April 21, 2020

MEMO RE: POINT OF CARE TESTING FOR COVID-19

The Department of Public Health has, through press releases and community observations, received multiple reports of private point-of-care testing for COVID-19 (novel coronavirus). These tests include both RT-PCR and antibody modalities.

In general, the Department supports increasing the availability and accessibility of COVID-19 testing as part of a robust strategy for sufficient community monitoring. However, facilities who choose to offer such testing are reminded of the following:

- **The use of tests without Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration requires a high-complexity CLIA certificate.** In addition, facilities with a CLIA waiver may only use tests that have an FDA EUA permitting it. As many facilities have selected serology testing, the FDA as of this writing only shows four serology assays on their EUA listing at [https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations](https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) and none may be performed by facilities with only a CLIA waiver. Facilities interested in this modality should monitor the FDA list regularly. The use of non-EUA tests without a high-complexity CLIA certificate is a **violation of federal law.**

- **Facilities must report tests administered as well as positive results.** Under emergency amendments to California Code of Regulations §2500 and the Order of the Public Health Officer issued April 3, 2020 and updated April 20, 2020, facilities performing testing for COVID-19 **must** report both positive results and tests administered.
  - COVID-19 **positive** results should be faxed on a standard Confidential Morbidity Report form to 951 436 7776.
  - COVID-19 **testing** performed should be reported electronically. The Public Health Officer Order requires that facilities performing this testing **coordinate reporting through Manifest MedEx**, which serves as the county health information exchange. For assistance, please contact Vikram Kumar, MD, chief health information officer for the Riverside University Health System at 951 486 5143 or v.kumar@ruhealth.org.

Attentively,

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County of Riverside