.

A test administered by a public resource without a public health or healthcare professional's order does not identify if a person is a high risk or low-risk individual, if they have a medical complication that needs

to be intervened on, or if they have something else going on that explains their symptoms. It is good for disease prevalence detection, potentially allows for more contact tracing work, but also leads to an inappropriate frequency of testing, unnecessary testing, and inappropriate use of testing results to justify breaking requiring isolation and quarantine periods, which are not dependent on the individual's test result.

For the sick who recover within 10 days, they are still required to finish the 10-day isolation period. The CDC has moved away from a test-based return to work strategy (10). Currently, the State's public health order does not allow a sick person to exit isolation even with a negative COVID-19 test. The CDC guidance on return to work does discuss that a test-based return to work strategy is no longer recommended to "determine when to discontinue home isolation, except in certain circumstances." Those circumstances are reserved for the "severely immunocompromised, in consultation with infectious disease experts." The CDC goes on to state that when the test-based strategy is used, "at least two consecutive respiratory specimens collection ≥ 24 hours apart (total of two negative specimens)." However, this also assumes that the person has improving symptoms and is fever free. Using a test-based strategy, which is not recommended by the CDC except in limited cases, would be a large drain on limited public resources. Therefore, Montrose County Public Health has not and does not endorse a test-based return to work strategy. An employer who requires a negative COVID test from their employee is also not following the current guidelines.

Our policy correlates with a 22% increase in primary care attribution for the Medicaid Prime program in Montrose County. This yields short- and long-term benefit to reducing unnecessary emergency department care, health expenditure, avoidable hospitalizations, poorly controlled chronic illnesses that shorten lifespans, and decrease the quality of life (11).

For the sick individual, requiring that the individual consult with their healthcare professional ensures that the individual is professionally cared for. An accurate diagnosis can be rendered, and a treatment plan developed. With this early intervention, appropriate counseling around isolation can occur. Pharmacy delivery can be organized. In-home services can be arranged.

Non-Outbreak Exposure

If there is potential exposure to COVID-19, then that person is required to have an order for testing by a public health official or healthcare professional if they are to use public resources for that specimen collection and testing. Both the CDC and the CDPHE require that a person who is exposed to COVID-19 enter quarantine. **A negative test does not release that individual from quarantine early** and therefore, the test provides limited value. The reasoning for this stance is that the false-negative rate in an asymptomatic but exposed individual is quite high. One study concluded that the false-negative rate was 100% on day one and by day four, that false-negative rate was still 67% (12). On the day of symptom onset, the false-negative rate was still 38% and 20% by day 3 of symptoms.

Requesting that an individual consults with their healthcare professional if they suspect an exposure allows that individual to receive professional guidance on if that exposure meets criteria and what level of risk that individual has. It allows for personalized care that considers that person's health history, risk factors, in-home needs, resource limitations for quarantine or isolation, and allows for planning in case symptoms do develop.

Pre-Operative Testing

Testing for COVID-19 in asymptomatic, non-exposed individuals before a scheduled surgery is not a public health intervention and has not been endorsed locally. Montrose Memorial Hospital chose to do pre-operative testing for scheduled procedures, a procedure consistent with other hospitals in the State. These tests, however, are ordered and collected by staff at the hospital. The Hospital has recently changed its position on requiring pre-operative testing and will defer to the judgment of the surgeon or anesthesiologist.

Community Screening

Community screening, meaning assessing those who do not have evidence of an illness before illness begins so that very early isolation can occur is not presently available via public health. It is not available due to the inherent limitations of our current tests, the need for heavy human and financial capital, centralized lab locations that demand transport, and slow turnaround times. For an effective community screening program, a test would need to be inexpensive, sensitive, able to be conducted quickly and comfortably, and present results within minutes. This must then be backed by a confirmatory process and appropriate isolation preparation and implementation.

“The key question is not how well molecules can be detected in a single sample but how effectively infections can be detected in a population by the repeated use of a given test as part of an overall testing strategy – the sensitivity of the testing regimen [rather than the test itself]” (13). We need low cost, easy to implement tests with near-immediate test results. A lower specificity might be expected. A positive will need confirmation. This method when applied until vaccination or herd immunity is obtained is a reasonable strategy that would result in less COVID-19 spread. We have seen that testing weekly with results coming back a week later has not resulted in satisfactory protection of these populations. Unfortunately, we do not have the technology to bring this to bare.

