



COVID-19 Classroom Pooled Testing: Informed Consent
Concentric by Ginkgo –classroom pooled COVID-19 surveillance testing pilot program

Ginkgo Bioworks, Inc., d/b/a Concentric by Ginkgo is conducting a classroom pooled COVID-19 surveillance testing pilot program (the “Program”) using a molecular assay to detect a substance in collected samples called RNA associated with diseases like COVID-19. Each participant must read and sign this form before taking part in the Program. If the participant is a student and/or a minor (under the age of 18), a parent or legal guardian must read and sign this form before his/her/their participation in the Program.

KEY INFORMATION

1. This Program involves collecting nasal swab samples and combining samples from groups of students within a classroom and school staff for pooled testing.
2. Potential risks from sample collection include minor discomfort from the insertion of the swabs. This irritation, if experienced, is expected to be brief.
3. The Program does not generate individual test results. The Program may return pooled surveillance test results (subject to Concentric by Ginkgo’s discretion, including assessment of successful collection, testing and analysis) to the school. For clarity, **Concentric by Ginkgo will not provide COVID-19 classroom pooled test results to students or their parent/legal guardian.**
4. The test being evaluated in this Program is not approved or authorized by the U.S. Food & Drug Administration (FDA).
5. The student or parent/legal guardian and any participant in the Program should tell the Program staff or school staff about any side effects or problems or if the student or parent/legal guardian changes his/her/their mind about participating in the Program.
6. Student records of being in this Program will be kept by the school only. The sample(s) a student or participant provides under this Program will not contain any of his/her/their personally identifiable information; all classroom pooled sample(s) will be identified with a barcode and/or classroom identifier.
7. The student or participant will not lose any legal rights by signing this consent form.

The following are the aims of the Program:

- To Assess the ease and effectiveness of the sample collection process for classroom pooled testing, (i.e. determining opportunities for improvement, and ensuring user safety);
- To determine the minimum age for self-administered sample collection in order to gauge the need for test administration by a healthcare professional.
- To assess the ease and effectiveness of Concentric by Ginkgo’s classroom pooled testing program components, including its digital portal, test results sharing, student registration, and shipping logistics;
- To support Concentric by Ginkgo laboratory analysis of the samples collected in a real-world setting;
- To collect student and school feedback on the overall sample collection experience;
- To allow schools and their affiliates to better understand classroom pooled COVID-19 surveillance testing as part of a comprehensive COVID-19 safety program; and
- To help schools and their affiliates develop COVID-19 safety protocols.

Please carefully read and sign the following Informed Consent:

- a. I authorize the _____ (the “School”) classroom pooled COVID-19 surveillance testing pilot program (the “Program”), which includes Ginkgo Bioworks, Inc., d/b/a Concentric by Ginkgo, to conduct sample collection and classroom pooled testing for COVID-19.
- b. I understand that the Program is to test group(s) of students and staff in classroom(s) for COVID-19, that the test is not an individual test nor a medical diagnostic test, and that participation in the Program is entirely voluntary.
- c. I understand that a nasal swab will be collected from each student and school staff member. For adults and students in grade 4 and higher, this will be by self-collection. Self-collection for students in grade 3 or lower is voluntary and sample collection will be either supervised or administered by a healthcare professional accordingly. Potential risks from sample collection include discomfort from the insertion of the swabs. The irritation is expected to be brief.
- d. I understand that the purpose of the Program is to assess the ease and effectiveness of student and staff registration, sample collection, digital portal, shipping logistics, and laboratory testing. Program results (including leftover samples) may be used for improvement of the Concentric by Ginkgo classroom pooled testing product.
- e. I understand that (a) Concentric by Ginkgo may or may not provide test results to the School, (b) School will have sole access to any test results, and (c) test results should not be used for medical decisions.
- f. I understand that, as with any COVID-19 test, there is the potential for a false positive or false negative COVID-19 test result and that the potential for a false negative COVID-19 test result may be higher with pooled testing than individual testing.

I, the undersigned, have read the key information and aims of the Program, the description of the test samples to be collected, and possible risks of the Program and I understand that this information may also be provided to me by Concentric by Ginkgo upon written request to the School. I have been told that I can ask additional questions at any time. I voluntarily agree to participate in the Program.

<u>If this consent is for a student/minor:</u>	<u>If this consent is for an adult or School staff member:</u>
_____	_____
Student Name (print)	
_____	_____
Parent/Legal Guardian Name (print)	Name (print)
_____	_____
Parent/Legal Guardian Signature	Signature
_____	_____
Date	Date