Molecular SARS-CoV-2 Testing During the COVID-19 Outbreak: Experiences of a Hospital in Southeast Michigan, USA.

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INTRODUCTION

The novel Coronavirus SARS CoV-2 (COVID-19) outbreak was complicated by the lack of diagnostic testing kits. In early March 2020, leadership at Beaumont Hospital, Royal Oak Michigan (Beaumont) identified the need to develop high capacity testing modalities with appropriate sensitivity and specificity and rapid turnaround time. We describe the molecular diagnostic testing experience since initial rollout on March 16, 2020 at Beaumont, and results of repeat testing during the peak of the COVID-19 pandemic in MI.

OBJECTIVES

- Review trends in COVID-19 testing results as guidance on who to test has been changing
- Review how implementing different infection prevention methods may affect the outbreak curve
- Develop a tool to help clinicians decide to keep symptomatic patients in isolation in case of false negative COVID-19 testing

METHODOLOGY

Beaumont is an 1100 bed hospital in Southeast MI. In March, testing was initially performed with the EUA Luminex NxTAG CoV Extended Panel until March 28, 2020 when testing was converted to the EUA Cepheid Xpert Xpress SARS-CoV-2 for quicker turnaround times. Each assay was validated with a combination of patient samples and contrived specimens. The below tool (figure 1) helped clinicians determine if a patient may have tested falsely negative for COVID-19.

Epidemiology COVID-19 Isolation Removal Screening
Admission Date: @admitdt@

Yes	No		
☐	☐	1.	Does the patient have an abnormal chest x-ray, compared to prior, without an alternative explanation (such as CHF)?
☐	☐	2.	Are the patient's LFTs abnormal without alternative explanation (such as cholecystitis)?
☐	☐	3.	Is the patient's renal function abnormal without alternative explanation (such as CHF, CKD, chronic dialysis)?
☐	☐	4.	Does the patient have a non-chronic low lymphocyte (*not total WBC*) count?
☐	☐	5.	Has the patient had a fever of 100.3 F or greater within the past 72 hours that does not have an alternative explanation (such as post-op fever, cellulitis, abscess, etc)?
☐	☐	6.	Does the patient have any non-improving hypoxia that does not have an alternative explanation or normal for baseline (such as COPD, CHF, asthma)?
☐	☐	7.	Did the patient already have a positive rapid influenza/RSV NAAT, respiratory viral panel, atypical respiratory bacterial NAAT panel, Legionella urine antigen, or Streptococcus pneumoniae antigen which would explain illness?