What we currently have is the ability for everyone to do a self-assessment to see if they have signs or symptoms of an illness. Much like we expect pilots to do a self-assessment on their fitness for duty before flight, the conscientious citizen must self-assess for fever, cough, shortness of breath, loss of taste and smell, and other symptoms of COVID-19. That may allow for the early detection of infection and if the conscientious citizen places themselves in isolation, then the transmission of the virus will be slowed or stopped. Unfortunately, we have a reliance on lab data and a mistrust in our own ability to assess our signs and symptoms. In a world where the individual believes they know their body better than anyone else, we have largely turned over finding out if we are sick or well to a piece of lab equipment. If one feels sick, they are encouraged to stay home.

Effectiveness of Local Testing Efforts

How do we define the effectiveness of testing? Should we use resident satisfaction, cost containment, reproductive value (r -naught) for spread, hospital census, number of outbreaks, death count, something different, or a combination of these? Of course, the effectiveness, or lack thereof, of a pandemic response cannot be summed up in one tool, such as testing. However, correlations can be made.

Montrose County has detected 632 confirmed positive COVID19 cases as of 11/16/2020. The local model predicts that 9.2% of the population has been infected by COVID-19. At a population of 42,758, this is equal to 3,918. 632 confirmed cases of 3,918 modeled cases indicate a 16% detection rate. The Colorado COVID-19 Modeling Group reports that “9.1% (95% CI: 9.0, 9.2) of the Colorado population has

been infected to date” (14). That is consistent with our local model indicating 9.2% of Montrose County has been infected. On 11/4/2020, the date of the modeling report cited above, 117,637 cases had been identified in Colorado (15). That is equal to 22% of modeled cases (cases divided by (9.1% multiplied by 5.758736 million)). More effective than a testing regimen is for the sick to stay home and the exposed to anyone with COVID-19 symptoms to do the same. We have seen breaches locally in containment because of sick employees going to work with high-risk populations.

Montrose County ranks 47th (higher the number, lower tests per 100,000 during the pandemic) out of 64 counties in Colorado (16). Comparing this rank to surrounding counties, Delta is ranked 44th. Ouray is 7th. Mesa is 20th. San Juan is 22nd. San Miguel is 36th. Gunnison is 54th. The point to emphasize here is that testing tends to correlate with case rates but does not correlate with better pandemic control. For example, Ouray, San Miguel, Mesa, and San Juan Counties are all under tighter restrictions than Montrose. Gunnison and Delta are in mitigation currently and are under lower levels of restriction.

Montrose is also in mitigation and this is not a competition amongst counties. We are all in this together and as the ocean swells, we all go up. Montrose will likely soon meet the dial restriction levels of some of our neighbors as we have seen increasing case counts. This does show that 5 of the 6 counties test at a higher rate than Montrose and 4 of the 6 counties are in tighter restrictions. Therefore, higher testing rates correlate with more restrictions in our local region. We will explore the entire state below.

Montrose County ranks 44th (higher the number, lower the cases per 100,000 during the pandemic) out of 64 counties in Colorado for number of cases per 100,000 during the pandemic. Our testing is consistent with our rank in the counties for case count. If we tested more, we would likely find more cases. Yet, this would be unlikely to positively impact the spread any more than staying focused on the non-test-based prevention strategy of the response team. Hospital use becomes the ultimate indicator of case spread given that each community has different testing access and community interest levels in testing.

Montrose Memorial Hospital has had sustained reductions in total hospital census during the pandemic of nearly 30%. That does not mean that they are not busy, working hard, admitting and discharging, and using creative solutions in the emergency department to find outpatient options for people to avoid an admission. That figure does not recognize that because of sick employees and exposure related quarantine in the community, capacity may not be the same as it did in years past despite having open beds. Even with the hospital bringing on additional nursing staff to support operations, they work hard to maintain their workforce as employees are exposed in the community or become ill.

Even though there may be less people occupying a hospital bed at the end of the day, the stress, workload, and demand is high and reportedly as high as it was back in April 2020 during that first uncertain wave of COVID. Yet, we have not overwhelmed our hospital resources and no one in Montrose has died because they did not have access to care at the hospital. The EOC has always prioritized preservation of the healthcare system integrity above all else. We have achieved that, thus far.

