A new low cost, high throughput COVID-19 PCR test has been developed in conjunction with a grant from the Bill & Melinda Gates Foundation. In order to demonstrate the throughput of this new test, the Gates Foundation is supporting the goal of testing 100,000 subjects in a single day, (December 18, 2020). If your organization (single center or multi-facility company) would like to participate you may sign up, at no charge, to have your staff tested. This test satisfies the CMS requirements for COVID-19 testing of staff. In addition, friends and family of staff are able to attend on testing day to register and participate.

****IMPORTANT: RESIDENTS ARE NOT ELIGIBLE TO BE TESTED IN THIS STUDY. In ADDITION, ONLY ASYMPTOMATIC INDIVIDUALS ARE ELIGIBLE TO PARTIVIPATE ****

Q: Where did this test come from?

A: Development of this test was funded by the Bill and Melinda Gates Foundation. Development was conducted by Quantigen and Corteva Agriscience, who have deep expertise in clinical test development and low-cost PCR, respectively.

Q: Is the test FDA approved?

A: Clinical validation studies have been performed according to FDA requirements and guidance, and ≥95% clinical concordance with existing tests has been demonstrated. Study reports and a full Emergency Use Authorization will be pending at the FDA at time of testing. As with many other COVID-19 tests, once EUA is filed the test can be operated as a laboratory derived test under CLIA prior to receiving emergency use authorization.

Q: Can this satisfy the CMS requirements for "regular testing of staff" in a nursing home?

A: Yes. This test is a molecular diagnostic for COVID-19 and is being operated under CLIA by a certified high complexity laboratory as a laboratory derived test.

Q: What is the sample type?

A: Self-administered nasal (anterior nares) swab collection. NOTE: This is not a nasopharyngeal swab collection. After collection the swab is placed in a dry tube, with no transport solution. Transportation does not require refrigeration.

Q: Is this test accurate?

A: The sensitivity of this test is similar to many widely used RT-PCR tests, and like other molecular (PCR) tests, has a lower false positive rate than is often seen with antigen tests.

Q: How do I sign up my site for this study?

A: Reply all to this email with your name and contact information and a member of PRA Health Sciences will be with you shortly to discuss next steps. There will be a series of phones calls set up soon after Thanksgiving to provide additional detail.

Q: What will be required of my facility if I am selected to participate?

A: 1. Prior to sampling, create accounts for test participants by uploading a staff list (csv file) to the EllKay system

2. You will receive a shipment of testing supplies and instructions the week of December 14th, 2020.

3. On the day of testing (December 18, 2020) you will need to have established a collection site (i.e., table with a single staff member, collection tubes, and instructions). The collection is self-administered, but the collection site needs to be staffed by you

for you to provide participants with directions and to ensure samples are properly collected.

4. Participants will need to download the CareEvolve app onto their mobile phone and create an account. This app will associate participants health records with samples, using their cellphone camera to scan a bar code on the collection tube. The app is also how results are reported, to the nursing home administration, to the participants, and positive results to the department of health. (Nursing homes will be required to report to CMS separately).

5. In order to sample, participants are given a tube and swab and instructions for use.

6. Participants scan their tube with their cell phone, swab the inside of their nose, and place their tube in a rack.

7. At the end of the day the samples need to be paced with materials provided and shipped via FedEx overnight (prepaid).

Q: How long will it take to get test results?

A: Results are planned to be returned within 48 hours, in many cases it may be less than 24 hours

Q: How are these results reported?

A: All results will be accessible to the participants via the CareEvolve application. Facility administrators will also have visibility to their site results