

August 27, 2020

COVID-19 Direct Response Update—Diagnostic Testing

As California moves forward with the state's response to the COVID-19 pandemic, testing continues to be essential. Adequate testing that is timely, equitable, and cost-effective will support the public health goal of "flattening the curve" while enabling critical sectors of the economy to stay open. Currently, laboratories are processing tests within three to seven days. However, to contain the virus, turnaround times must be within 48 hours, and ideally under 24 hours. Despite efforts to expand the existing public and private laboratory footprint, the state's overall capacity remains inadequate.

To address this problem, the California Department of Public Health (CDPH) has contracted with PerkinElmer to build out new laboratory capabilities within the state to expand testing capacity by up to 150,000 diagnostic tests per day with a contractual turnaround time of 24-48 hours. This new testing capacity will be additive to the capacity currently available in the network of laboratories, and is not intended to replace existing capacity.

Summary of the PerkinElmer Contract

- The contractor will establish a laboratory in California to process up to 150,000 tests per day for one year, with guaranteed test results provided within 24 to 48 hours.
- Under the contract, the cost per test will be \$37.78 at 100,000 tests per day and decreasing for every additional 10,000 tests to \$30.78 at 150,000 tests per day. Additional costs to recover facility and logistics costs will be added to this per test charge.
- For context, Medicare and Medicaid both reimburse at roughly \$100 per test, while the average reimbursement by other payers ranges from \$150 to \$200.
- Contract terms include a 45-day termination clause, adjustments if new technology becomes available and a most favored nation clause.
- The term of the Agreement is fourteen months and is subject to renewal for two additional year terms.
- The state will be responsible for making two upfront payments to help facilitate the enormous investment required for this endeavor.
 - First payment in the amount of \$100.2 million will be made upon notification by PerkinElmer of the completion of the following actions:
 - Ordered all equipment necessary for the lab;

- Hired recruiting agency for hiring personnel for performance of the services at a facility;
 - Completed federal Emergency Use Authorization (EUA) for the test to be used to perform the services; and
 - Obtained all accreditations necessary for performance of the services.
- Second payment in the amount of \$100.2 million will be made upon delivery to CDPH the first reported result of the tests performed at the lab.
- All these upfront costs will be recovered in a per test offset of \$5.51 until all costs have been recovered.
- As an incentive to reach a testing performance of over 120,000 tests per day, an additional \$ 74.8 million will be paid upfront but also will be recovered from each testing charge.
- Once the lab is operational, PerkinElmer will be paid for the prior month based on how many tests it averaged per day.
- The state will make the required payment to PerkinElmer and then a third-party billing vendor will recover costs from health insurers, employers, Medi-Cal and other payers. In the event there are still costs unrecovered, the state will coordinate with FEMA to help address those costs.
- If the lab is successful at averaging over 150,000 tests per day for the 12-month duration, the total cost could reach \$1.7 billion over that period.

Mitigation to Help Reduce Fiscal Exposure

To mitigate the fiscal exposure and overall risk to the state, there are a number of provisions in the contract, including:

- **Change in Technology Provision:** The contractor has agreed to work with the state to deploy new technology. If the contractor is not able to implement the technology, or an equivalent technology, then the state has the ability to terminate the contract with a 30-day written notice.
- **Termination Provision:** To limit the state's fiscal exposure, the contractor has agreed to a 45-day termination notice period. Additionally, the state will have the ability to terminate the contract with 30-day notice for material breach of contract.
- **Test Reliability Provision:** To ensure that all tests will be performed to the specifications (reliability and specificity) outlined in the federal EUA, and in accordance with federal Clinical Laboratory Improvement Amendments rules, the contractor agreed to warranty the test. The contractor warrants further that the testing services will detect as few as twenty copies per milliliter.
- **Test Turnaround Provision:** To ensure timely turnaround times, the contractor has agreed to a penalty for test results delivered outside 48 hours. This includes a 5 percent reduction in the variable cost if less than 90 percent of test are not

processed within 48 hours. Similarly, a 15 percent reduction in the variable cost will be applied if less than 80 percent of tests are not processed within 48 hours.

- **Claw Back Provision:** To mitigate the state's fiscal exposure, the contractor has agreed that in the event of a material breach, the State will be repaid all of the startup costs, less any amount that has already been credited back as a discount (with a credit of \$5.51 per reported result until the startup costs have been fully credited). If the material breach is not intentional, fraudulent or in bad faith, the refund would be the same as above, but capped at roughly \$100 million.

Additional Costs to Facilitate this Effort

The PerkinElmer contract is limited to laboratory services and does not include specimen collection kits (swabs), transportation of the specimen to the lab or third party billing services.

The state will be responsible for three lines of effort to support this contract:

- The Department of General Services will manage the build out of the laboratory with estimated one-time costs of \$20 to 25 million. The goal is to have the laboratory operational by the beginning of November.
- The state will contract with a third-party billing vendor to collect reimbursement from health insurers. This contract will likely to cost between \$3-5 million.
- The state will procure a logistics contract for the transportation of specimens from the specimen collection sites to the laboratory. These costs are variable as they will need to account for: (1) number of sites; (2) quantity per site; and (3) weight of package.