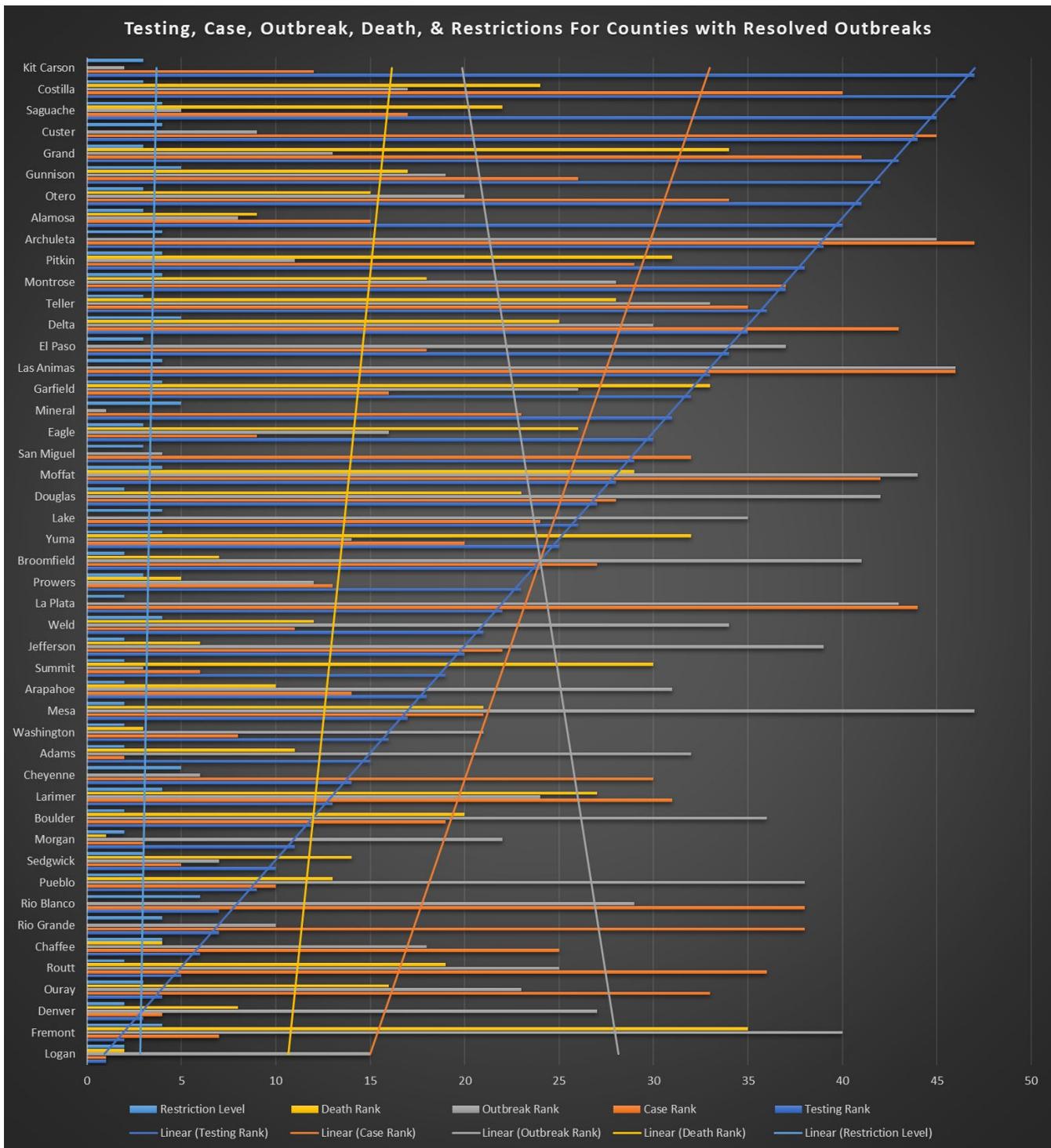


Figure 1. Created from data taken from CDPHE's case summary as of 11/19/2020 (17), CDPHE's resolved outbreak data from 11/18/2020 (18), and World Population Review's "Population of Counties in Colorado (2020)" (19).