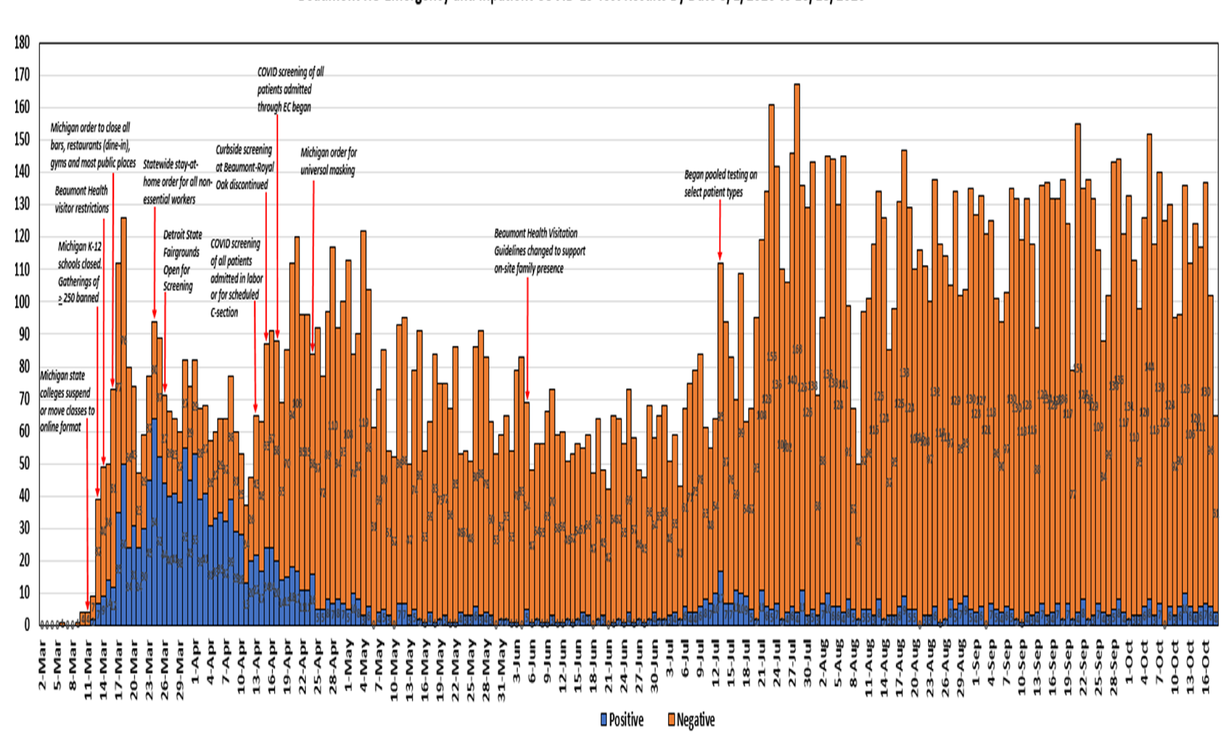
☐ **Patient REMOVED from COVID-19 isolation precautions. First six responses are no OR seventh response is yes, patient discussed with primary attending and/or ID physician and the bedside nurse, and no lingering concerns for COVID-19 reported. (May need to maintain in droplet isolation)**

☐ **COVID-19 isolation precautions CONTINUED and repeat testing ordered if appropriate. At least one of first six response is yes AND seventh response is no, or the attending, ID physician or bedside nurse have lingering COVID-19 concerns.**

RESULTS

During the initial week of testing there was > 20 % specimen positivity. As the prevalence grew the positivity rate reached 68% by the end of March (Figure 2). Many state and hospital initiatives were implemented during the outbreak, including social distancing and screening of asymptomatic patients to increase case-finding and prevent transmission. We also adopted a process for clinical review of symptomatic patients who initially tested negative for COVID-19 by a group of infectious disease physicians (Figure 1). This process was expanded to include other trained clinicians who were redeployed from other departments in the hospital. Repeat testing was performed to allow consideration of discontinuation of isolation precautions. During the surge of community cases from March 16 to April 30, 2020, we identified patients with negative PCR tests who subsequently had repeat testing based on clinical evaluation, with 7.1% (39/551) returning positive for COVID-19. Of the patients who expired due to COVID-19 during this period, 4.3% (9/206) initially tested negative before ultimately testing positive.

Figure 2



DISCUSSION

- Since January 2020, over 8 million cases of COVID-19 have been identified in the United States of America and nearly 40 million cases worldwide[1]
- Infection prevention (hand hygiene, social distancing, masking) and early identification, isolation, and treatment of cases may likely be the best strategy to end the pandemic
- There is a low, but significant rate of false negative molecular testing in persons infected with COVID-19
- False negative tests may provide persons invalid reassurance which may result in heightened transmission of the virus
- Admitted patients who falsely test negative are at risk of transmitting COVID-19 to healthcare workers, patients, and visitors

CONCLUSIONS

- Many state and hospital initiatives helped us flatten the curve for COVID-19.
- Our hospital testing experience indicates that repeat testing may be warranted for those patients with clinical features suggestive of COVID-19.
- We will further analyze these cases and clinical features that prompted repeat testing.

REFERENCES

1. WHO Coronavirus Disease (COVID-19) Dashboard. http://covid19.who.int. Last accessed October 19, 2020.

ACKNOWLEDGEMENTS

- The Molecular Probe lab for their tireless work
- Diane Kamerer for weekly updates on Figure 2 as the pandemic has evolved