Montrose County has 4 active outbreak sites according to the latest publicly available data on CDPHE's website as of 11/18/2020 (18). Of the 64 counties, 47 counties show a resolved outbreak. Figure 1 shows the 47 counties that have one or more resolved outbreaks. For all measures, the higher the rank

(lower number shown on the x axis), the more cases, testing, deaths, or outbreaks. A high rank number, 47 for example, would indicate low testing, cases, deaths, and outbreaks. This graph suggests that with more testing, there are more cases and more deaths but fewer outbreaks. With more cases, the communities are placed in more restrictions. It is a correlation that with more testing there are more cases and fewer outbreaks. It may be that more testing reduces outbreak sites or it may be that more testing causes businesses to shut down through public health order which prevents them from being labeled an outbreak site.

This data set does not indicate that a test-based mitigation strategy leads to lower spread. Rather, the opposite is true. More testing correlates with more cases. Thousands of people in Montrose County have been infected with COVID-19 to date, an estimated 9.2% of the population and growing each day. Yet, only a few hundred cases have been identified and only a few dozen have been hospitalized. Whether we detect the cases or not, they are out there. The ones that matter the most are those that jeopardize high-risk populations.

Notes on Current Testing

Limitation of PCR Testing

- Current PCR-based testing catches illness late in the disease course making its value as a mass containment intervention poor (20).
- Comparing testing rates by county in Colorado, we do not find a correlation between high testing and better pandemic control. Rather, we often see that communities with higher testing rates have high levels of hospital demand and heavy social and business restrictions.
- Current PCR based testing results in a high number of false-positive results when applied to low to moderate prevalence areas such as Montrose County (21).

Local Financial Implications of Testing

- May be generating around \$100,000 in avoidable costs per 1,000 samples (we are currently collecting around 1200 samples per 14 day period) due to false positive and false negative results (22). This could be a cost of \$3,096,000 a year in Montrose County.
- There is a lack of a financially sustainable specimen collection and handling model without tax increases or government service reduction and shifting budgeted expenses. A sizeable payer source runs out at the end of 2020.
- Even if there were a sustainable financial model for direct-to-consumer COVID specimen collection, local public health lacks the staffing to perform specimen collection and handling to the degree necessary for community screening or large scale testing operations (even current testing levels). Surrounding county public health agencies have either contacted our local public health indicating their inability to sustain an open testing model or they have had to call in State resources to back up testing operations. We need decentralized specimen collection with rapid results. This could be managed by getting all clinics in the county to do specimen collection and would be best if each had in-house POCT options with confirmatory testing as a backup.

Limitations on Direct to Consumer Testing

- Direct-to-consumer (no order required) testing leaves “a significant opportunity for exploitation of the patient” and “places patients at risk of iatrogenic harm” (23).

- Direct-to-consumer testing may lead to higher detection of disease prevalence without actual changes in disease prevalence that then motivates government entities to implement higher levels of restriction without any real risk to the sustainability of the healthcare system. This means that we need to be following hospital census and not rely on case counts alone.
- Direct-to-consumer test results may be provided without adequate counseling on how to interpret and what to do with the result.
- Direct-to-consumer testing may decrease the likelihood that a sick person will seek primary care and may increase the likelihood that they will seek emergency department care. Without primary care being available to the patient, the emergency department providers are more likely to admit the patient for observation to ascertain the direction of the patient's disease course.
- Montrose County has encouraged primary care attribution and this correlates with a greater than 22% increase in Medicaid PRIME patient primary care attribution during the pandemic compared to last year. This leads to better healthcare, lower cost, and reduced hospitalizations (11). Overall, that saves our healthcare system and saves lives.
- Direct-to-consumer testing may encourage relaxation in the actual public health measures that are evidence-based interventions: social distancing, mask use, self-isolating of the sick, and quarantine of the exposed.
- Direct-to-consumer testing is often not used correctly because there is not wide-spread understanding of the current definition of close contact. This leads to over-testing and when coupled with risks for false-positive results, this can lead to unnecessary isolation, contact tracing, and additional population testing due to false exposures. Conversely, it may lead to a false-negative and further the spread of COVID if the test timing is not correct.
- Direct-to-consumer testing resulting in a negative result does not mean that a person does not have the virus and does not mean that they are not contagious. It also does not mean that the person will not become sick.

Test Result Interpretation Limitations

- A negative COVID-19 test does not release someone from the required 14-day quarantine after a close contact. One might be returned to work during quarantine under a critical worker pathway (where additional limitations exist) but this is not dependent on receiving a negative COVID test.
- A negative COVID-19 test in a symptomatic person does not mean that the person does not have COVID-19. There are false negatives. Therefore, all persons with COVID symptoms, regardless of their test result, are required to isolate. A negative COVID-19 test does not stop the isolation period for a person who has symptoms of COVID-19.
- A false-positive COVID-19 test generates fear and is best avoided with appropriate clinical evaluation, counsel, and test result planning between the patient and their provider.
- A false-negative COVID-19 test without clinical evaluation may lead to late access to care that could have prevented complications.

Strengths and Weaknesses of Different Tests

Each test has strengths and weaknesses. We will not exhaustively detail the tests. However, there are some points to note about these tests.

Antibody Tests

Antibody (serology) tests are not advised for the guidance of clinical management. The results are highly variable. They may indicate a past infection and a positive is considered a suspected case of COVID-19 unless that person also meets critical criteria or an epidemiologic link is established (24). These results, due to relatively low sensitivity and specificity are highly dependent on the community prevalence. They are subject to false positives and false negatives. The equipment used highly influences these results. Montrose Memorial Hospital is using the Ortho VITROS, which has high-performance marks.

This test helps calculate what percent of the population has contracted COVID-19 during the pandemic. This helps public health to check the accuracy of model data. There is a large selection bias in the sample. This means that people usually get the antibody test because they think they had the illness. It would be most accurate if a random sample was selected but that has not been done and is not currently planned as it would be unlikely to significantly impact containment efforts.

Molecular Point-of-Care Testing

Molecular point-of-care testing (POCT) presents the result within 15 minutes, by most makers, but the user loses on sensitivity (the likelihood that it will find a true positive) and specificity (the likelihood that it will identify a true negative as negative). The November 5, 2020, HAN indicates that the test has “Generally lower sensitivity than PCR tests but good specificity (unlikely false positives).” When you consider community prevalence and if mass testing was performed, the performance of the test results in a high number of false positives despite having a good specificity.

With appropriate clinical decision making, this tool can be useful. If used for the masses without clinical pre-test consideration, a significant and costly number of false positives will result. For example, if the community prevalence of active COVID-19 was 1.8% and the Abbott ID NOW system was exclusively used, then the likelihood that a positive test result is a true positive test is only 49.2%. That is worse than flipping a coin. If the community prevalence of COVID-19 increases to 8%, then the likelihood that a positive test result represents a truly positive test is 82.1%. This particular test will miss many true positives with only 7.2% of tests returning positive while true prevalence is at 8.0%, in this example. 0.8% may not sound like much but if this were used on the entire county, then over 3400 cases would be missed.

Essentially, if your clinician thinks you have COVID-19, then a negative result on this test cannot be trusted.

These POCT tests can be obtained by private practices by ordering them directly from the manufacturer. Many long-term care facilities were supplied these POCT tests from the federal government. CDPHE also supplied Montrose County Public Health a POCT unit and we have placed this machine in Montrose Memorial Hospital. Until just recently, CDPHE had not allowed long-term care facilities to use the POCT molecular test machines supplied by the federal government due to concerns about the test performance. They have since reversed that decision and two of the three skilled nursing facilities in Montrose County have begun using their POCT machines to meet both CMS and CDPHE testing requirements.

Private manufacturers are reportedly not able to ship cartridges directly. Rather, they must ship to government entities first. This is causing challenges for some of our practice in obtaining test cartridges.

Molecular RT-PCR

PCR based testing is what the State Reference Lab has been doing. It is considered the gold standard despite being approved under an emergency use authorization by the FDA (25) (26) (21) (27). However, it is also subject to errors and the results need to be interpreted in the context of the individual. The FDA's "Fact Sheet for Healthcare Providers" updated June 12, 2020, states that:

"A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is **presumptively infected** with the virus and **presumed** to be contagious. Laboratory test results should always be considered in the context of clinical observation and epidemiological data in making a final diagnosis and patient management decisions. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines." Emphasis has been added.

Although considered the gold standard, no test is perfect. This test does have a higher sensitivity which allows it to detect true cases better than POCT options. For example, if the community prevalence (number of active cases) of COVID-19 in Montrose was 1.8%, then a positive result represents a true infection in 94.6% (using a sensitivity of 95% and specificity of 99.9%). In this case, a negative result is likely to be a true negative. Yet, this is highly dependent on when the person was tested. If tested too early in their illness or after exposure, then there is a chance of returning a negative result.

Access to Medical Care in Montrose

Access to medical care in Montrose is high. Montrose Memorial Hospital has determined that the service area (which is larger than the population of Montrose County) does not require an additional primary care provider. The Health Resources and Services Administration's (HRSA) Health Professional Shortage Area does not identify a primary care shortage for the City of Montrose. However, it does identify a 1.13 FTE (full-time equivalent) shortage for the "Nucla/Norwood Service Area." They further identify a 3.35 FTE shortage in the "East Montrose/Ouray" named region (28). HRSA is not as up to date on community needs as the local medical community.

Montrose Memorial Hospital serves all that require services following EMTALA (29). The emergency department serves as the safety net for all emergency services within our community. There are several primary care safety net practices. There is a federally qualified health center, two practices that provide sliding scale fee schedules, cash discount clinics, and two membership-based primary care offices in town. Numerous private practices take Medicaid, Medicare, and various commercial insurance plans. There is also a VA clinic in town. Therefore, if one has a public insurance plan, a private plan, or no plan, there are various options for access. Resources for the consumer include calling the Montrose Memorial Hospital physician referral line at 970-249-2211 or if the person does have insurance or a health sharing plan, they can contact that company's physician referral line. A bridge between primary care and emergency care is urgent care. We have one urgent care in Montrose.

Those who do not have an established provider and those who do not want to establish care can use CDPHE's "Telehealth and nurselines directory" found at <https://covid19.colorado.gov/are-you-sick/use-telehealth/telehealth-nurselines-directory>. This resource lists several options that cover all residents of Colorado to help answer COVID-19 related questions and provide guidance to concerned individuals (30).

Montrose County Public Health and the Montrose County Emergency Operations Center, approved by the Montrose County Board of Health, has staffed a COVID-19 hotline at 970-252-4545 since the beginning of our pandemic response. This hotline provides basic COVID related information, best practices, and guides the caller through obtaining a healthcare provider and potential testing. The hotline also helps to connect callers with their test results if the order was from public health.

History of COVID-19 Testing in Montrose

During the early part of the pandemic, local public health was not supplied with test kits. Our local hospital, Montrose Memorial Hospital, was able to convert viral transport media that it had for other laboratory testing and additional supply of that media for COVID-19 testing purposes. At great expense of human and financial capital, the hospital lab personnel separated their media into different kits and made these kits available to clinicians, patients, and public health at no cost. Because the supply was limited, testing criteria were tight. At this time, limited testing was endorsed by all major public health agencies due to the limitations in supply. As the pandemic progressed, the State of Colorado was able to acquire more collection kits with appropriate media and then began to ship those supplies to hospitals and local public health.

Using hospital resources and using Montrose Memorial Hospital lab to process the orders required a provider order. It was a way to be respectful of the limited supply of tests and the limited supply of specimen collectors within the county. Montrose County continues to use Montrose Memorial Hospital's lab to handle the vast majority of specimens collected within Montrose County. This has served the County well on several fronts.

This allowed for "one source of truth." This was instrumental to our Emergency Operations Center, Medical Response Team, Hospital Incident Command, and Board of Health for situational awareness that shaped policy discussions early in the pandemic response. Montrose Memorial Hospital recorded all test results into their electronic records system. This allowed for transparency of data when the ill presented to the emergency department anywhere on the Western Slope where, through our regional health information exchange, that clinical team could readily know what testing results were. This prevented unnecessary delays in care, the unnecessary expenditure of limited PPE supplies, and prevented inappropriate exposures to healthcare personnel.

Over the term of the pandemic to date, the local public health agency has become the source of truth as all sources of Montrose County resident specimen collection (within Colorado) can be linked back to our datasets if that data is known to the State surveillance program. However, we have not solved the need for data transparency to our medical teams for all positive results (on an as-needed data query basis through hospital records or the regional health information exchange) unless that test either goes through the State reference lab or Montrose Memorial Hospital.

Using newer State contracted vendors, such as MAKO and Curative Labs does not get that test results back to the health information exchange automatically, at least not currently. That leaves our healthcare professionals working in the dark if a sick patient were to present for acute care. Public Health will submit a file of positives in a secure fashion to the health information exchange so that at the minimum, a patient's healthcare team can access the test result if and when needed.

Additionally, by partnering with Montrose Memorial Hospital, we gained the workforce that the local government did not possess to handle the growing demand for specimen collection and processing. That freed up limited public health resources to focus on preventative measures. Initially, public health had one registered nurse (RN) and a couple of assistants (including a volunteer from the local school district) that would do all specimen collection. This quickly became overwhelming.

The Hospital offered to lend support for collection efforts at no cost to the County but at great cost to themselves. It was fortunate that they did else we could not have sustained with the growing demand. Eventually, the County allocated CARES funding to the support of specimen collection carried out by Hospital specimen collectors. Public Health also trained interested clinics in the County on safe and appropriate specimen collection and the EOC distributed PPE to those clinics for safe specimen collection. This support allowed our RN and her assistants to return to their other public health duties, which did not go away.

Contact Tracing

Contact tracing efforts have been ongoing since the very beginning of our public health response and of the Emergency Operations Center efforts. However, we have often been subject to long term around times on test results. Results have stretched from 5 to 14 days. Anecdotally, contact tracing work has been ineffective at slowing the rising reproductive number in the County and the State despite well trained and hard-working staff.

The reason why current contact tracing efforts are ineffective is likely due to the long test turnaround times. Although we would see more optimal disease control if people would isolate and quarantine without a test result, we find that compliance is higher if a positive test result is delivered. Contact tracing becomes ineffective if that contact is made more than 4 days from the start of symptoms (31). With test turnaround times taking around a week, by the time contact is made, many exposures have occurred, and the reproductive number is kept above one.

Furthermore, one must question how effective a contact tracing effort could be with a 2-16% disease detection rate.

Future of COVID-19 Testing

The following is simply a potential list of things to come over the 6 months but does not imply a plan, endorsement, or guaranteed path. With an impending vaccination, a depletion of public funding, consumer demand for better access to COVID-19 testing, manufacturer interest in market capture, and CDC's interest in spread mitigation, the following may occur in the near term:

1. Testing will decentralize. Oral swab collections will soon be the normal means of specimen collection for PCR based testing. This will be performed at most clinics in Montrose, the hospital, and as confirmatory tests for associated healthcare facilities performing surveillance testing.
2. Rapid testing equipment will be implemented in most healthcare facilities. A positive test will be followed by a confirmatory PCR based test.
3. Eventually, vaccinations will start to become available but it will be 5-6 months before the general population is participating in mass vaccination. In the meantime, low cost, low specificity, but adequate sensitivity tests will become market available for employers or

individuals to use frequently, maybe even daily, that will cost around \$5 per trial. After mass vaccination, this style of testing will no longer be relevant.

4. Contact tracing will become more effective because of faster turnaround times on test results.
5. More widespread detection of cases will force a modification to the existing dial system as case counts increasingly disassociate with healthcare demand.
6. Schools will experience more student absences and if school cohorting rules are not updated to reflect the earlier detection capabilities of more “screening” style community testing using low cost and home-based kits, then the schools will remain in a remote learning scenario.
7. If we could get to daily community screening using a low-cost and self-administered test, then the exposed could avoid quarantine with a daily rapid test resulting in negative until such time that it becomes positive as long as usual public health interventions were maintained and high-risk groups avoided.
8. We will also have better access to treatments, such as Bamlanivimab, for mildly ill individuals who have risk factors. That will help reduce mortality and hospitalizations.
9. Eventually, mass vaccination or herd immunity will stop the pandemic and the virus will settle into one of those known human pathogens that can infect the non-immune. Booster immunizations may be necessary as we learn as a society how long antibodies or memory cell immunity last after immunization or infection.

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